PROTECTING THE RIGHTS OF CONSUMERS – CLICKWRAP CONTRACTS AND DIRECT–TO–CONSUMER GENETIC TESTING

ANDELKA MATIJA PHILLIPS

ST HILDA'S COLLEGE

DPHIL

Trinity Term 2014−15

PROTECTING THE RIGHTS OF CONSUMERS

– CLICKWRAP CONTRACTS

AND DIRECT-TO-CONSUMER GENETIC TESTING

ANDELKA M. PHILLIPS, ST HILDA'S COLLEGE

DPHIL, TRINITY TERM, 2014-15

ABSTRACT

This thesis examines the regulation of the direct-to-consumer genetic testing industry through analysis of the industry's use of wrap contracts (clickwrap and browsewrap), A significant portion of the thesis consists of a comparative document review of the publicly available wrap contracts of DTCGT companies provided tests for health purposes. It also considers other regulatory responses to date. Due to the lack of industry specific regulation it argues that the use of wrap contracts can be viewed as a means of industry self-regulation and a form of private legislation. This means that governance is skewed heavily in favour of companies and it creates an imbalance in the respective rights and obligations of the parties – company and consumer – which is likely to result in consumer detriment. It is argued that certain types of terms commonly include in DTCGT contracts, including: unilateral variation clauses; some exclusion clauses; choice of law clauses; indemnity; and consent clauses are likely to be deemed unfair and unenforceable under UK law. It recommends that in the short-term the Competition and Markets Authority should undertake a compliance review of DTCGT contracts in order to improving contracts for consumers. In the long term, companies should also be complying with data protection law, as well as legislation on medical devices and the provisions of the Human Tissue Act and there may be a need for industry specific legislation.

DEDICATION

To my husband Kent and to my parents, Michelle and Petar.

Table of Contents

TABLE OF STATUTES

UK Legislation

EU Legislation

International:

TABLE OF CASES

UK:

EU:

USA:

TABLE OF ABBREVIATIONS

Additional Protocol	Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes
AIMD	Directive 90/385/EEC Regarding Active Implantable Medical Devices
AMP	Association for Molecular Pathology
ASHG	American Society of Human Genetics
Brussels I-Regulation (recast)	Regulation (EU) No 1215/2012 of the European Parliament and of the Council of 12 December 2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (recast) OJ 2012, L 251/1
CCMG	Canadian College of Medical Geneticists
CMA	Competition & Markets Authority
CPUTR	Consumer Protection from Unfair Trading Regulations 2008
CRA	Consumer Rights Act 2015
DPA	Data Protection Act 1998
HRA	Human Rights Act 1998
DTCGT	Direct-to-consumer genetic testing
EASAC	European Academies of Science Advisory Council
ECJ	European Court of Justice
ESHG	European Society of Human Genetics
FCA	Financial Conduct Authority
FEAM	Federation of European Academies of Medicine
Framework of Principles	A Common Framework of Principles for direct-to-consumer genetic testing services
ICO	Information Commissioner's Office (UK)

GAO	Government Accountability Office
GPSD	Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety
HGC	Human Genetics Commission
IVD Directive	Directive 98/79/EC on In Vitro Diagnostic Medical Devices
Draft IVD Regulation	Proposal for a Regulation 9770/15 of the European Parliament and of the Council on *in vitro* diagnostic medical devices of 12 June 2015. Interinstitutional File: 2012/0267 (COD)
LDTs	Laboratory Developed Tests
MDD	Directive 93/42/EEC of 14 June 1993 concerning medical devices
OFT	Office of Fair Trading
OPC	Office of the Canadian Privacy Commissioner
Oviedo Convention	Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine
Rome I	Regulation (EC) No 593/2008 of the European Parliament and of the Council of 17 June 2008 on the law applicable to contractual obligations (Rome I)
SACGHS	The Secretary's Advisory Committee on Genetics, Health, & Society
SNPs	Single Nucleotide Polymorphisms
UTCCR	The Unfair Terms in Consumer Contracts Regulations 1999
Unfair Terms Directive	Directive 93/13/EEC of 5 April 1993 On Unfair Terms In Consumer Contracts

TABLE OF COMPANIES

Companies:
1) 23andMe[1]
2) 23DNA[2]
3) Accu-metrics Viaguard[3]
4) Accurate Paternity Testing[4]
5) AccuraScience[5]
6) Advanced Healthcare Inc[6]
7) African Ancestry[7]
8) African DNA[8]
9) All About Truth DNA Services[9]
10) Alpha Biolabs[10]
11) American International Biotechnology, LLC (AIBioTech)[11]
12) American Paternity[12]
13) Ancestry DNA[13]
14) AncestrybyDNA[14]
15) ANTAGENE[15]
16) Any Lab Test Now®[16]
17) Any Time Lab[17]
18) ARCpoint Labs[18]

1 23andMe, <https://www.23andme.com/health/> accessed 5 January 2013. [Checked again 22 January 2014 and still operating]. [Checked again 24 April 2014].

2 23DNA, <http://23dna.co> accessed 28 August 2013. [Checked again 22 January 2014 and still operating]; and <http://brooklyn.23dna.co/DNAKit?gclid=CKDXpfrBoLwCFVKWtAodf3MAJQ> accessed 28 January 2014. [Checked again 8 April 2014]

3 Accu-metrics Viaguard, <http://accu-metrics.com> accessed 28 August 2013. [Checked again 22 January 2014 and still operating].

4 Accurate Paternity Testing, <http://philadelphiadnatesting.com> accessed 28 August 2013. [Checked again 22 January 2014 and website not displaying]. [Check again!]

5 AccuraScience, <http://www.accurascience.com> accessed 28 January 2014.

6 Advanced Healthcare Inc, <http://www.advanceddna.in> accessed 28 August 2013. [Checked again 22 January 2014 and still operating], [and again 7 April 2014].

7 African Ancestry, <http://www.africanancestry.com> accessed 8 September 2013. [Checked again 22 January 2014 and still operating].

8 AfricanDNA, <http://www.africandna.com> accessed 8 September 2013. [Checked again 22 January and 7 April 2014 and still operating].

9 All About Truth DNA Services, <http://www.allabouttruthdna.com> accessed 28 April 2014.

10 Alpha Biolabs, <http://www.alphabiolabs.com> accessed 28 August 2013. [Checked again 22 January 2014 and still operating]. [Checked again 30 April 2014].

11 AIBioTech, <http://www.aibiotech.com> 22 January 2014. [Checked again 7 April 2014].

12 American Paternity, <http://www.paternity.us/index.html> accessed 28 August 2013. [Checked again 22 January 2014 and still operating]. [Checked again 9 April 2014].

13 Ancestry DNA, <http://ldna.ancestry.com/offers/buyKit.aspx> accessed 28 August 2013. [Checked again 22 January 2014 and still operating].

14 AncestrybyDNA, <https://www.ancestrybydna.com/lineage-faq.php> accessed 28 August 2013. [Checked again 22 January 2014 and still operating].

15 ANTAGENE, <http://www.antagene.com/en> accessed 22 January 2014.

16 Any Lab Test Now®, <http://www.mylabsa.com/index.html> accessed 28 August 2013. [Checked again 22 January 2014 and still operating].

17 Any Time Lab, <http://anytimelab.com/index.html> accessed 7 April 2014.

19) ARUP Lab[19]
20) Asper Biotech[20]
21) AssureDNA[21]
22) Athena Diagnostics Inc
23) Athleticode[22]
24) Atlas Sports Genetics[23]
25) BalanceDiet™[24]
26) Beta Paternity[25]
27) Beyond Nutrition[26]
28) Biocod Biotech[27]
29) BioClinics (Genetic Health Management)[28]
30) Biophysical[29]
31) Bio Logis[30]
32) Biotechnology Group Inc[31]
33) Bio Wellness Inc[32]
34) Boston Paternity[33]
35) BritainsDNA[34]
36) BRT Labs Inc[35]
37) Cambridge DNA Services[36]

18 ARCpoint Labs, <http://www.arcpointlabs.com> accessed 28 August 2013. [Checked again 28 January 2014 and still operating].

19 ARUP Lab, <http://www.aruplab.com/genetics/tests> accessed 22 January 2014.

20 Asper Biotech, <http://www.asperbio.com/genetic-tests> accessed 28 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 9 April 2014].

21 AssureDNA, <http://www.assuredna.co.uk> accessed 28 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 30 April 2014].

22 Athleticode, <http://athleticode.com> accessed 10 August 2013. [Checked again 22 January 2014 and still operating]. [Checked again 9 April 2014].

23 Atlas Sports Genetics, <http://www.atlasgene.com> accessed 28 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 9 April 2014].

24 BalanceDiet, <http://www.gobalancediet.com/about/about-balancediet/> accessed 28 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 30 April 2014].

25 Beta Paternity, <http://www.betagenetics.com/terms.html> accessed 28 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 10 April 2014].

26 Beyond Nutrition, <http://www.beyond-nutrition.co.uk/dna-diet/> accessed 28 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 10 April 2014].

27 Biocod Biotech, <http://www.biocod.com.br/about-biocod/> accessed 22 January 2014. [Checked again 28 January 2014 and still operating].

28 BioClinics, 'About' <http://www.weightloss-dnatesting.co.uk/about> accessed 7 April 2014.

29 Biophysical, <http://www.biophysicalcorp.com/patients/> accessed 10 April 2014.

30 Bio Logis, <https://pgsbox.com> accessed 22 January 2014. [Checked again 28 January 2014 and still operating]. [Checked again 10 April 2014].

31 Biotechnology Group Inc, <http://www.biotechnologygroup.com/index.html> accessed 22 January 2014. [Checked again 28 January 2014 and still operating]. [Checked again 10 April 2014].

32 Bio Wellness Inc, <http://www.biowellinc.com/index.html> accessed 22 January 2014. [Checked again 28 January 2014 and still operating]. [Checked again 10 April 2014].

33 Boston Paternity, <http://www.bostonpaternity.com/paternity-dna-testing/overview.aspx> accessed 28 August 2013. [Checked again 28 January 2014 and still operating].

34 BritainsDNA, <http://www.britainsdna.com> accessed 8 September 2013. [Checked again 28 January 2014 and still operating]. [Checked again 10 April 2014].

35 BRT Labs Inc, <http://www.brtlabs.com> accessed 22 January 2014. [Checked again 28 January 2014 and still operating]. [Checked again 10 April 2014].

38) Cancer Genetics Inc[37]
39) The Carlson Company LLC[38]
40) Cosmetics DNA[39]
41) C2DNA (Canadian Centre for DNA Diagnostics)[40]
42) CD Genomics[41]
43) Cellmark [42]
44) Center for Medical Genetics[43]
45) Check Mate Test LLC[44] (Getcheckmate)
46) And also has the website Checkmatetest.com[45]
47) Consumer Genetics[46]
48) Counsyl[47]
49) Cygene Direct[48]
50) Dadchecksilver[49]
51) Darwin Dieticians[50]
52) DeCODEme[51]
53) Definite DNA[52]
54) Dermagenetics[53]

[36] Cambridge DNA Services, <http://web.archive.org/web/20111228002431/http://www.cambridgedna.com> accessed 9 September 2013.

[37] Cancer Genetics Inc, <http://www.cancergenetics.com> accessed 22 January 2014. [Checked again 28 January 2014 and still operating]. [Checked again 10 April 2014].

[38] The Carlson Company LLC, <http://thecarlsoncompany.net/infidelity.html> accessed 20 January 2014. [Checked again 10 April 2014].

[39] Cosmetics DNA, <http://www.cosmetics-dna.com/index.htm> accessed 30 April 2014.

[40] C2DNA, <http://www.c2dna.com/index.html> accessed 28 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 10 April 2014].

[41] CD Genomics, <http://www.cd-genomics.com> accessed 29 January 2014. [Checked again 10 April 2014].

[42] Cellmark, <https://www.cellmark.co.uk/geninfo/information.php> accessed 28 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 10 April 2014].

[43] Center for Medical Genetics, <http://www.geneticstesting.com> accessed 27 January 2014. [Checked again 28 January 2014 and still operating].

[44] CheckMate Test LLC, <http://www.getcheckmate.com> accessed 28 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 30 April 2014]

[45] CheckMate Test, <http://www.checkmatetest.com> accessed 28 August 2013. [Checked again 28 January 2014 and still operating].

[46] Consumer Genetics, <http://www.consumergenetics.com> accessed 28 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 10 April 2014].

[47] Counsyl, <https://www.counsyl.com> accessed 28 January 2014. [Checked again 10 April 2014].

[48] Cygene Direct, <http://cygene.infinityarts.com> accessed 9 September 2013. [Checked again 28 January 2014 and still operating].

[49] Dadchecksilver, <http://www.dadchecksilver.com/who-are-we.htm> accessed 9 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 10 April 2014].

[50] Darwin Dietitians, <http://www.darwindietitians.com.au> accessed 22 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 10 April 2014].

[51] DeCODEme, <http://www.decodeme.com> accessed 22 August 2013. [Checked again 28 January 2014 and still operating, but not as DTC].

[52] Definite DNA, <http://defdna.com/our-advantage/> accessed 12 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 10 April 2014].

[53] Dermagenetics, <http://dermagenetics.com> accessed 22 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 10 April 2014].

55) Determigene[54]
56) Diagnomics[55]
57) DNALYSIS Biotechnology[56]
58) DNA Ancestry Project[57]
59) DNA Ancestry & Family Origin[58]
60) DNA Bioservices[59]
61) DNA Clinics[60]
62) DNA Connect[61]
63) DNA Consultants[62]
64) DNA Diagnostics Center[63] (DDC)
65) DNA Diagnostics Centre[64] (DDC)
66) DNA Diagnostics Ltd[65]
67) DNA Dimensions[66]
68) DNA DTC[67]
69) DNA Findings[68]
70) DNA Genie[69]
71) DNA Heritage[70]
72) DNA Identifiers[71]
73) DNA Ireland[72]

54 Determigene, <http://www.determigene.com> accessed 22 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 10 April 2014].

55 Diagnomics, <http://www.diagnomics.com> accessed 27 January 2014.

56 DNALYSIS Biotechnology, <http://www.dnalysis.co.za/About-us.aspx> accessed 22 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 10 April 2014].

57 DNA Ancestry Project, <http://www.dnaancestryproject.com/ydna_intro_about.php> accessed 10 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 10 April 2014].

58 DNA Ancestry & Family Origin, <http://www.dnaancestry.ae/index_eg.php> accessed 11 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 10 April 2014].

59 DNA Bioservices, <http://www.dnabioservices.com.au/> accessed 13 May 2014.

60 DNA Clinics, 'About' <http://www.dnatestingclinics.co.uk/about> accessed 16 April 2014.

61 DNA Connect, <http://www.dnaconnect.com> accessed 11 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 10 April 2014].

62 DNA Consultants, <http://www.dnaconsultants.com> accessed 16 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 10 April 2014].

63 DDC DNA Diagnostics Center, <http://www.dnacenter.com> accessed 16 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 11 April 2014].

64 DDC DNA Diagnostics Centre, <http://www.dna-bioscience.co.uk> accessed 16 August 2013 [Checked again 11 April 2014]; and <http://www.dnacentre.co.uk> accessed 16 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 11 April 2014].

65 DNA Diagnostics, <www.dnadiagnostics.co.nz> accessed 13 May 2014.

66 DNA Dimensions, <http://detroitdna.com> accessed 7 April 2014.

67 DNADTC <http://www.dnadtc.com/about.aspx> accessed 1 February 2013. [Checked 11 April 2014 and still operating].

68 DNA Findings, <https://www.dnafindings.com> accessed 9 August 2013. [Checked again 11 April 2014 and still operating].

69 DNA Genie, <http://www.dna-genie.com/?gclid=COjOn4zSo7wCFZHJtAodnWEAdA> accessed 29 January 2014. [Checked again 11 April 2014].

70 DNA Heritage, <https://twitter.com/DNAHeritage> accessed 9 September 2013. [Checked again 28 January 2014].

71 DNA Identifiers, <http://www.dna-testing-paternity.com/testing-services> accessed 11 August 2013. [Checked again 31 January 2014 and still operating]. [Checked again 11 April 2014].

72 DNA Ireland, <http://www.dnaireland.ie/about.html> accessed 10 February 2013.

74) DNA Labs[73]
75) DNA People Diagnostics[74]
76) DNA Plus[75]
77) DNA Print Genomics
78) DNAQ[76] owned by Genomics For Life Pty Ltd
79) DNA Services of America[77]
80) DNA Spectrum[78]
81) DNA Solutions[79]
82) DNA Test[80]
83) DNA Test.ie[81]
84) DNA Testing Center of America[82]
85) DNA Testing Centre Inc[83]
86) DNA Testing Centres of Canada[84]
87) DNA Traits[85]
88) DNA Tribes[86]
89) DNA Worldwide[87]
90) DNADirect[88]
91) DNAme[89]
92) DNA-Fingerprint[90]

73 DNA Labs, <www.dnalabs.com/home.aspx> accessed 13 May 2014.

74 DNA People Diagnostics, <http://www.dnapeoplediagnostics.com> accessed 11 September 2013.

75 DNA Plus, 'Products' <http://www.dnaplus.de/en/products/dna-verdauung-3/> accessed 3 February 2014. [Checked again 14 April 2014].

76 DNAQ, <dnaq.com.au/about-us/> accessed 13 May 2014.

77 DNA Services of America, <http://www.dnasoa.com/dna-testing/> accessed 15 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 11 April 2014].

78 DNA Spectrum, <http://www.dnaspectrum.com> accessed 8 September 2013. [Checked again 28 January 2014 and still operating]. Checked again 11 April 2014].

79 DNA Solutions, <www.dnanow.com> accessed 22 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 11 April 2014].

80 DNA Test, <http://www.dnatest.co.za> accessed 8 September 2013. [Checked again 28 January 2014 and still operating]. [Checked again 11 April 2014].

81 DNA Test, <http://www.dnatest.ie/relationship-test-services/> accessed 8 September 2013. [Checked again 28 January 2014 and still operating].

82 DNA Testing Center of America, <http://www.dnatca.com> accessed 10 February 2013. [Checked again 28 January 2014 and still operating]. [Checked again 11 April 2014].

83 DNA Testing Centre Inc, <http://www.dnatestingcentre.com> accessed 7 April 2014. [Checked again 11 April 2014].

84 DNA Testing Centres of Canada, <http://dnatestingcanada.com/about-us/> accessed 7 April 2014. [Checked again 12 April 2014].

85 DNA Traits, <http://www.dnatraits.com/about.aspx> accessed 15 August 2013. [Checked again 28 January 2014 and still operating]. Website is now <https://www.genebygene.com/pages/dnatraits> accessed 2 February 2014. [Checked again 11 April 2014].

86 DNA Tribes, <http://www.dnatribes.com> accessed 8 September 2013. [Checked again 28 January 2014 and still operating]. [Checked again 12 April 2014].

87 DNA Worldwide, <http://www.dna-worldwide.com> accessed 15 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 12 April 2014].

88 DNADirect, <http://www.dnadirect.com/dnaweb/consumers/consumers.html> accessed 9 September 2013. [Checked again 28 January 2014 and still operating]. [Checked again 12 April 2014].

89 DNAme, <http://www.dna-me.co.uk> accessed 9 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 12 April 2014].

93) DNAFit[91]
94) DNAForce[92]
95) easyDNA[93]
96) EnteroLab[94]
97) Eurofins Medigenomix GmbH[95]
98) EuroPaternity[96]
99) Existence Genetics[97]
100) Fairfax Identity Labs[98]
101) Family Tree DNA[99]
102) Gene by Gene
103) FitGenes[100]
104) FitnessHub[101]
105) Forensics Genetics Center[102]
106) ForuMed Biotechnology[103]
107) Foundation Medicine Inc[104]
108) Full Genomes Corporation[105]
109) GATC Biotech AG[106]
110) Genebase[107]

90 DNA-Fingerprint, <http://www.dna-fingerprint.com> accessed 9 September 2013. [Checked again 28 January 2014].

91 DNAFit, <http://www.dnafit.com/uk/> accessed 15 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 11 April 2014].

92 DNAForce, <https://www.dnatest.ca> accessed 12 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 11 April 2014].

93 easyDNA, <http://www.easydna.co.uk> accessed 15 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 12 April 2014].

94 EnteroLab, <https://www.enterolab.com> accessed 15 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 12 April 2014].

95 Eurofins Medigenomix GmbH, <http://www.medigenomix.de/en/> accessed 27 January 2014. [Checked again 14 April 2014].

96 Europaternity, <http://www.europaternity.co.uk> accessed 15 August 2013. [Checked again 28 January 2014]. [Checked again 14 April 2014].

97 Existence Genetics, <http://www.existencegenetics.com> accessed 27 January 2014. [Checked again 14 April 2014].

98 Fairfax Identity Labs, <http://www.fairfaxidlab.com> accessed 27 January 2014. [Checked again 14 April 2014].

99 Family Tree DNA <http://www.familytreedna.com> accessed 27 January 2014. [Checked again 14 April 2014].

100 FitGenes, <http://www.fitgenes.com> accessed 27 January 2014. [Checked again 28 January 2014 and still operating]. [Checked again 14 April 2014].

101 FitnessHub, <http://www.fitnesshub.ie> accessed 30 April 2014.

102 Forensics Genetics Center, <http://www.forensicgeneticscenter.com/contact.asp> accessed 10 February 2013. [Checked again 28 January 2014 and still operating]. [Checked again 14 April 2014].

103 ForuMed Biotechnology, <http://www.forumed.eu/επικοινωνία> accessed 30 April 2014.

104 Foundation Medicine Inc, <http://www.foundationmedicine.com> accessed 27 January 2014. [Checked again 14 April 2014].

105 Full Genomes Corporation, <https://www.fullgenomes.com> accessed 27 January 2014. [Checked again 28 January 2014 and still operating]. [Checked again 14 April 2014].

106 GATC Biotech AG, <http://www.gatc-biotech.com/en/index.html> accessed 27 January 2014. [Checked again 28 January 2014 and still operating]. [Checked again 14 April 2014].

107 Genebase, <http://www.genebase.com> accessed 9 September 2013. [Checked again 29 January 2014 and still operating]. [Checked again 14 April 2014].

111) GeneCare[108]
112) GenEffect[109]
113) GeneLex[110] has linked up with DDC DNA Diagnostics Center for paternity testin [14 August 2013]
114) GenePlanet[111]
115) Genepeeks[112]
116) Genetica DNA Laboratories Inc [113]
117) Geneticom[114]
118) Genetic Profiles[115]
119) Genetic Center Company Limited[116]
120) Genetic Health[117]
121) Genetic Healthcare Group (geneLAB)[118]
122) Genetic Performance[119]
123) DNA Slim[120]
124) Genetic Testing Laboratories Inc (GTL)[121]
125) Genetic Technologies[122]
126) Genetrack Biolabs[123]
127) GeneTree
128) Genewiz[124]
129) Genex Diagnostics Inc[125]
130) Genomic Express Inc[126]

108 GeneCare, <www.genecare.com.au> accessed 13 May 2014.

109 GenEffect, <http://www.geneffect.com/actn3/en/index.html> accessed 13 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 14 April 2014].

110 Genelex, <http://genelex.com> accessed 5 January 2013. [Checked again 28 January 2014 and still operating]. [Checked again 14 April 2014].

111 GenePlanet, <http://www.geneplanet.com> accessed 2 January 2013. [Checked again 28 January 2014 and still operating]. [Checked again 14 April 2014].

112 Genepeeks, <http://www.genepeeks.com> accessed 27 January 2014. [Checked again 14 April 2014].

113 Genetica DNA Laboratories, <http://www.genetica.com/geneticawebv2.nsf/?Open> accessed 10 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 14 April 2014].

114 Geneticom, <http://www.geneticom.nl> accessed 10 September 2013. [Checked again 28 January 2014, <http://www.mijndomein.nl/?rf=9971>].[May not be operating - Checked again 14 April 2014].

115 Genetic Profiles, <http://www.geneticprofiles.com> accessed 27 January 2014. [Checked again 28 January 2014 and still operating]. [Checked again 14 April 2014].

116 Genetic Center Company Limited, <http://www.genetic-center.com> accessed 13 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 14 April 2014].

117 Genetic Health, <http://www.genetic-health.co.uk> accessed 2 January 2013. [Checked again 29 January 2014 and still operating]. [Checked again 14 April 2014].

118 Genetic Healthcare Group, <http://genetic-healthcare.com/gh_about_us.html> accessed 30 April 2014.

119 Genetic Performance, <http://geneticperformance.com> acceassed 29 April 2014.

120 DNA Slim, <https://www.dnaslim.org> accessed 29 April 2014.

121 GTL DNA, <http://www.gtldna.com> accessed 2 January 2013. [Checked again 29 January 2014 and still operating]. [Checked again 15 April 2014].

122 Genetic Technologies, <gtmedical.com.au/about_us.php> accessed 13 May 2014.

123 Genetrack Biolabs, <http://www.genetrack.co.uk> accessed 5 January 2013. [Checked again 28 January 2014 and still operating]. [Checked again 14 April 2014].

124 Genewiz, <http://www.genewiz.com> accessed 27 January 2014. [Checked again 14 April 2014].

125 Genex Diagnostics Inc, 'Welcome to Genex Diagnostics' <http://www.genexdiagnostics.com> accessed 24 April 2014.

131)	Genomic Health Inc[127]
132)	Genosense (and DNA Plus)[128]
133)	Gensys[129]
134)	GenoVive[130]
135)	Gentle[131]
136)	GFI Lab[132]
137)	Gonidio[133]
138)	Graceful Earth[134]
139)	Halo Health[135]
140)	HealthCheckUSA[136]
141)	HairDX[137]
142)	Hair Loss Control Clinic (HLCC)[138]
143)	Health Street[139]
144)	Holistic Health International[140]
145)	HomeDNAdirect[141]
146)	Home DNA Inc[142]
147)	Identigene Inc[143]
148)	iGENEA[144]
149)	Independent Forensics[145]

126 Genomic Express Inc, <https://secure.genomicexpress.com/home.html> accessed 27 January 2014. [Checked again 28 January 2014 and still operating]. [Checked again 14 April 2014].

127 Genomic Health Inc, <http://www.genomichealth.com/en-US.aspx#.UuuKSv07S44> accessed 15 January 2014. [Checked again 31 January 2014 and still operating]. [Checked again 14 April 2014].

128 Genosense, <http://www.genosense.com> accessed 2 January 2013. [Checked again 28 January 2014 and still operating]. [Checked again 14 April 2014].

129 Gensys, <http://www.paternity-answers.com> accessed 12 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 14 April 2014].

130 GenoVive, <https://www.genovive.com/index.php/how-genovive-works.html> accessed 7 April 2014.

131 Gentle, <https://gentlelabs.com> accessed 7 April 2014.

132 GFI Labs, <http://www.gfilab.com/dna-testing-services/infidelity-dna-test/> accessed 7 April 2014.

133 Gonidio, <http://www.gonidio.com/whyus.php> accessed 13 August 2013. [Checked again 29 January 2014 and still operating]. [Checked again 15 April 2014].

134 Graceful Earth, <http://gracefulearth.com> accessed 2 January 2013. [Checked again 29 January 2014 and still operating]. [Checked again 15 April 2014].

135 Halo Health, <http://halohealth.com/item/home-4/> accessed 14 August 2013. [Checked again 29 January 2014 and still operating]. [Checked again 15 April 2014].

136 HealthCheckUSA, <http://www.healthcheckusa.com> accessed 10 August 2013. [Checked again 29 January 2014 and still operating]. [Checked again 15 April 2014].

137 HairDX, <http://www.hairdx.com/en-us/> accessed 8 July 2014.

138 Hair Loss Control Clinic, <http://www.hlcconline.com/about.html> accessed 8 July 2014.

139 Health Street, <http://www.health-street.net/dna-tests.html> accessed 3 July 2014.

140 Holistic Health International, <http://www.holisticheal.com> accessed 3 February 2013. [Checked again 29 January 2014 and still operating]. [Checked again 15 April 2014].

141 HomeDNAdirect, <http://www.homednadirect.com/about-us.html> accessed 10 February 2013. [Checked again 29 January 2014 and still operating]. [Checked again 15 April 2014].

142 Home DNA Inc, <https://www.homedna.com > accessed 11 August 2013. [Checked again 29 January 2014 and still operating]. [Checked again 15 April 2014].

143 Identigene Inc, <http://www.identigene.com> accessed 27 January 2014. [Checked again 29 January 2014 and still operating]. [Checked again 15 April 2014].

144 iGENEA, <http://www.igenea.com/en/home> accessed 8 September 2013. [Checked again 29 January 2014 and still operating]. [Checked again 15 April 2014].

150)	ION (Institute for Optimal Nutrition)[146]
151)	IDNA Systems[147]
152)	Indian Biosciences[148]
153)	Infidelity Testing[149]
154)	Inherent Health[150]
155)	Instant Chemistry[151]
156)	Interleukin Genetics, Inc[152]
157)	International Biosciences[153]
158)	iTest DNA LLC[154]
159)	Kimball[155]
160)	Knome[156]
161)	LabCorp[157]
162)	LifeGenetics[158]
163)	Lumigenix[159]
164)	Map My Gene[160]
165)	Map My Genome[161]
166)	Matt Roberts[162]
167)	Matrix Genomics[163]

145 Independent Forensics, <http://www.ifi-test.com/index.php> accessed 27 January 2014. [Checked again 29 January 2014 and still operating]. [Checked again 15 April 2014].

146 ION, (Institute for Optimal Nutrition), <http://www.ion.ac.uk/performance/dna_testing> accessed 24 April 2014.

147 IDNA Systems, <http://www.idna-systems.com> accessed 27 January 2014. [Checked again 29 January 2014 and still operating]. [Checked again 15 April 2014].

148 Indian Biosciences, <http://www.inbdna.com> accessed 9 September 2013. [Checked again 29 January 2014 and still operating]. [Checked again 15 April 2014].

149 Infidelity (non-consensual testing)Testing, <http://www.infidelitydnatesting.com> accessed 8 September 2013. [Checked again 28 April 2014].

150 Inherent Health, <http://www.inherenthealth.com/our-tests.aspx> accessed 13 August 2013. [Checked again 29 January 2014 and still operating]. [Checked again 15 April 2014].

151 Instant Chemistry, <https://instantchemistry.com> accessed 10 April 2014.

152 Interleukin Genetics, <http://ilgenetics.com/content/products-services> accessed 15 April 2014.

153 International Biosciences, <http://www.ibdna.com/regions/UK/EN/> accessed 9 September 2013. [Checked again 29 January 2014 and still operating]. [Checked again 15 April 2014].

154 iTest DNA, <http://www.itestdna.net> accessed 8 September 2013. [Checked again 29 January 2014 and still operating]. [Checked again 16 April 2014].

155 Kimball, <http://www.kimballgenetics.com/tests.html> accessed 2 January 2013. [Checked again 29 January 2014 and still operating]. [Checked again 16 April 2014].

156 Knome, <http://www.knome.com/knome-blog/direct-to-consumer-genomics-reinvents-itself/> accessed 10 August 2013. [Checked again 16 April 2014].

157 Labcorp, <https://www.labcorp.com/wps/portal/> accessed 27 January 2014. [Checked again 16 April 2014].

158 LifeGenetics, <http://lifegenetics.net/shop/dna-test-premium/> accessed 13 August 2013. [Checked again 29 January 2014 and still operating]. [Checked again 16 April 2014].

159 Lumigenix, <https://www.lumigenix.com/services/overview.html> accessed 5 January 2013. [Checked again 16 April 2014].

160 Map My Gene, <http://www.mapmygene.com/index.htm> accessed 2 January 2013. [Checked again 29 January 2014 and still operating]. [Checked again 16 April 2014].

161 Map My Genome, <http://www.mapmygenome.in> accessed 27 January 2014. [Checked again 29 January 2014 and still operating]. [Checked again 22 April 2014].

162 Matt Roberts, <http://www.mattroberts.co.uk/store/performance/dna-fit-body-performance-pro/> accessed 7 April 2014.

168)	Medigenomix[164]
169)	MEDomics[165]
170)	MLSBioDNA Ltd[166]
171)	Molecular Diagnostic Services (PTY) LTD[167]
172)	WellPro[168]
173)	MVP Testing[169]
174)	myDNA[170]
175)	MyGene[171]
176)	My Gene Diet (Natures Remedies Ltd)[172]
177)	Mygenome.com[173]
178)	MyHeritage[174]
179)	Myriad[175]
180)	National Geographic's Genographic Project[176]
181)	Navigenics[177]
182)	Nimble Diagnostics[178]
183)	North American DNA Testing[179]
184)	Northgene[180]

163 Matrix Genomics, <http://www.matrixgenomics.com/aboutourlabCRL.php> accessed 14 August 2013. [Checked again 29 January 2014 and still operating]. [Checked again 22 April 2014].

164 Medigenomix, <http://www.medigenomix.de> accessed 14 August 2013. [Checked again 29 January 2014 and still operating]. [Checked again 22 April 2014].

165 MEDomics, <http://www.medomics.com> [Checked again 29 January 2014 and still operating]. [Checked again 22 April 2014].

166 MLSBioDNA Ltd, <http://mlsbiodna.net> accessed 18 October 2014 [Checked again 25 August 2015].

167 Molecular Diagnostic Services (PTY) LTD, <http://www.mdsafrica.net/site/default.asp> accessed 27 January 2014. [Checked again 22 April 2014].

168 WellPro, <http://www.wellpro.co.za/tests-landing/> accessed 27 January 2014. Checked again 22 April 2014].

169 MVP Testing, <http://www.mvptesting.org> accessed 8 September 2013. [Checked again 29 January 2014 and still operating]. [Checked again 22 April 2014]. [Checked again 22 April 2014].

170 myDNA, <http://www.mydna.co.in/index.html> accessed 13 August 2013. [Checked again 29 January 2014 and still operating]. [Checked again 22 April 2014].

171 My Gene, <http://www.mygene.com.au> accessed 13 August 2013. [Checked again 29 January 2014 and website suspended]. [Checked again 22 April 2014].

172 My Gene Diet, <http://www.my-gene-diet.com/products.php> accessed 13 August 2013. [Checked again 29 January 2014 and still operating]. [Checked again 23 April 2014].

173 Mygenome.com, <http://mygenome.com/mygenomehome.html> accessed 6 January 2013. [Checked again 29 January 2014 and not operating]. [Checked again 24 April 2014]

174 My Heritage, <http://www.myheritage.com/dna-tests> accessed 12 August 2013. [Checked again 29 January 2014 and still operating]. [Checked again 24 April 2014].

175 Myriad, <https://www.myriad.com/patients/> accessed 29 January 2014. [Checked again 24 April 2014].

176 National Geographic's Genographic Project, <https://genographic.nationalgeographic.com> accessed 14 August 2013. [Checked again 29 January 2014 and still operating]. [Checked again 24 April 2014].

177 Navigenics, <http://www.navigenics.com> accessed 6 January 2013. [Checked again 29 January 2014]. [Checked again 24 April 2014].

178 Nimble Diagnostics, <http://www.nimblediagnostics.co.uk> accessed 8 September 2013. [Checked again 29 January 2014 and still operating]. [Checked again 24 April 2014].

179 North American DNA Testing, <http://northamericandnatesting.com> accessed 7 April 2014. [Checked again 24 April 2014].

180 Northegene, <http://www.paternitytesting.co.uk> accessed 10 August 2013. [Checked again 29 January 2014 and still operating]. [Checked again 24 April 2014].

185)	Nutrigenomix[181]
186)	Oxford Ancestors[182]
187)	Paternity Testing Corp[183]
188)	PaternityUSA[184]
189)	Pathway Genomics[185]
190)	Perkin Elmer Genetics[186]
191)	PerioPredict™ Genetic Risk Test[187]
192)	Personal Genomics[188]
193)	Personal Genome Diagnostics Inc[189]
194)	PHENOM Biosciences Inc[190]
195)	Priority Investigations[191]
196)	Progenika Inc[192]
197)	Prophase Genetics[193]
198)	Relative Genetics
199)	Remede[194]
200)	Roots for Real[195]
201)	Salugen[196]
202)	ScientificMatch
203)	Sciona
204)	Scotlands DNA[197]

181 Nutrigenomix, <https://www.nutrigenomix.com/information-for-dietitians> accessed 3 July 2014.

182 Oxford Ancestors, <http://www.oxfordancestors.com/content/view/86/137/> accessed 10 August 2013. [Checked again 29 January 2014 and still operating]. [Checked again 24 April 2014].

183 Paternity Testing Corp, <http://www.ptclabs.com> accessed 27 January 2014. [Checked again 29 January 2014 and still operating]. [Checked again 24 April 2014].

184 PaternityUSA, <https://paternityusa.com/dnatests.htm> accessed 8 September 2013. [Checked again 29 January 2014 and still operating]. [Checked again 24 April 2014].

185 Pathway Genomics, <https://www.pathway.com > accessed 11 February 2013. [Checked again 29 January 2014 and still operating]. [Checked again 24 April 2014].

186 Perkin Elmer Genetics, <http://www.perkinelmer.com/AboutUs/ContactUs/ContactUs> accessed 10 August 2013. [Checked again 24 April 2014].

187 PerioPredict™, 'What is PerioPredict™?' <http://periopredict.com/patient/about.php> accessed 15 April 2014.

188 Personal Genomics, website still coming. [24 April 2014]

189 Personal Genome Diagnostics Inc, <http://personalgenome.com/about-personal-genome-diagnostics> accessed 13 August 2013. [Checked again 24 April 2014].

190 PHENOM Biosciences, <http://www.phenombio.com/about-us> accessed 30 April 2014.

191 Priority Investigations, <http://www.pilimited.com/pages/index.asp?title=About_Us> accessed 8 September 2013. [Checked again 29 January 2014 and still operating]. [Checked again 24 April 2014].

192 Progenika Inc, <http://www.progenika.com/us/index.php> [Checked again 29 January 2014 and still operating]. [Checked again 24 April 2014].

193 Prophase Genetics, <http://www.prophase-genetics.com/about_prophase_genetics.html> accessed 13 August 2013. [Checked again 29 January 2014 and still operating]. [Checked again 24 April 2014].

194 Remede, <http://remede.com.au/dna-profiles-nutrigenomics/> accessed 7 April 2014. [Checked again 24 April 2014].

195 Roots for Real, <http://www.rootsforreal.com> accessed 13 August 2013. [Checked again 29 January 2014 and still operating]. [Checked again 24 April 2014].

196 Salugen, <http://salugen.com> accessed 13 August 2013. [Checked again 29 January 2014 and website malfunctioning, check again]. [Checked again 24 April and seems to no longer be operating]

197 Scotlands DNA, <http://www.scotlandsdna.com> accessed 8 September 2013. [Checked again 29 January 2014 and still operating]. [Checked again 24 April 2014].

205)	SecureDNA Technologies
206)	Serotech Laboratories LTD[198]
207)	She Cheated[199]
208)	Signal Genetics Inc[200]
209)	Silbase Genetics[201]
210)	Smart DNA[202]
211)	Sorenson Genomics[203]
212)	SwabTest[204]
213)	Test Country[205]
214)	Test Diagnostics[206]
215)	Test Infidelity[207]
216)	That DNA Company[208]
217)	The Makings Of Me[209]
218)	The Wellness Brothers[210]
219)	The Wellness Gene[211]
220)	Theranostics Lab[212]
221)	Toldot Genetics[213]
222)	Triangle Wellness & Sports Center
223)	ULISSES WORLD[214]
224)	Universal Genetics DNA Testing Laboratory[215]

198 Serotech Laboratories LTD, <http://serotech.com/contact.php> accessed 12 August 2013. [Checked again 29 January 2014 and still operating]. [Checked again 24 April 2014].

199 She Cheated, <http://www.shecheated.net> accessed 2 February 2013. [Checked again 24 April 2014].

200 Signal Genetics Inc, <http://www.signalgenetics.com> accessed 27 January 2014. [Checked again 29 January 2014 and still operating]. [Checked again 24 April 2014].

201 Silbase Genetics, <www.silbase.com.au> accessed 13 May 2014.

202 Smart DNA, <http://www.smartdna.net.au/howitworks.html> accessed 13 August 2013. [Checked again 29 January 2014 and still operating]. [Checked again 24 April 2014].

203 Sorenson Genomics, <http://www.sorensongenomics.com> accessed 27 January 2014. [Checked again 29 January 2014 and still operating]. [Checked again 24 April 2014].

204 SwabTest, <http://www.swabtest.com/findatest/paternity.php> accessed 10 August 2013. [Checked again 29 January 2014 and still operating]. [Checked again 24 April 2014].

205 Test Country, <http://www.testcountry.com> accessed 10 August 2013. [Checked again 29 January 2014 and still operating]. [Checked again 24 April 2014].

206 Test Diagnostics, <http://www.testdiagnostics.com/uk/category/genetic-health> accessed 5 February 2014. [Checked again 24 April 2014].

207 Test Infidelity, <http://www.testinfidelity.com> accessed 20 January 2014. [Checked again 24 April 2014].

208 That DNA Company, <http://www.thatdnacompany.com> accessed 9 September 2013. [Checked again 29 January 2014 and still operating]. [Checked again 24 April 2014].

209 The Makings of Me, <http://www.themakingsofme.com> accessed 7 April 2014. [Checked again 24 April 2014].

210 The Wellness Brothers, <http://thewellnessbrothers.com/dna-diet.htm> accessed 7 April 2014. [Checked again 24 April 2014].

211 The Wellness Gene, <http://www.wellnessgene.com/DNA-Test.html> accessed 29 April 2014.

212 Theranostics Lab, <http://www.theranostics.co.nz/afawcs0143120/tn-products.html> accessed 5 January 2013. [Checked again 29 January 2014 and still operating]. [Checked again 24 April 2014].

213 Toldot Genetics, <http://www.toldot-dna.com/content/about-us> accessed 28 January 2014. [Checked again 24 April 2014].

214 ULISSES World, <http://www.ulissesworld.com/570-2/> accessed 30 April 2014.

225)	vuGene[216]
226)	Who'z the daddy?[217]
227)	XRGenomics Ltd[218]
228)	YSEQ DNA Origins Project[219]
229)	YOUology[220]

215 Universal Genetics, <http://www.dnatestingforpaternity.com/other-dna-tests.html> accessed 3 July 2013.

216 vuGene, <http://www.mygenesdirect.com> accessed 2 January 2013. [Checked again 29 January 2014 and website not displaying]. [Checked again 24 April 2014].

217 Who'z the daddy?, <http://www.whozthedaddy.com/regions/UK/EN/contact.asp> accessed 5 January 2013. [Checked again 29 January 2014 and still operating]. [Checked again 24 April 2014].

218 XRGenomics, <http://www.xrgenomics.co.uk/about/> and <http://www.xrgenomics.com> accessed 1 May 2014.

219 YSEQ DNA Origins Project, <htp://www.yseq.net> accessed 1 May 2014.

220 YOUology, <http://www.youology.com/about-youology.html> accessed 7 April 2014. [Checked again 24 April 2014].

TABLE OF ABBREVIATIONS FOR DIRECT-TO-CONSUMER COMPANY CONTRACT DOCUMENTS

Company	Title of Contract or Privacy Policy	URL	Date Saved	Abbreviated Document Name
1. 23andMe	Terms of Service Privacy Statement Consent Document	<www.23andme.com/about/tos/>[221]	21 July 2013 10 August 2013	TOS Privacy Consent
2. 23DNA	Privacy Policy	<http://www.23dna.co/privacy.html >	28 August 2013	Privacy
3. Accu-metrics Viaguard	No document available	<http://accu-metrics.com>	28 August 2013.	
4. American International Biotechnology, LLC (AIBioTech)	Privacy Practices	<alphabiolabs.com>	2 October 2014	Privacy
5. Any Lab Test Now®	PayPal User Agreement PayPal Privacy Policy	<http://www.mylabsa.com/index.html>	28 August 2013 13 August 2013	Agreement Privacy
6. Any Time Lab	Privacy Policy	<http://anytimelab.com/index.html>	8 April 2014	Privacy
7. ARUP Lab	Disclaimer Online Privacy Policy (last updated 21 September 2008)	<http://www.aruplab.com/genetics/tests>	14 January 2014	Disclaimer Privacy

[221] Please note that all documents are on file both in soft and hard copy form and the websites have also been checked more recently, but for the purposes of the analysis of contracts herein these are the relevant dates.

8. Asper Biotech	Terms and conditions Genetic Testing Terms and Conditions	<http://www.asperbio.com/genetic-tests>	5 October 2014 13 August 2013	T&C
9. Athleticode	No document available	<http://athleticode.com>	10 August 2013 Checked again 22 January 2014 and still operating. Checked again 9 April 2014.	
10. BalanceDiet™	No document available	<http://www.gobalancediet.com/about/about-balancediet/>	Accessed 28 August 2013. Checked again 28 January 2014 and still operating. Checked again 30 April 2014.	
11. Beyond Nutrition	No document available	<http://www.beyond-nutrition.co.uk/dna-diet/>	Accessed 28 August 2013. Checked again 28 January 2014 and still operating. Checked again 10 April 2014.	
12. BioClinics (Genetic Health Management)	Client Privacy Policy	<http://www.weightloss-dnatesting.co.uk/about>	5 October 2014	Privacy
13. Bio Logis	Terms of Service Privacy	<https://pgsbox.com>	14 January 2014 14 January 2014	TOS Privacy

14. Biotechnology Group Inc	No document available	<http://www.biotechnologygroup.com/index.html>	Accessed 22 January 2014. Checked again 28 January 2014 and still operating. Checked again 10 April 2014.	
15. Cancer Genetics Inc	Legal Notice and Terms of Use Privacy Policy	<http://www.cancergenetics.com>	2 October 2014 5 January 2014	TOS Privacy
16. CD Genomics	Terms & Conditions Privacy Policy	<http://www.cd-genomics.com>	5 October 2014 5 October 2014	T&C Privacy
17. C2DNA (Canadian Centre for DNA Diagnostics)	Terms of Use Return Policy Privacy Policy	<http://www.c2dna.com/index.html>	13 August 2013 13 August 2013 13 August 2013	TOU Return Privacy
18. Center for Medical Genetics	Privacy Statement	<http://www.geneticstesting.com>	15 January 2014	Privacy
19. Counsyl	Terms of Service Informed Consent	<https://www.counsyl.com>	15 January 2014 5 October 2014	TOS IC
20. Cygene Direct	Cygene Direct Privacy Policy CyGene DNA Testing Security Policy	<http://cygene.infinityarts.com>	2 October 2014 22 August 2013	Privacy Security

21. Darwin Dieticians	No document available	<http://www.darwindietitians.com.au>	Accessed 22 August 2013. Checked again 28 January 2014 and still operating. Checked again 10 April 2014.	
22. DDC, DNA Diagnostics Center	Privacy Statement	<http://www.dnacenter.com>	3 October 2014	Privacy
23. DDC, DNA Diagnostics Centre	Terms and Conditions for Use of this Site	<http://www.dna-bioscience.co.uk>	16 August 2013	T&C
24. DeCODEme	Terms of Use Privacy Policy	<http://www.decodeme.com>	22 August 2013 22 August 2013	TOU Privacy
25. Diagnomics	No document available	<http://www.diagnomics.com>	27 January 2014.	
26. DNALYSIS Biotechnology	Privacy Policy	<http://www.dnalysis.co.za/About-us.aspx>	22 August 2013	Privacy
27. DNAFit	Terms of Use Privacy Policy	<http://www.dnafit.com/uk/>	20 January 2014 20 January 2014	TOU Privacy
28. DNA Dimensions	No document available	<http://detroitdna.com>	Accessed 11 April 2014. Checked again accessed 13 May 2014.	
29. DNA Direct	Terms of Use Privacy Policy	<http://www.dnadirect.com>	22 August 2013 10 August 2013	TOU Privacy

30. DNA DTC	DNADTC.com –Terms and Conditions – Individual Customer Privacy Policy Consent Document for Individual Research Use	<http://www.dnadtc.com/about.aspx>	10 August 2013 10 August 2013 10 August 2013	T&C Privacy Consent
31. DNA Genie	Terms & Conditions Privacy Policy	<http://www.dna-genie.com>	29 January 2014 29 January 2014	TOC Privacy
32. DNA Plus	Terms of Use	<http://www.dnaplus.de/en/products/>	20 January 2014	TOU
33. DNA Slim	No document available	<https://www.dnaslim.org>	29 April 2014	
34. DNA Spectrum	Terms of Use (Terms of Service)	<http://www.dnaspectrum.com>	9 September 2013	TOU
35. DNA Testing Centres of Canada	Disclaimer Privacy Policy	<http://dnatestingcanada.com/about-us/>	1 October 2014 1 October 2014	Disclaimer Privacy
36. DNA Traits	Terms and Conditions	<http://www.dnatraits.com/about.aspx>	10 August 2013	T&C
37. easyDNA	Terms and Conditions (Australia) Terms and Conditions (UK) Terms and Conditions (USA) Privacy Policy (USA)	<http://www.easydna.com.au> <http://www.easydna.co.uk> <http://www.easy-dna.com/>	15 August 2013 15 August 2013 10 August 2013 15 August 2013	T&C (Auz) T&C (UK) T&C (USA) Privacy (USA)
38. EnteroLab	About Privacy	<https://www.enterolab.com>	15 August 2013	Privacy
39. FitGenes	Privacy	<http://www.fitgenes.com>	3 October 2014	Privacy
40. ForuMed Biotechnology	Not available	<http://www.forumed.eu/επικοινωνία>	30 April 2014	
41. Foundation Medicine Inc	Legal Notice and Terms of Use	<http://www.foundationmedicine.com>	19 January 2014	TOU

42. Gene by Gene	Terms and Conditions	<https://www.genebygene.com>	1 October 2014	T&C
43. GenePeeks	GenePeeks, Inc. Terms of Use GenePeeks Privacy Policy	<http://www.genepeeks.com>	3 October 2014 3 October 2014	TOU Privacy
44. GenePlanet	Terms and Conditions Privacy Statement	<http://www.geneplanet.com>	10 August 2013 10 August 2013	T&C Privacy
45. Geneticom	No document available	<http://www.geneticom.nl>	10 September 2013. Checked again 28 January 2014.	
46. Genetic Center Company Limited	Terms and Conditions for Use of Website Privacy Statement	<http://www.genetic-center.com>	13 August 2013 13 August 2013	T&C Privacy
47. Genetic Health	No Terms and Conditions Privacy Policy	<http://www.genetic-health.co.uk>	10 August 2013	T&C Privacy
48. Genetic Healthcare Group (geneLAB)	No terms and Conditions	<http://genetic-healthcare.com/gh_about_us.html>	30 April 2014	
49. Genetic Performance	Genetic Performance – Terms and Conditions	ttp://geneticperformance.com> accessed 29 April 2014.	7 October 2014	T&C
50. Genetic Testing Laboratories Inc (GTL)	Genetic Testing Lab: Terms of Use Disclaimer GTL DNA Testing Privacy Policy	<http://www.gtldna.com>	10 August 2013 10 August 2013	TOU Privacy
51. Genewiz	GENEWIZ Intellectual Property GENEWIZ Confidentiality	<http://www.genewiz.com>	19 January 2014 3 October 2014	IP Confidentiality
52. Genex Diagnostics Inc	Terms and Conditions Security and Privacy	<http://www.genexdiagnostics.com>	2 October 2014 2 October 2014	T&C Security

53. Genomic Express Inc	Privacy Policy	<https://secure.genomicexpress.com/home.html>	19 January 2014	Privacy
54. Genomic Health Inc	Legal	<http://www.genomichealth.com/en-US.aspx#.UuuKSv07S44>	7 October 2014	Legal
55. Genosense	Standard terms of business	<http://www.dnaplus.de/en/products/>	20 January 2014	Terms
56. GenoVive	GenoVive Website Terms & Conditions of Use Privacy & Usage Policy	<https://www.genovive.com>	3 October 2014 3 October 2014	TOC Privacy
57. Gentle	Terms of service Informed consent information	<https://gentlelabs.com>	7 April 2014 7 April 2014	TOS Consent
58. Gonidio	Terms of Use Privacy Policy Security	<http://www.gonidio.com>	13 August 2013 13 August 2013 13 August 2013	TOS Privacy Security
59. Graceful Earth	No document	<http://gracefulearth.com>	2 January 2013. Checked again 29 January 2014 and still operating. Checked again 15 April 2014.	
60. Halo Health	Website Terms of Service Privacy Policy	<http://halohealth.com/item/home-4/>	13 August 2013 13 August 2013	TOS Privacy

61. Holistic Health International	No document available	<http://www.holisticheal.com/dna-oxidative-damage.html>	3 February 2013. Checked again 29 January 2014 and still operating. Checked again 15 April 2014.	
62. Indian Biosciences	General Terms and Conditions Privacy Policy	<http://www.inbdna.com>	9 September 2013 9 September 2013	T&C Privacy
63. Inherent Health	Terms of Use	<http://www.inherenthealth.com/our-tests.aspx>	3 October 2013	TOU
64. Interleukin Genetics, Inc	No document available	<http://ilgenetics.com/content/products-services>	15 April 2014.	
65. International Biosciences	Terms of Use Terms and conditions Privacy Policy	<http://www.ibdna.com/regions/UK/EN/>	14 August 2013 14 August 2013 14 August 2013	
66. ION (Institute for Optimal Nutrition)	Website usage terms and conditions Privacy Policy	<http://www.ion.ac.uk/performance/dna_testing>	3 October 2014 3 October 2014	T&C Privacy
67. Kimball	No terms and conditions.	<http://www.kimballgenetics.com/tests.html>	2 January 2013. Checked again 16 April 2014.	
68. Knome	No terms and conditions.	<http://www.knome.com/knome-blog/direct-to-consumer-genomics-reinvents-itself/>	accessed 10 August 2013. Checked again 16 April 2014.	

69. LifeGenetics	General Terms of Business Privacy And Personal Data Protection Statement	<http://lifegenetics.net/terms-of-business/> <http://lifegenetics.net/legal-notice-privacy-statement/>	13 August 2013 13 August 2013	T&C Privacy
70. Lumigenix	No terms and conditions.	<www.lumigenix.com> No longer operating	5 January 2013. Checked again 16 April 2014.	
71. Map My Gene	Terms & Conditions Privacy Policy	<http://www.mapmygene.com/terms.htm> <http://www.mapmygene.com/privacy.htm>	7 October 2014 7 October 2014	T&C Privacy
72. Map My Genome	No terms and conditions.	<http://www.mapmygenome.in>	27 January 2014. Checked again 29 January 2014 and still operating. Checked again 22 April 2014	
73. Matrix Genomics	Terms and Conditions Privacy Policy	<http://www.matrixgenomics.com/aboutourlabCRL.php>	14 August 2013 20 January 2014 Checked again 29 January 2014 and still operating. Checked again 22 April 2014.	T&C Privacy
74. Matt Roberts	Matt Roberts Disclaimer Matt Roberts Privacy Policy	<http://www.mattroberts.co.uk/legal/> <http://www.mattroberts.co.uk/privacy/> <http://www.mattroberts.co.uk/disclaimer/>	8 April 2014 8 April 2014	Disclaimer Privacy

75. MEDomics	No terms and conditions.	<http://www.medomics.com>	29 January 2014 and still operating. Checked again 22 April 2014	
76. Molecular Diagnostic Services (PTY) LTD	Legal	<http://www.mdsafrica.net/site/default.asp>	19 January 2014	Legal
77. Myriad	Terms of Use Safe Harbor Policy Privacy Policy	<http://www.myriad.com/terms-of-use/> <http://myriad.com/safe-harbor-policy/> <http://myriad.com/privacy-policy/>	3 October 2014 3 October 2014 3 October 2014	TOU Safe Privacy
78. myDNA	myDNA Terms of Service myDNA Privacy Policy	<http://mydna.co.in/Terms%20of%20Service.html> <http://mydna.co.in/Privacy%20Policy.html>	3 October 2014 3 October 2014	TOS Privacy
79. MyGene	No terms and conditions.	<http://www.mygene.com.au>	13 August 2013. Checked again 29 January 2014 and website suspended. Checked again 22 April 2014	
80. My Gene Diet (Natures Remedies Ltd)	Website Terms and Conditions and Privacy Policy	<http://www.my-gene-diet.com/terms.php?>	13 August 2013 Checked again 29 January 2014. Checked again 23 April 2014.	T&C Privacy

81. Navigenics	Navigenics Terms and Conditions Navigenics Privacy Policy	<http://www.navigenics.com>	13 August 2013 13 August 2013 Checked again 29 January 2014. Checked again 24 April 2014.	T&C Privacy
82. Nimble Diagnostics	No terms and conditions	<http://www.nimblediagnostics.co.uk>	8 September 2013 Checked again 29 January 2014 Checked again 24 April 2014	
83. Pathway Genomics	Terms and Conditions Privacy Statement	<www.pathway.com/about-us/terms-and-conditions> <www.pathway.com/about-us/privacy-policy>	13 August 2013 13 August 2013 Checked again 24 April 2014	T&C Privacy
84. Perkin Elmer Genetics	Terms and Conditions Privacy Policy	<http://www.perkinelmer.com/OurCompany/AboutUs/Legal/TermsAndConditions/default.xhtml> <http://www.perkinelmer.com/OurCompany/AboutUs/Legal/PrivacyPolicy/default.xhtml>	10 August 2013 10 August 2013	T&C Privacy
85. PerioPredict™ Genetic Risk Test	No terms and conditions	<http://periopredict.com/patient/about.php>	15 April 2014.	
86. Personal Genome Diagnostics Inc	Legal/Privacy	<http://www.personalgenome.com/legal-privacy>	19 January 2014 Checked again 24 April 2014.	Privacy
87. Personal Genomics	No terms and conditions	website still coming.	24 April 2014	
88. PHENOM Biosciences Inc	Terms of Service Privacy Policy	<www.phenombio.com/about-us>	6 October 2014 6 October 2014	TOS Privacy

89. Progenika Inc	Legal Disclaimer Privacy Policy	<www.progenika.com/us/index.php>	19 January 2014 19 January 2014 Checked again 24 April 2014	Disclaimer Privacy
90. Remede	No terms and conditions.	<http://remede.com.au/dna-profiles-nutrigenomics/>	7 April 2014 Checked again 24 April 2014	
91. Signal Genetics Inc	No terms and conditions.	<http://www.signalgenetics.com>	27 January 2014. Checked again 29 January 2014 and still operating. Checked again 24 April 2014.	
92. Smart DNA	Smart Terms	<http://www.smartdna.net.au/howitworks.htm>	14 August 2013	T&C
93. Test Country	Terms & Conditions Privacy Policy	<http://www.testcountry.com>	10 August 2013 10 August 2013	T&C PP
94. Test Diagnostics	Terms of Use Privacy and Cookies Policy	<http://www.testdiagnostics.com/uk/ >	5 February 2014 5 February 2014	TOU PP
95. Theranostics Lab	Terms and Conditions	<www.theranostics.co.nz/afawcs0143120/tn-products.html>	13 August 2013	T&C
96. The Makings Of Me	Terms of Use (dated 29 November 2011) Service Agreement (dated 29 November 2011) Privacy Policy (dated 29 November 2011)	<www.themakingsofme.com/terms-of-use.html> <www.themakingsofme.com/service-agreement.html> <www.themakingsofme.com/privacy-policy.html>	3 October 2014 3 October 2014 3 October 2014	TOU Agreement Privacy

97. The Wellness Brothers	No terms and conditions.	<http://thewellnessbrothers.com/dna-diet.htm>	7 April 2014. Checked again 24 April 2014.	
98. Toldot Genetics	No document available, although the website says there are terms. However, these are not accessible when the links are clicked upon.	<www.toldot-dna.com/>	28 January 2014 Checked again 24 April 2014	
99. vuGene	Important Notices and Disclaimers Privacy Policy	<http://www.mygenesdirect.com>	13 August 2013 13 August 2013	Disclaimer Privacy
100. The Wellness Gene	No terms and conditions	<http://www.wellnessgene.com/DNA-Test.html>	29 April 2014.	
101. WellPro	No terms and conditions	<http://www.wellpro.co.za/tests-landing/>	27 January 2014. Checked again 22 April 2014.	
102. YOUology	No terms and conditions	<http://www.youology.com/about-youology.html>	7 April 2014. Checked again 24 April 2014.	

INTRODUCTION

The direct-to-consumer genetic testing (DTCGT) industry has developed within the last decade, beginning with the launch of 23andMe and deCODEme's services[222] in 2007. It has since grown steadily with 229 companies identified during the course of research for this thesis.[223] The industry can be viewed as an example of disruptive innovation, as it has created a new market for genetic testing services as consumer services. The industry allows people to purchase genetic tests online for a variety of purposes, ranging from tests for health-related to ancestry and child talent. Previously genetic tests for health purposes were provided in a face-to-face medical setting and whether to have the test was determined by medical professionals. Non-health related tests would normally only be performed as part of legal proceedings or a criminal investigation, but again the tests were performed in person and according to strict standards. By bringing genetic tests outside of these structures and into people's homes, the nature of the industry poses challenges for regulation. At present, it is not subject to specific regulation (although the Human Tissue Act does set requirements for consent and has made it an offence to analyse DNA without appropriate consent) and as with many other web-based industries, companies have tended to rely on clickwrap and browsewrap contracts (wrap contracts) to govern their relationship with their purchasers. This thesis will examine the use of wrap contracts by DTCGT companies as the dominant governance mechanism for the industry and the effects such contracts have on the rights of consumers in their sequenced

222 Sancy A Leachman et al, 'Direct-to-consumer genetic testing: personalized medicine in evolution'34, 36; Pascal Su, 'Direct-to-Consumer Genetic Testing: A Comprehensive View' (2013) 86 The Yale Journal of Biology and Medicine 359

223 Please see my recent article for a further update figure on the number of companies currently operating. Andelka M Phillips, 'Only a click away—DTC genetics for ancestry, health, love… and more: A view of the business and regulatory landscape' (2016) 8 Applied & Translational Genomics 16-22.

genetic information. It will explore whether the use of such contracts appropriately balances the respective rights of companies and consumers and whether reform is needed. It will also consider whether the use of such contracts can be construed as a form of private legislation that serves to allow the industry to self-regulate. This will primarily be done through a comparative document analysis of the publicly available wrap contracts used by DTCGT companies. The conclusions of this thesis are that: certain terms commonly included in DTCGT contracts could be construed as unfair terms under English law. Specifically, the following terms are likely to be deemed to be unfair: terms allowing for unilateral alteration of terms; clauses forcing a consumer to resolve disputes in another jurisdiction; indemnity clauses; exclusion clauses disclaiming liability for fitness for purpose or personal injury caused by the company's negligence; scope of purpose clauses; and clauses deeming consent or assent; the Competition & Markets Authority (CMA) should seek to improve DTCGT contracts and discontinue the use of problematic terms; and that the use of wrap contracts in this context can be viewed as a form of private legislation which is effectively industry self-regulation that is skewed heavily in favour of companies and does not afford sufficient protection to the rights of consumers and improved legal regulation of the industry is desirable. The focus herein is on reviewing the contracts as they are currently framed and how these might be reformed through challenging certain types of terms on the basis of their unfairness and how this might be achieved through the intervention of the CMA. It is possible to compare DTCGT services with other web-based industries and a useful comparison can be made with cloud storage providers. Given that the CMA has only recently completed a review of compliance of cloud storage providers, which has already resulted in a number of

companies agreeing to improve their terms,[224] the possibility of the CMA conducting a similar compliance review of DTCGT companies does seem a workable solution to improving consumer protection in this context. It may be that this is not the best long-term solution for consumers and that specific legislation or enforcement action from the UK's Human Tissue Authority, Information Commissioner's Office (ICO) and Medicines and Healthcare products Regulatory Agency (MHRA) are necessary. At present, there are several options that might be taken to improving the regulation of the industry and it is hoped that the discussion herein will serve to assist regulators and policymakers in thinking about regulation of the industry and that it can highlight any current industry practices which might be problematic.

Given the nature of DTCGT services and the various areas of law that might have applicability to the industry's regulation, the aim herein is not to argue strongly for one position, but to suggest several possibilities. I have chosen to argue for an increased role of the CMA in regulating DTCGT in the short-term. This is primarily due to the fact that the industry has been allowed to operate as a consumer facing industry in the UK and as existing legislation has not already been enforced against the industry, the content of DTCGT contracts has taken on a governance role. Furthermore, as several terms commonly included in DTCGT contracts are challengeable on the grounds of unfairness and the CMA's predecessor, the Office of Fair Trading, had success with working with industries to discontinue the use of specific terms, suggesting that the CMA takes on a more active role in policing the terms used by the DTCGT industry seems a pragmatic short-term solution, that might enhance the protection of consumers' rights.

---

224 CMA, *Consumer Law Compliance Review: Cloud Storage* (CMA, Findings Report, 2016) <https://assets.digital.cabinet-office.gov.uk/media/57472953e5274a037500000d/cloud-storage-findings-report.pdf> accessed 29 May 2016.

As noted above, there are several sources of regulation, which might be drawn upon to regulate the DTCGT industry. These include existing medical devices and data protection regulation as well as consumer protection and human rights. However, contract law currently governs the transaction between DTCGT company and consumer when she purchases a test online. It is also a changing time for regulation in the sense that data protection law and regulation of medical devices may undergo significant reform in the UK. The European Council has now approved the new General Data Protection Regulation ((EU) 2016/679) as of April 2016[225] and there are two draft regulations on medical devices. The GDPR will significantly change data protection law within the European Union over the coming years. Should the In Vitro Diagnostic Medical Devices Regulation (IVD Regulation) also be approved the law on this throughout the EU will also be significantly altered.[226] Both data protection and medical devices reform are likely to impact upon the oversight of the DTCGT industry, but that impact will have to be considered in future research. This thesis focuses primarily on contract law together with applicable consumer protection law, as the legal mechanism for regulating DTCGT and a major component of this thesis consists of a comparative document analysis of the contracts used by DTCGT companies, although chapter four discusses the various applicable areas of law and policy guidance. Questions regarding the legality of DTCGT services are beyond the scope of the thesis, but may be touched upon briefly in the context of discussion of the concerns raised by various commentators. The focus herein is on consumers' rights in relation to their sequenced genetic information, rather than the physical sample of DNA itself.

225 European Commission, 'Reform of EU data protection rules', last updated 10th of May 2016, <http://ec.europa.eu/justice/data-protection/reform/index_en.htm> accessed 12 May 2016.

226 There are draft versions of the Data Protection Regulation and two separate Medical Devices Regulations.

In so doing, it will consider whether current business practice in this field appropriately balances the respective rights of companies and consumers. Crucial to this analysis is the UK legislation on unfair terms in contracts. This legislation is also in the process of significant reform with the enactment of the Consumer Rights Act 2015 and an important question which the thesis will explore is whether several of the terms commonly included in DTCGT contracts ought to be construed as 'unfair terms' which may be unenforceable under UK and EU law.

It should be noted at the outset that DTCGT contracts are of a specific type. They are wrap contracts, which are either framed as clickwrap or browsewrap agreements. In this work wrap contracts is used in the same manner as in Nancy Kim's leading text, *Wrap Contracts: Foundations and Ramifications*. Accordingly, the term 'wrap contract' is used as:

> a blanket term to refer to a unilaterally imposed set of terms which the drafter purports to be legally binding and which is presented to the nondrafting party in a nontraditional format. Nontraditional in this context means that the contracting form wasn't commonly used prior to 1980 and includes electronic media and offline mediums. The single common characteristic is that the adhering party does not have to use a pen in order to accept the terms.[227]

Both clickwrap and browsewrap are contractual forms common to all types of e-commerce and many DTCGT contracts strongly resemble the contracts used by Google, iTunes, Twitter, and Amazon. Such contracts are normally extremely lengthy. For instance, a recent article compared the lengths of iTunes' and Amazon's contracts to the

[227] Nancy S Kim, *Wrap Contracts: Foundations and Ramifications* (OUP 2014) 2

length of Macbeth and Hamlet[228] respectively and both contracts are longer than these plays, so now people can choose whether to read Wrap contracts or Shakespeare.

1 Structure of thesis

The first part introduces the challenges, which DTCGT poses to existing legal regulation due to its disruptive nature. Chapter two provides a discussion of the science, which has made the industry possible, emphasizing the complex and ambiguous nature of genetic test results and the lack of clinical utility and validity of many DTCGT tests offered currently. Chapter three provides an overview of the industry and considers the diverse variety of tests currently available and the issues which different types of test raise. Chapter four summarises the regulatory response to date, which has primarily been a policy response. It identifies the common themes raised by policy makers and also addresses the existing regulatory regimes, which might be applicable to the industry. These are: medical devices regulation; data protection; consumer protection; and human rights.

The second part consists of an examination of wrap contracts used by DTCGT companies providing tests for health purposes and how certain types of terms might be challenged on the grounds of their potential unfairness under English law. Chapter five reviews the wrap contracts of DTCGT companies that provide health-related tests. It provides examples of terms commonly found in these contracts. This is essentially a case study of one category of testing, which is representative of the challenges, which the industry in general poses for regulation and for society. It argues that the use of these

[228] Wigley + Company Solicitors, 'To read or not to read… Online Ts and Cs. Or Hamlet' (*Wigley + Company Solicitors*, 2015) <wigleylaw.com/assets/Uploads/To-read-or-not-to-read.pdf> accessed 7 July 2015

contracts can be viewed as a form of private legislation used by companies to protect their interests. Chapter six then considers how it might be possible to challenge certain terms based on their potential unfairness and considers applicable legislation on unfair terms in the UK.

As genetic information serves as both a unique identifier for the individual tested and can also be used to identify family members, it is important to consider how the industry deals with genetic information and this will be discussed in chapter three. Although, the content of DTCGT companies' privacy policies has been considered during the course of this research, it is not possible to cover this in detail herein.

(a) What is Direct-to-Consumer Genetic Testing?

In providing genetic tests directly to consumers companies are taking genetics out of the medical clinic and into the domestic realm. DTCGT companies are selling products to consumers, which involve several elements, each of which can trigger different legal mechanisms to apply.

A DTCGT test begins with the online purchase of the service, which is dependent upon the provision by the company of a test kit, which the consumer uses to collect a DNA sample, which is in turn sent back to the company, which then carries out the sequencing service and then ultimately provides the consumer with test results in digital form. In the context of companies that provide testing for health purposes, testing which has previously been considered as medical is being provided in a new space, a consumer space. The consumer space differs significantly from the medical space, but in the

context of health related testing it is also not clear that DTCGT services ought to be viewed as consumer services and not medical services.[229]

DTCGT is also sometimes referred to as personal genome testing (PGT).[230] There are a wide variety of definitions available for what constitutes a genetic test.[231] In the UK, the definition of a genetic test given by the Human Genetics Commission is a useful starting point. It defines the term as follows:

> A test to detect the presence or absence of, or a change in, a particular sequence of DNA, gene or chromosome or a gene product or other specific metabolite that is primarily indicative of a specific genetic change.[232]

Meanwhile, the US Task Force on Genetic Testing defines a genetic test as:

> The analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites in order to detect heritable disease-related genotypes, mutations, phenotypes or karyotypes for clinical purposes. Such purposes include predicting risk of disease, identifying carriers and establishing prenatal and clinical diagnosis or prognosis. Prenatal, newborn and carrier screening, as well as testing in high-risk families, are included. Tests for metabolites are covered only when they are undertaken with high probability that an excess or deficiency of the metabolite indicates the presence of heritable mutations in single genes.[233]

There is some commonality between these definitions, but the overall lack of consistency is problematic for the law and some commentators argue for the need for more consistency in definitions, which is something that is desirable.[234] For present

---

229 Kenneth Offit, 'Genomic profiles for disease risk: predictive or premature?' (2008) 299 JAMA : the journal of the American Medical Association 1353

230 G Samuel, CFC Jordens and I Kerridge, 'Direct-to-Consumer Personal Genome Testing: Ethical and Regulatory Issues That Arise From Wanting to 'Know' Your DNA' (2010) 40 Internal Medicine Journal 220-4

231 J Sequeiros et al, 'The wide variation of definitions of genetic testing in international recommendations, guidelines and reports' (2012) 3 J Community Genet 113-124

232 Human Genetics Commission, *A Common Framework of Principles for direct-to-consumer genetic testing services* (Department of Health, 2010) 3

233 Neil A Holtzman and Michael S Watson, 'Promoting safe and effective genetic testing in the United States: final report of the Task Force on Genetic Testing' (1997)

234 RL Zimmern, 'Issues Concerning the Evaluation and Regulation of Predictive Genetic Testing' (2012) 5 J Community Genet 49; O. Varga et al, 'Definitions of genetic testing in European legal documents' (2012) 3 J Community Genet 125-141

purposes though a broad definition is required, as there is much variety in the services offered by DTCGT companies.

The term 'direct-to-consumer' has primarily developed in the context of advertising and sale of pharmaceutical drugs.[235] DTCGT can either be advertised to the public but only available through an intermediary (normally a medical practitioner), or it can be both advertised directly and available for order directly by a consumer, normally over the Internet, sometimes also with the involvement of a medical practitioner.[236]

DTCGT companies offer a wide variety of services. Many of these tests do have implications for a person's health. A distinction is often made between tests, which have direct relevance for health and those, which are carried out for the purposes of 'recreational genomics' (or lifestyle testing) that is carried out essentially 'for fun'. Recreational genomics can include tests revealing information about ancestry and the ability to taste or smell certain substances. Examples include: testing for hair thickness[237]; and bitter taste perception, which identifies whether Brussels sprouts taste bitter to you.[238] Examples of health-related tests include: pre-symptomatic testing; carrier screening; pharmacogenetic testing, which focuses on making connections between genetics and an individual's responsiveness to particular drugs; and

235 Wayne L Pines, 'History and Perspective on Direct-to-Consumer Promotion, A' (1999) 54 Food & Drug LJ 489

236 S Hogarth, G Javitt and D Melzer, 'The current landscape for direct-to-consumer genetic testing: legal, ethical, and policy issues' (2008) 9 Annu Rev Genomics Hum Genet 161-82, 163-4

237 John Lynch and et al, 'Media Coverage of Direct-to-Consumer Genetic Testing ' (2011) 20 J Genet Counsel 486;R Geransar and E Einsiedel, 'Evaluating online direct-to-consumer marketing of genetic tests: informed choices or buyers beware?' (2008) 12 Genet Test 13;A Caplan and E Matloff, 'Direct to Confusion: Lessons Learned from Marketing BRCA Testing ' (2008) 8(6) The American Journal of Bioethics 5;P Barry, 'Seeking Genetic Fate Personal genomics Companies Offer Forecasts of Disease Risk, but the Science behind the Packaging Is Still Evolving' (2009) 176(1) Science News 16 ibid;A Nordgren, 'Neither as harmful as feared by critics nor as empowering as promised by providers: risk information offered direct to consumer by personal genomics companies' (2014) 5(1) J Community Genet 59;National Center for Biotechnology Information, 'Genetic Testing Registry' (2012) <ncbi.nlm.nih.gov/gtr/> accessed accessed 23rd October 2012.

238 Samuel, Jordens and Kerridge (n 230) 220-4

predictive/susceptibility testing.[239] However, the distinction between what is health-related and what is recreational is not clear-cut and much information, which may seem irrelevant, can in fact have implications for a person's health. For instance, ancestry testing has primarily been treated as being recreational, but sometimes it can reveal information that does have medical relevance.[240] This becomes more apparent when one considers the abundance of research, which has already been conducted on the incidence of diseases in particular family groups. Also, the lines between ancestry testing and health testing are increasingly blurred. The example of Ancestry.com's recent announcement that it will be moving into health research highlights this trend.[241]

Although the focus herein is primarily on the UK environment, it will consider applicable EU law and provide brief discussion of the US situation due to the majority of DTCGT companies being based in the USA. It will also include some brief mention of the Canadian situation in the context of policy response to date. As of March 2015, there are approximately 229 companies with English language websites offering DTCGT services around the world.[242] Many of these are based in the USA, (55 of the 102 health related testing companies are based in the USA)[243] where there is a strong market

---

239 P Borry et al, 'Legislation on direct-to-consumer genetic testing in seven European countries' (2012) 20 Eur J Hum Genet 715-721;P Borry, MC Cornel and HC Howard, 'Where are you going, where have you been: a recent history of the direct-to-consumer genetic testing market' (2010) 1 J Community Genet 101; T Caulfield and AL McGuire, 'Direct-to-consumer genetic testing: perceptions, problems, and policy responses' (2012) 63 Annu Rev Med 23-33

240 J Sequeiros, 'Regulating genetic testing: the relevance of appropriate definitions' in Ulf Kristoffersson, Jörg Schmidtke and JJ Cassiman (eds), *Quality Issues in Clinical Genetic Services* (Springer 2010)23-32, 26

241 Daniela Hernandez, 'Ancestry.Com Is Quietly Transforming Itself Into A Medical Research Juggernaut' *The World Post* (6 April 2015) <http://www.huffingtonpost.com/2015/04/06/ancestrycom-medical-research-juggernaut_n_7008446.html> accessed 6 April 2015

242 SW Gray et al, 'The impact of risk information exposure on women's beliefs about direct-to-consumer genetic testing for BRCA mutations' (2012) 81 Clin Genet 29 29–37; AL Beaudet, 'Assign Regulation Appropriate to the Level of Risk' (2010) Nature - Opinion 817-8; G Javitt, 'Which Way for Genetic Test Regulation' 816

243 For the sake of clarity numerals will be used rather than words, when discussing figures.

evolving in health delivery and personalised medicine.[244] (nine are based in Australia, four are based in Canada, ten are based in the UK). Many DTCGT companies offer testing internationally.

The DTCGT field is new and continuing to develop rapidly with companies entering or leaving the market. Some, such as Navigenics and DeCODE have been purchased by biomedical research companies and others are merging with or have acquired others.[245] For instance, Gene By Gene's FamilyTreeDNA has also acquired DNA Heritage and DNA-Fingerprint, and MyHeritage has partnered with both Family Tree DNA and 23andMe. 23andMe has also entered partnerships with fourteen entities, most notably Pfizer, Genentech, and Reset Therapeutics[246] and may also collaborate with Google's Calico due to its links with Google.[247] 23andMe has also very recently started a pharmaceutical branch.[248] 23andMe also purchased CureTogether in 2012. [249] More

---

244 Health Law Institute, *Analysis of Privacy Policies and Practices of Direct-to-Consumer Genetic Testing Companies: Private Sector Databanks and Privacy Protection Norms* (Report funded by the Office of the Privacy Commissioner of Canada, 2010)16-17; R Dvoskin and D Kaufman, 'Tables of direct-to-consumer genetic testing companies and conditions tested–August 2011' (2011) <dnapolicy.org/images/reportpdfs/NewMethodsForDTCTable_updated_Jan2012.pdf> accessed 11 October, 2012; Genetics & Public Policy Center, *Table of Direct-to-Consumer Genetic Testing Companies listed alphabetically* (Gentics & Public Policy Center, 2011)

245 Please note, this section cites material from an article I wrote which was published as part of the proceedings of the GenoPri 2015 Workshop in San Jose, California. Andelka M Phillips, 'Genomic Privacy and Direct-to-Consumer Genetics Big Consumer Genetic Data – What's in that Contract?' (2015 IEEE CS Security and Privacy Workshops)

246 Mark Sullivan, '23andMe has signed 12 other genetic data partnerships beyond Pfizer and Genentech' *VentureBeat* (14 January 2015) <venturebeat.com/2015/01/14/23andme-has-signed-12-other-genetic-data-partnerships-beyond-pfizer-and-genentech/> accessed 20 August 2015

247 Christine Lagorio-Chafkin, '23andMe Exec: You Ain't Seen Nothing Yet' *Inc* (7 January 2015) <http://www.inc.com/christine-lagorio/23andMe-new-partnerships.html> accessed accessed 9 March 2015; The Associated Press, 'Pfizer, 23andMe team up to study bowel disease' *Associated Press* (12 August 2014) <medicalxpress.com/news/2014-08-pfizer-23andme-team-bowel-disease.html 10 September 2014> accessed 10 September 2014; Andrew Ward, 'Google-backed genetic testing company hires veteran scientist' *The Financial Times* (12 March 2015) <ft.com/cms/s/0/ead07e84-c8d8-11e4-bc64-00144feab7de.html> accessed 20 August 2015

248 Arielle Duhaime-Ross, '23andMe plans to move beyond genetic testing to making drugs' <theverge.com/2015/3/12/8199303/23andme-drug-development-testing> ;GenomeWeb staff reporter, '23andMe Launches Therapeutics Group with Former Genentech Exec at Helm' (GenomeWeb, 12 March 2015) <genomeweb.com/drug-discovery-development/23andme-launches-therapeutics-group-former-genentech-exec-helm> accessed 12 March 2015

recently, as of 2015, AncestryDNA has begun collaboration with Calico,[250] which is in turn owned by Google meaning that some of the most prominent DTCGT companies are interconnected.

DTCGT companies offer a variety of services, but their normal procedure is to allow people to order a test kit from their website. The customer then receives a kit in the mail and uses the kit to take a sample of their DNA, normally in the form of saliva.[251] The customer will then send this sample back to the company for analysis.[252] After the sample has been analysed the company will convey the results of the test to the consumer and sometimes provide on-going updates on their health information. These results and on-going updates are normally accessible through an IT interface. So web-based return of results is the primary mode of delivering results to consumers and this is often done without recourse to genetic counselling, although the state of California requires DTCGT companies to offer genetic counselling.[253] It is difficult to assess the size of the DTCGT market at present, but it is likely that with the reduction in costs of sequencing the market will grow in the near future.[254] 23andMe recently exceeded 1 million customers[255] with 'more than 80 percent consented to participate in research'.[256]

---

249 A Proffitt, 'Deals center on self-reported patient data services' (2012) 30 Nature Biotechnology 1016; 23andMe, '23andMe Acquires CureTogether, Inc.' (*Press Release,* 12 July 2012), <23andme.com/about/press/curetogether/> accessed 6 January 2013; CureTogether Inc, <23andme.com/about/press/curetogether/> accessed 6 January 2013

250 GenomeWeb Staff Reporter, 'AncestryDNA, Calico to Collaborate on Genetics of Human Longevity' *GenomeWeb* (21 July 2015)

251 23andMe, 'How It Works' <https://www.23andme.com/howitworks/> accessed 7 January 2013.

252 Anna Harris, Sally Wyatt and Susan E Kelly, 'The Gift of Spit (And the Obligation to Return it) How consumers of online genetic testing services participate in research' (2013) 16(2) Information, Communication & Society 236

253 J Kaye, 'The Regulation of Direct-to-Consumer Genetic Tests' (2008) 17 Hum Mol Genet R180

254 European Academies Science Advisory Council (EASAC) and the Federation of European Academies of Medicine (FEAM), *Direct-to-Consumer Genetic Testing- Summary Document* (EASAC-FEAM Project on Direct-to-Consumer Genetic Testing, October 2012) 4-6; Dr Spencer Wells of National Geographic's Genographic Project speaking at the Consumer Genetics Conference in Boston in 2013 suggested that the most likely growth area in the immediate future in consumer genetics would be in the field of ancestry testing.

2 Methodology

A major component of this thesis consists of a document review of DTCGT Companies' contracts, which appear on websites as Terms of Use, Terms of Service, Privacy Policies, and Disclaimers of Liability. In order to do this, a list of companies currently operating in this field was compiled. The list was compiled between October 2011 and November 2014.[257] This work builds upon work conducted by the Human Genetics Commission (HGC), the Government Accountability Office (GAO), and the Genetics and Public Policy Center (GPPC) at Johns Hopkins, which have all compiled lists of DTCGT companies.[258] This data was compiled with the long-term intention of creating a publicly available database, which listed relevant information about these companies.

In order to compile this catalogue of companies searches were performed using an Internet search engine (Google) and the following terms were entered: order genetic test online, order disease risk genetic test, genetic test diet, order genetic predisposition test, genetic test for athletic ability, genetic paternity test, genetic test for drug response, genetic test nutrition, genetic test metabolism, DNA diet test, DNA health risk test, infidelity DNA test, genetic test for Warfarin, genetic test for statin, genetic test for

---

255 Anne Wojcicki, 'Power of One Million' (*23andMeBlog*, 2015) <blog.23andme.com/news/one-in-a-million/> accessed 18 June 2015

256 Kurzweil, '23andMe granted authorization by FDA to market first direct-to-consumer genetic test' (*KurzweilAI*) <kurzweilai.net/23andme-granted-authorization-by-fda-to-market-first-direct-to-consumer-genetic-test> accessed 23 February 2015

257 I am still updating the list, but for the purposes of the thesis I will not be considering the contracts of companies that have entered the market place since November 2014. I am also grateful to Mary Chitty of Cambridge Healthtech Institute, as in 2013 I had the benefit of comparing her list of companies with my own,

258 The Genetics and Public Policy Center, 'Table - Tested listed by disease category ' (11 August 2011) <http://www.dnapolicy.org/news.release.php?action=detail&pressrelease_id=145> accessed 11 April 2012; Human Genetics Commission, *Genes Direct: Ensuring The Effective Oversight Of Genetic Tests Supplied Directly To The Public* (Department of Health, 2003); Human Genetics Commission, *More Genes Direct* (Department of Health, 2007); HGC, *A Common Framework of Principles* (n 232); Gregory Kutz, *Direct-to-Consumer Genetic Tests: Misleading Test Results are Further Complicated by Deceptive Marketing and Other Questionable Practices: Congressional Testimony* (DIANE Publishing 2010)

prostate cancer, genetic test for breast cancer risk, genetic carrier test, ancestry DNA test, genetic ancestry test. These searches were used to identify English language websites for potential DTCGT companies (229 companies). This procedure was repeated on a semi-regular basis. In conducting these searches reference was also made to the work conducted by the HGC, the GAO, and the GPPC and all websites of companies listed in the work of these organisations were examined.

Each candidate website was inspected manually to confirm that it was for a DTCGT company (229 companies). Each DTCGT company was assigned to one of the following categories: health (subdivisions of pharmacogenetic; predisposition; pre-symptomatic; nutrigenetic; carrier testing; and testing available through physicians) 102 companies in total; ancestry – 68 companies; paternity – 85 companies; non-consensual – 34 companies; DNA dating – 4 companies; and child talent and athletic ability – 29 companies. All companies identified were tabulated with one master table (229 companies) and then tables of the various categories running to 481 pages. The tables briefly summarise the services offered by each company and also classify the companies into groups based on the type of services they offer.[259] If a company's website was no longer functioning or the company ceased to operate this was also recorded. Chapter four will provide an overview of the industry and the issues, which each category of testing raises based on this list.

In compiling the list of health related testing companies, those companies, which market their services to physicians and/or allow consumers to order through physicians were also included for the sake of comprehensiveness. The websites of DTCGT

[259] Andelka M Phillips, 'Think Before You Click Ordering A Genetic Test Online' (2015) 11 Scitech Lawyer 8

companies in the health category (102 companies) were examined to identify those whose terms and conditions were available to the public (71 companies).

The online contracts and privacy policies of health-related DTCGT companies were saved as electronic documents (PDF files). Where available the contracts and privacy policies were also saved for all other categories of testing and these will be examined in future research. Common clauses have then been tabulated and the tabulation runs to 468 pages. Chapter five provides an overview of the typical DTCGT contract using examples of terms commonly found in the contracts. The contracts were read to ascertain similarities, differences and overall trends and chapter six will present these findings and provide a description of the typical DTCGT contract.

CHAPTER ONE – DTCGT AS A DISRUPTIVE TECHNOLOGY POSING CHALLENGES FOR REGULATION

1 Introduction

The DTCGT industry is an example of disruptive innovation and as it is centred on genetic and genomic sequencing technology, it poses challenges for existing regulatory mechanisms and is representative of a broader paradigm shift in the area of personalised and precision medicine. [260] The thesis is concerned with current industry governance, which at present relies on DTCGT companies' contracts. Individuals purchasing such tests are no longer solely to be regarded as patients; they are consumers. In the context of health-related DTCGT services though they maybe healthcare consumers and it is also possible that they may be regarded as patients or akin to research participants depending on the specific circumstances. As the industry is currently framed it sits outside existing regulation. Due to the industry's web-based nature companies make use of wrap contracts to govern the purchase of genetic tests and this use will be explored herein as a means of industry self-governance. Previously, such tests were confined to a medical setting and individuals underwent testing as either patients or research participants. In the medical setting there are a variety of governance mechanisms that have served to protect people and ensure standards. Patients would generally receive genetic counselling before and after undergoing a test, which meant that they would have a better understanding of

260 Heidi Howard, Bartha Knoppers and Pascal Borry, 'Blurring lines. The research activities of direct-to-consumer genetic testing companies raise questions about consumers as research subjects' (2010) 11 EMBO Reports 579; R Hastings et al, 'The changing landscape of genetic testing and its impact on clinical and laboratory services and research in Europe' (2012) 20 Eur J Hum Genet 911; Hugh McLaughlin, 'What's in a name: 'client', 'patient', 'customer', 'consumer', 'expert by experience', 'service user'—what's next?' (2009) 39 British Journal of Social Work 1101; DH Gustafson, 'Expanding on the role of patient as consumer' (1991) 17 QRB Quality review bulletin 324

what to expect from the process and the limitations of such tests. The provision of tests by DTCGT companies allows for testing outside these structures and challenge existing governance. The present chapter will set out the various ways in which DTCGT is challenging for existing regulation, policy, and society. This shift is important and it is this shift, which in turn gives rise to many of the challenges, which DTCGT poses in terms of how to appropriately regulate it.

DTCGT can be viewed as an example of a disruptive innovation,[261] as it offers an innovative new service, which cuts across paradigms and does not fit within existing regulatory frameworks, which in turn means that it also poses difficulties when considering its appropriate regulation. Disruptive innovation is a term coined by Clayton Christensen and it can be defined as, 'a process by which a product or service takes root initially in simple applications at the bottom of a market and then relentlessly moves up market, eventually displacing established competitors'.[262] Disruptive innovations often create new markets that did not exist previously, which is true of DTCGT. One of the leading DTCGT companies, 23andMe, has actually been described as:

> an example of what we call a "Big Bang Disruption" — a product or service innovation that undermines existing markets and industries seemingly overnight by being simultaneously better and cheaper than the competition. What's happening in genomic testing (and healthcare in general) is consistent with our research in over 30 different industry segments, from manufacturing to financial services to consumer products.
>
> When technologies improve exponentially, many industry incumbents — and the regulators who oversee them — are kept constantly off-balance. That's because incumbents have been indoctrinated by a generation of academic literature and MBA training to ignore disruptive products until they had a chance to mature in the market, assuming they would first

261 James P Evans and Robert C Green, 'Direct to consumer genetic testing: avoiding a culture war' (2009) 11 Genetics in Medicine 568; Geoffrey S Ginsburg and Huntington F Willard, 'Genomic and personalized medicine: foundations and applications' (2009) 154 Translational Research 277

262 Clayton Christensen, 'Disruptive Innovation' <claytonchristensen.com/key-concepts/> accessed 25 August 2015

> appear as cheaper but inferior substitutes that would only appeal to niche market segments.
>
> Doctors — who are also incumbents in this situation — are struggling to respond to disruptive medical technologies that change the power dynamic in the patient relationship. Several 23andMe users have reported taking the FDA's advice of reviewing their genetic results with their physicians, only to find the doctors unprepared, unwilling, or downright hostile to helping interpret the data.[263]

2 What makes DTCGT challenging?

The industry has developed very rapidly. As a web-based industry it poses challenges for regulation which are not unique, but which are common to many web-based industries and also wearable and mobile health technology. By offering their services online companies can sell tests to consumers globally, rather than nationally. This also means that if a dispute were to arise between the company and a consumer jurisdictional issues arise.

The industry has developed as a consequence of recent advances in genetic and genomic sciences together with advances in computing technology. However, the cost of sequencing technology is dropping faster than Moore's law.[264] Thus, what is new about the DTCGT industry is the speed at which advances can be made. This changes the context considerably and makes it more difficult for law to keep up with the times. Of course this problem is not unique to genetics and is a feature in the digital sphere more generally. Advances in genetics have also been facilitated by the rapid advances made in computing technology. Computing technology has been tremendously influential in

---

263 Larry Downes and Paul Nunes, 'Regulating 23andMe Won't Stop the New Age of Genetic Testing' *Wired* (1 January 2014) <wired.com/2014/01/the-fda-may-win-the-battle-this-holiday-season-but-23andme-will-win-the-war/> accessed 25 August 2015

264 Erica Check Hayden, 'The $1,000 genome' (2014) 507 Nature 294

improving the ability and speed with which large quantities of data can be processed.[265] Without computers much of modern genomic science would not be possible. The rapidity of scientific progress in this area does give rise to new problems, not only for scientists or medical researchers, but also for lawyers and laypeople.

In the context of companies that provide testing for health purposes, testing which has previously been considered as medical is being provided in a new space, a consumer space. The consumer space differs significantly from the medical space, but in the context of health related testing it is also not clear that DTCGT services ought to be viewed as consumer services and not medical services.[266] This shift is emblematic of the industry's disruptive nature.

(b) Consumers rather than patients

There are several features of the DTCGT industry and its mode of operation, which are worthy of consideration and need to be addressed in legal scholarship. Prior to the advent of the DTCGT industry, genetic testing services were primarily restricted to a clinical setting. However, many DTCGT companies offer genetic testing services and whole genome scans outside of this setting. They normally offer their services without the involvement of a medical practitioner, which results in a paradigm shift in the nature of the parties involved in this activity. The person tested is dealt with primarily as a consumer, rather than being treated as a medical patient or research participant. So there

---

265 Andrew Pollack, 'DNA Sequencing Caught in Deluge of Data' *The New York Times* (New York, 30 June 2011) <beacon-center.org/wp-content/uploads/2010/10/NYT113011_DNASeqDelugeData.pdf> accessed 2 December 2012; D Greenbaum and M Gerstein, 'The Role of Cloud Computing in Managing the Deluge of Potentially Private Genetic Data' (2011) 11 The American journal of bioethics : AJOB 39; G et al Timp, 'Third Generation DNA Sequencing With A Nanopore' in SM Iqbal and R Bashir (eds), *Nanopores: Sensing and Fundamental Biological Interactions* (Springer 2011) 287

266 Offit (n 229)

has been a shift from the relationship that is formed between a patient and clinician, to the relationship that exists between a consumer and a company. This lends support to the idea that an appeal to consumer protection law may be appropriate in this context and the issues raised by this shift will be discussed. On the basis of the review of company contracts and policies, it is possible that the DTCGT customer in most situations is in a position more analogous to a research participant than a patient, but it is also possible that in some situations a doctor patient relationship may develop in the DTCGT context.

Currently, DTCGT companies primarily offer either genetic testing for specific conditions and less commonly whole genome scans. It is likely that in the near future these companies will offer whole genome sequencing at very competitive rates. Gene by Gene's DNA DTC currently performs a whole genome sequencing service for $7,395 (US).[267]

Those who express concern about possible harms resulting from undergoing testing through a DTCGT company have advised consumers to be cautious in deciding whether to utilise these services and also in how they deal with the information they receive from DTCGT companies. Much of this concern stems from the potential harm that may ensue when an individual receives test results indicating that she has a genetic predisposition to develop a particular condition, although this is debated. There is some evidence suggesting that individuals may in fact not be significantly affected by receiving knowledge of their disease risk, but there is also a possibility that people will experience psychological harm.[268] A good example of this is where a person tests positive for either of the BRCA 1 or 2 mutations, which have a strong association with

---

267 Gene By Gene, 'Whole Genome Sequencing' <genebygene.com/pages/dnadtc> accessed 1 October 2014. As of 25 August 2015 the price has actually increased to $10,395.00(US).

268 T Caulfield, 'DTC genetic testing: pendulum swings and policy paradoxes' (2012) 81 Clinical Genetics 4; Su (n 222)

breast cancer.[269] Even in a clinical setting it has been found that people who receive this type of information may undergo some form of psychological harm.[270] Although this experience may be temporary, it is important that consumers who undergo genetic testing using DTCGT are protected and this harm could be minimised by providing adequate genetic counselling services and only conducting such tests through accredited laboratories. Another area of concern relates to prenatal testing and the testing of children and minors and companies offering such services need to be carefully monitored.[271] Currently, it seems fairly easy for consumers to purchase DTCGT tests for minors and others who have not necessarily provided their consent. In the UK, this may be in breach of the Human Tissue Act 2004, which sets requirements for consent for DNA tests and creates an offence under section 45, where DNA is analysed without appropriate consent.

(c) The Shift From Patient to Consumer

In discussion of the DTCGT industry it is important to consider the consequences of the shift from 'patient' to 'consumer' and the specific implications of existing definitions of these terms. It should be noted that the shift from patient to consumer is also a feature in the wider context of innovations in personalised medicine and DTCGT raises similar issues to those posed by wearable technology and mobile health technology.[272]The

---

269 SM Mahon, 'Impact of Direct-to-Consumer Genetic Testing' (2012) 8 J Oncol Pract 260; ME Robson et al, 'American Society of Clinical Oncology Policy Statement Update: Genetic and Genomic Testing for Cancer Susceptibility' (2010) 28(5) J Clin Oncol 893

270 MJ Khoury, WF Rogowski and SD Grosse, 'Challenges of Translating Genetic Tests into Clinical and Public Health Practice' (2009) 10 Nat Rev Genet 489, 490.

271 A F Patenaude, 'Commentary: Save the Children: Direct-to-Consumer Testing of Children is Premature, Even for Research' (2011) 36 J Pediatr Psychol 1122–1127.

272 Melanie Swan, 'Emerging patient-driven health care models: an examination of health social networks, consumer personalized medicine and quantified self-tracking' (2009) 6 International journal of environmental research and public health 492; UA Meyer, 'Personalized medicine: a personal view' (2012) 91 Clinical Pharmacology & Therapeutics 373; Margaret A Hamburg and Francis S Collins, 'The path to personalized medicine' (2010) 363 New England Journal of Medicine 301; Charles Ornstein, 'Tracking Your Own Health Data Too Closely Can Make You Sick' (*NPR*, 2015) <npr.org/sections/health-shots/2015/04/06/397848621/tracking-your-own-

'patient' and 'consumer' have traditionally been conceptualised in quite different contexts, with patients normally thought about in a medical context and consumers normally envisaged as operating in a commercial environment. Patients are often envisaged as vulnerable in some sense and the relationship between a doctor and patient imposes a variety of duties on doctors. There is protection for consumers in the form of legislation on unfair terms in contracts, product liability, and regulation of advertising, but for some time the duties owed by doctors to patients have tended to be more onerous than those of companies to their consumers. However, there is now growing interest in the idea of the consumer as 'vulnerable' and EU legislation is notable for providing protection for vulnerable consumers.[273] In the context of DTCGT, it is possible to argue that all DTCGT consumers ought to be perceived as being vulnerable to a certain degree. This argument is based on the complex nature of genetic testing services.

(i.) *The Consumer*

DTCGT services are offered in the UK as consumer services and companies have in fact been permitted to market health-related genetic tests to consumers. Currently, DTCGT companies use their contracts to govern their relationship with their consumers. Because of this much of the focus in this thesis is on contract and consumer law and individuals purchasing genetic tests from DTCGT companies will be referred to as consumers as this is how they are viewed under current law.

---

health-data-too-closely-can-make-you-sick> accessed 7 April 2015; C Petersen and P DeMuro, 'Legal and Regulatory Considerations Associated with Use of Patient-Generated Health Data from Social Media and Mobile Health (mHealth) Devices' (2015) 6 Appl Clin Inform 16

273 Lisa Waddington, 'Reflections on the Protection of 'Vulnerable' Consumers Under EU Law' (2013) 2 Maastricht Faculty of Law Working Paper 1-41; Iris Benöhr, *EU Consumer Law and Human Rights* (OUP 2013) 3, 7-9

In the UK, a useful starting point for defining what the term 'consumer' means is Article 2 (1) of the EU Directive 2011/83/EU, which states that:

> 'consumer' means any natural person who, in contracts covered by this Directive, is acting for purposes which are outside his trade, business, craft or profession.

This definition is also consistent with definition of consumer provided in the new Consumer Rights Act, which will be discussed at length in chapter six. Section 2(3) of the Consumer Rights Act defines a consumer as 'an individual acting for purposes that are wholly or mainly outside that individual's trade, business, craft or profession'.

(ii.) *The Vulnerable Consumer*

However, if the position of the 'vulnerable consumer' is considered, then it is important to draw upon the Consumer Rights Directive, the Unfair Commercial Practices Directive, and the General Product Safety Directive.[274] All three documents include reference to the 'particularly vulnerable consumer'.[275] The Unfair Commercial Practices Directive distinguishes between' 'average' and 'particularly vulnerable consumers in providing protection from certain unfair commercial practices'.[276]Article 5(3) of this Directive affords 'special protection to 'a clearly identifiable group of consumers who are particularly vulnerable' to a certain commercial practice or product'.[277]The European

274 Directive 2011/83/EC on Consumer Rights; Directive 2005/29/EC Of The European Parliament And Of The Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council and Regulation (EC) No 2006/2004 of the European Parliament and of the Council (Unfair Commercial Practices Directive); Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety

275 Waddington-41, 4; Benöhr (n 270) 3, 7-8

276 ibid 5

277 ibid 6

Commission has stated that 'the reasons for establishing vulnerability are listed indicatively and cover a wide range of situations'.[278]

In the context of the regulation of the financial services industry consumer vulnerability has strong recognition and the UK's Financial Conduct Authority (FCA) has conducted extensive work on consumer vulnerability and its Occasional Paper on Consumer Vulnerability is pertinent to this discussion. The FCA defines a vulnerable consumer as 'someone who, due to their personal circumstances, is especially susceptible to detriment, particularly when a firm is not acting with appropriate levels of care'.[279] In the context of DTCGT it is possible to envisage certain consumers who already have health problems, especially those suffering from psychiatric illnesses as potentially fitting into this category. Consumers who possess genetic variants that are strongly associated with particularly serious diseases may also be vulnerable.

(iii.) *The Patient*

The innovations of personalised medicine are challenging traditional conceptions of what it means to be a patient. A traditional definition of the term patient is one 'enduring pain, affliction, inconvenience, etc., calmly, without discontent or complaint; characterized by or showing such endurance'.[280] A more specific definition of the patient in the modern medical context is:

> A person receiving or (in later use) registered to receive medical treatment, esp. at a particular establishment or from a particular practitioner; a person staying in a hospital for medical treatment.[281]

---

278 ibid 6 citing European Commission, Staff Working Document, *Guidance on the Implementation of Directive 2005/29/EC on unfair commercial practices*, SEC (2009) 1666, 29-31

279 Financial Conduct Authority, *Consumer Vulnerability* (FCA, Occasional Paper No 8, 2015) 20

280 ibid

281 OED Online, '"patient, adj. and n."' in *Oxford English Dictionary* (Web edn, Oxford University Press 2014)

Under UK, EU, and USA law the rights of patients are protected and doctors in a qualifying relationship will owe duties to their patients. These include: a duty of care; keeping patients' information confidential; making decisions that are in a patient's best interests; and seeking to cure or treat their condition. More recently, there have also been suggestions that patients also have obligations in this context. The NHS Constitution is a good example of this.[282] In the traditional doctor patient relationship there has also been a strong emphasis on providing adequate consent, (this is discussed further in subsection (f). It is questionable whether DTCGT companies are being sufficiently transparent and providing enough information for their consumers to be making informed choices regarding consent. This theme of the implications of this paradigm shift will also be considered in subsequent chapters and it will be argued that test kits provided for testing for health related purposes should be regarded as medical devices and regulated as such. It may be possible to regulate DTCGT testing which is not carried out for health related purposes in a different way, but for DTCGT test results that have clear medical relevance, it seems advisable to take a more cautious approach.[283]

(iv.) *When a patient is also a consumer*

While it may be possible to view certain types of recreational testing as low risk, all DTCGT tests do entail potential risks to consumer privacy and security. And in the context of DTCGT tests that have medical relevance, it is possible that at some point the

---

<http://www.oed.com/view/Entry/138820?rskey=BIE58d&result=1&isAdvanced=false> accessed 15 June 2014

282 J Herring, *Medical Law and Ethics* (4th edn, OUP 2012) (n 302) 22-23; H Martyn Evans, 'Do patients have duties?' (2007) 33 Journal of Medical Ethics 689; Michael J Meyer, 'Patients' duties' (1992) 17 Journal of Medicine and Philosophy 541

283 Donna Dickenson, *Me Medicine vs. We Medicine: Reclaiming Biotechnology for the Common Good* (Columbia UP 2013) 45-6.

individual tested is no longer a consumer, but a patient or a research participant. With recent developments in personalised medicine more generally the distinctions between consumers and patients are blurring, as it is possible that a patient may also be a healthcare consumer and in the context of private medical care this is increasingly the case. Whether this is beneficial for individuals undergoing genetic testing is questionable.

(d) Why do people purchase DTCGT tests?

While there has been much concern expressed about the availability of DTCGT, it is useful to consider the motivations of individuals in ordering these tests.[284] These do vary. Consumers may choose to have a DTCGT test, because it enables them to learn information about their physical and genetic characteristics, about predispositions to disease, which they may possess or whether they are carriers for particular diseases or conditions,[285] and also about their familial heritage.[286] Thus, some people may purchase a test to satisfy personal curiosity, while others may have genuine medical concerns.[287] They may also choose to have a test with a company, rather than through a clinic because

284 Su (n 222); Juli Murphy Bollinger, Robert C Green and David Kaufman, 'Attitudes about regulation among direct-to-consumer genetic testing customers' (2013) 17 Genetic testing and molecular biomarkers 424;Jessica S Ancker et al, 'Consumer experience with and attitudes toward health information technology: a nationwide survey' (2013) 20 Journal of the American Medical Informatics Association 152; AL McGuire et al, 'Social networkers' attitudes toward direct-to-consumer personal genome testing' (2009) 9 The American journal of bioethics : AJOB 3; Sandra Soo-Jin Lee et al, 'Attitudes towards Social Networking and Sharing Behaviors among Consumers of Direct-to-Consumer Personal Genomics' (2013) 3 Journal of Personalized Medicine 275; S B Trinidad et al, 'Genomic research and wide data sharing: views of prospective participants' (2010) 12 Genet Med 486

285 A Frumkin et al, '"The Most Important Test You'll Ever Take"?: attitudes toward confidential carrier matching and open individual testing among modern-religious Jews in Israel' (2011) 73 Soc Sci Med 1741; KL Edwards et al, 'Genetics researchers' and IRB professionals' attitudes toward genetic research review: a comparative analysis' (2012) 14 Genet Med 236; Alex Wilde et al, 'Public interest in predictive genetic testing, including direct-to-consumer testing, for susceptibility to major depression: preliminary findings' (2010) 18 Eur J Hum Genet 47

286 LA Daley et al, 'Personal DNA testing in college classrooms: perspectives of students and professors' (2013) 17 Genetic testing and molecular biomarkers 446; J K Wagner and K M Weiss, 'Attitudes on DNA ancestry tests' (2012) 131 Hum Genet 41

287 Ancker et al, 152; Daley et al (n 288) 446

they do not want the test to be included in their health records.[288] It seems doubtful that customers would in fact purchase tests for disease risk, such as tests for breast cancer susceptibility 'for fun'. While it is not possible to interview consumers herein consumers' perceptions of DTCGT will be touched upon with reference to secondary sources.[289]

Borry and Howard in referring to McGuire's study noted that:

> Survey results from McGuire and colleagues (2009) imply that a portion of social networkers who responded to their questionnaire believe that personal genome testing (PGT) offers diagnostic information. They report that 34% (374/1087) of all survey respondents (including a majority who have not used PGT) believe the information provided by PGT to be a medical diagnosis, and 74% (549/745) would consider using PGT for themselves "to see if a specific disease runs in family or is in DNA". This is of particular interest for many reasons, one of which being that many companies, including those mentioned in McGuire and colleagues' survey (2009) in fact, have statements or disclaimers on their websites stating that their services are not meant to have a medical purpose.[290]

It should be noted that colleagues conducting research on consumer experiences with DTCGT have found that consumers generally trust companies not to share data inappropriately.[291] Yet, 23andMe and AncestryDNA's partnerships with pharmaceutical companies show that data sharing is a real probability and some consumer trust may be

---

288 Health Law Institute (n 244) 5

289 Lee et al(n 35) 275; Daley et al (n 288) 3; Susan Brown Trinidad et al, 'Genomic research and wide data sharing: views of prospective participants' (2010) 12 Genetics in Medicine 486; Eric Vermeulen et al, 'Public attitudes towards preventive genomics and personal interest in genetic testing to prevent disease: a survey study' (2013) The European Journal of Public Health ckt143; Wagner and Weiss (n 288) 41

290 Heidi C Howard and Pascal Borry, 'Personal genome testing: do you know what you are buying?' (2009) 9 The American Journal of Bioethics 11

291 Two colleagues (Teresa Finlay and Jan Charbonneau) are working on research projects investigating consumer understanding of genetic test results and consumers' perceptions of the DTCGT industry. In interviews some consumers likened DCTGT contracts to their iTunes agreements and admitted that they did not read these documents. Andelka M Phillips and TMD Finlay, '"DNA a click away" -Workshop on 'agreements' in DTCGT' (Translation in Healthcare – Exploring the Impact of Emerging Technologies, Oxford, 23-25 June 2015)

misplaced. There is at present a disconnect between consumer perception and business practice.[292]

(e) Variety of tests available

The DTCGT industry is in a volatile state with companies entering and leaving the market. Companies provide testing for a wide variety of purposes, ranging from health related testing with some utility and ancestry testing to more dubious types of testing, such as testing for child talent or infidelity. Chapter three discusses the variety of tests available in greater depth. Notably, as some of the most prominent companies engaged in ancestry testing are moving into the field of health research the lines between health and ancestry testing are increasingly blurred. An illustrative example here is that of Ancestry.com's AncestryDNA. This began as a genealogy company, which has been operating for several decades. It allows its customers to compile family trees and search for related family members and also search archival documents. More recently, Ancestry.com launched its genetic ancestry testing service and the company has recently announced its intention to transition into the field of medical research.[293] Thus, a company, which began as an ancestry testing company has become a health testing company and this does make regulation more complicated.

Central to all categories of DTCGT testing are the related issues of data privacy and data security. These issues will be considered in the context of the discussion of data protection law in chapter four. However, it should be noted here that in the DTCGT context this necessitates a balancing of interests. While in the context of health research it

---

[292] Jan Charbonneau, 'Straight from the lab to the market: General Public Engagement with Direct-to-Consumer Genetic Testing (conference slides)' (DTC genetics – consumers, contracts and complexities, King's College London, 19th June 2015)

[293] Hernandez, 'Ancestry.com' (n 241); Justin Petrone, 'Ancestry Sees AncestryHealth Offering as First Step in New Health-Focused Strategy' *GenomeWeb* (17 July 2015)

might be easier to justify limitations on participants' privacy on the basis that such research is for the benefit of the public situation is not as straightforward for DTCGT companies carrying out research and DTCGT companies' research endeavours should not automatically be treated in the same manner as medical research carried out in the public and academic sectors.

(f) Outside the Clinic – genetic testing in a non-clinical setting

Another shift stems from changes in the location of testing. Thus, there is a move from the clinic to the home environment with self-sample collection. Whereas, a clinical genetic test would normally be carried out in a hospital or other clinical setting, DTCGT services normally require the consumer to collect their own sample and send it to the company. This does increase the potential for errors and abuse of the system. Issues of sample contamination or misrepresented identity can arise here.[294]

Recently, there has been a shift in the practice model of some DTCGT companies. This shift involves more interaction with medical practitioners. Some companies who previously provided their services direct to the consumer without any involvement of a medical practitioner now will only allow people to order their tests through a medical practitioner.[295] Navigenics was a notable example of this, although since its acquisition by Life Technologies it has ceased to offer DTCGT services. Nevertheless, its previous mode of operations can provide an illustrative example of this shift. Prior to its acquisition, Navigenics moved to a model where it allowed a person to

---

294 Canadian College of Medical Geneticists, 'CCMG Statement on Direct-to-Consumer Genetic Testing' (2012) 81 Clin Genet 1

295 Heidi Howard and Pascal Borry, 'Is there a doctor in the house? : The presence of physicians in the direct-to-consumer genetic testing context' (2012) 3 J Community Genet 105

order a test only through 'physicians, clinicians, and wellness programs'.[296] It also provided contact details for physicians who had undergone training with Navigenics and who could assist consumers in ordering a test.[297] A more recent example is Gene by Gene's DNA DTC service which allows consumers to order a whole genome or whole exome scan through a physician.

This shift in policy may not be entirely altruistic, as companies may be seeking to limit their liability. Also, as Howard and Borry point out simply having an ordinary medical physician on staff may provide a level of false reassurance to consumers, when in fact what is really needed to improve DTCGT practices in this context is the involvement of qualified clinical geneticists who are best equipped to provide counselling for consumers and explain test results and limitations.[298] An alternative approach would be to require all physicians to have further training in genetics, as many advances in current genomic sequencing technology have been made very recently and were not studied by the majority of physicians practising medicine now.[299]

(g) The wrap contract as a governance mechanism

As DTCGT is framed as a consumer service offered and marketed via the Internet DTCGT companies are using wrap contracts to govern the transaction between the company and the consumer.[300] This contrasts with the provision of genetic tests in a

296 Navigenics, <navigenics.com/visitor/what_we_offer/how_it_works/international_orders/> accessed 2 April 2012; Navigenics, 'Our Acquisition by Life Technologies' <navigenics.com> accessed 10 December 2012

297 Howard and Borry, 'Is there a doctor in the house? : The presence of physicians in the direct-to-consumer genetic testing context' (n 295) 109; Navigenics, 'Find a Physician' <navigenics.com/visitor/about_us/find_a_physician/> accessed 5 April 2012

298 Howard and Borry, 'Is there a doctor in the house? : The presence of physicians in the direct-to-consumer genetic testing context' (n 295) 110-11.

299 Sara Pirzadeh-Miller et al, 'Direct-to-consumer genetic testing: helpful, harmful, or pure entertainment?' (2011) 8 Community Oncology 263

300 See generally Kim (n 227)

clinical setting, where there are a variety of governance mechanisms applicable including institutional review boards, genetic counselling requirements, consent requirements and the guidance released by professional bodies. These contracts are used to govern several matters including: the sale of tests; participation in research activities; use, sharing and storage of genetic and other types of personal information; and use of their websites. The use of wrap contracts in this context can be viewed as a form of private legislation and industry self-regulation, which is heavily biased in favour of companies. These contracts are a form of adhesion contract and are common in online commerce more generally and their use in the DTCGT context is representative of the shift from patient or research participant to consumer. It is also representative of this being a web-based industry.

Such contracts often are much longer than more traditional paper contracts and may include provisions relating to assent or consent, both of which are often conflated and might be deemed from a consumer's use or viewing of a website. Kim argues that assent in adhesion contracts and wrap contracts has generally been understood 'to mean acquiescence rather than agreement, devoid of any requirement of voluntariness or volition'.[301] This conception is in opposition to the traditional conception of mutual assent in contract law and also, the normal requirements of consent in a medical context under UK law. In the medical context an individual undergoing medical treatment in the UK must provide valid consent in order to undergo treatment. In order to provide valid consent there are three elements, which must be shown. These are that:

- the person is competent,
- the person is sufficiently informed,
- and the person is not subject to coercion or undue influence.[302]

---

301 Kim (n 227) 193 citing Karl N Llwellyn, 'What Price Contract? – An Essay in Perspective' (1931) 40 Yale LJ 704, 728 n 49

302 Herring (n 282) 155

In other words, consent needs to be 'voluntary and informed'.[303] The recent UK Supreme Court decision of *Montgomery v Lanarkshire Health Board*[304] reinforces the importance of providing patients with adequate information,[305] so that they are able to make informed decisions about treatment options. This may suggest that were a dispute to arise involving a DTCGT company providing health testing to a UK consumer, a court might hold that the company is required to provide consumers with more information.

As in the DTCGT context wrap contracts are often used to govern the purchase of a genetic test and also, to participate in companies' research these contracts often cover assent or consent. The assent or consent is often intended to cover the transaction, participation in research and general use of personal data. This raises issues regarding the validity of both consent and assent and it also highlights the issue of whether DTCGT companies are in fact obtaining adequate consent from their consumers in line with the requirements of the HTA, as might be expected in a clinical setting, especially given the lack of voluntariness. In the digital environment, which has allowed for the proliferation of wrap contracts consumers have also become habituated to clicking, which means that obtaining valid assent or consent may be challenging.[306] While wrap contracts are often treated as valid contracts, the complex nature of the services offered by DTCGT companies, especially those providing health tests might mean that it could be argued that it is not in the best interests of consumers to rely solely on contracts to govern the range of activities which DTCGT companies engage in. It should also be noted that DTCGT companies are likely to be subject to data protection law when offering services

303 NHS Choices, 'Consent to treatment' (*NHS Choices*) <nhs.uk/Conditions/Consent-to-treatment/Pages/Introduction.aspx> accessed 31 July 2015

304 (Scotland) [2015] UKSC 11

305 Mark Campbell, 'Montgomery v Lanarkshire Health Board' (2015) 44(3) Common Law World Review 222-228.

306 Kim (n 227) 59

to UK or EU consumers and current practice may not be sufficient to meet the requirements of current data protection law or the new GDPR. Data protection regulators may also have a role to play in assessing and enforcing compliance.

(h) Bringing disruptive technology to the public

The current genetic testing technologies used by DTCGT companies have their origins in the methods developed by Sanger and the Human Genome Project. The scientific background will be covered in chapter two, but it is useful to touch upon it here. Many DTCGT companies utilise Next Generation Sequencing methods to conduct their tests, but the technology is continuing to change rapidly. The majority of DTCGT companies only sequence part of a person's genome, focussing on testing for specific single nucleotide polymorphisms (SNPs) and not the whole genome.

Although much progress has been made, scientific understanding of how genes function and their role especially in the development of complex diseases has not advanced as rapidly as once hoped. Understanding of how epigenetic factors contribute to health is also continuing to develop. There is also growing interest in the impact of the Microbiome on human health. Consequently, some of the information that DTCGT companies offer to their consumers may currently have little practical application for the individuals tested.[307]

Where companies offer health related tests without proven utility or validity there is a need to consider what the nature of the product they are in fact selling is. There is

[307] JM Dreyfuss, 'How Accurate Can Genetic Predictions Be?' (2012) 13 BMC genomics 340; Peter Kraft and David J Hunter, 'Genetic risk prediction: Are We There Yet?' (2009) 360 N ENGL J Med 1701-3; Peter Kraft et al, 'Beyond odds ratios—communicating disease risk based on genetic profiles' (2009) 10 Nature Reviews Genetics 264; Sabrina Prudente et al, 'Genetic Prediction Of Common Diseases. Still No Help For The Clinical Diabetologist!' (2012) 22 Nutrition, Metabolism and Cardiovascular Diseases 929-936.

evidence suggesting that some consumers believe that the test results they receive from DTCGT companies constitute a medical diagnosis. This is problematic because while many companies do offer health-related tests, they also commonly have exemption clauses including quite broad disclaimers indicating that these tests should not be viewed as medical tests.[308] In line with Caulfield and the views expressed by Javitt, Hudson, Su and the various policymakers that have released guidance, (which will be discussed in chapter three), it seems desirable that information provided by DTCGT companies needs to at least be accurate.[309] If it is possible to regulate the industry in such a manner, as to improve the quality of services offered this will be beneficial for both consumers and scientific progress.

(i) Data Deluge

The DTCGT industry fits into broader trends both in personalised medicine and the growth of information technology. The cost of genetic sequencing has fallen drastically in large part due to further advances in information technology. Increasing use of the Internet is generating vast amounts of data and similarly,[310] sequencing technology is allowing for the generation of significant amounts of genetic data.[311] However, the cost of interpretation and analysis of genetic data has not decreased at the same rate and it may take a significant period of time before this gap can be ameliorated.[312]

---

308 Howard and Borry, 'Personal genome testing: do you know what you are buying?'11

309 Caulfield (n 268); Su (n 222);Gail H Javitt and Kathy Hudson, 'Federal Neglect: Regulation of Genetic Testing-Government needs to ensure that genetic tests provide useful medical information and that the test results are reliable' (2006) 22 Issues in Science and Technology 59

310 McKay Cunningham, 'Next Generation Privacy: The Internet of Things, Data Exhaust, and Reforming Regulation by Risk of Harm' (2015) 2 Groningen Journal of International Law; Greenbaum and Gerstein

311 Pollack (n 262)

312 Muhammad Naveed et al, 'Privacy and Security in the Genomic Era' (2014) arXiv preprint arXiv:14051891;

(j) Using Web-Based Interfaces

As most DTCGT companies are web-based and offer their services internationally, the consumer will interact with the company primarily through a web-based interface. This marks a significant shift from the traditional genetic testing setting. In this online environment, it is important to consider the policies companies have in place for the storage and use of sequenced data and the consent mechanisms they employ. The focus herein is on the sequenced genomic data itself, rather than the biological sample, although there is also a need for further analysis of company policies regarding storage and use of biological samples.

Web-based interaction is not necessarily harmful, if companies have procedures in place to govern their use and storage of consumers' data, the manner in which they provide results of tests to consumers and also adequate processes for obtaining informed consent from consumers. Currently, many companies do have privacy policies and other terms governing data use, but these are not uniform and the majority of companies' privacy policies do not address the issues of use, storage, and sharing of genetic data in a comprehensive fashion.[313] This may indicate that DTCGT companies are often not complying with UK and EU data protection law. It is hoped that in the future companies may consider how web-based interfaces could be improved to enhance the protection of consumers. A comparison could be made here with cloud computing service providers.[314] The Article 29 Data Protection Working Party and the European Data Protection Supervisor have both produced opinions on the subject of cloud computing which

313 Phillips, 'Genomic Privacy and Direct-to-Consumer Genetics Big Consumer Genetic Data – What's in that Contract?'; Health Law Institute (n 244)

314 Kevin McGillivray, 'Conflicts in the Cloud: Contracts and Compliance with Data Protection Law in the EU' (2014) 17 Tul J Tech & Intell Prop 217

included discussion of problematic contractual clauses and indicated that there was often a lack of transparency in the cloud computing context.[315]

Several companies, including most notably 23andMe are also offering social networking functions on their websites.[316] Users can share their genomic data online with other 23andMe users. Social networking platforms allow and encourage consumers to interact with others who may have similar genetic conditions. Companies encourage consumers to share their genetic information and other health information, which may be potentially sensitive. While this functionality is not necessarily harmful the fact that some companies that provide these services also allocate themselves licences to use user generated content in their contracts is potentially problematic. These functions also allow users to attempt to find unknown relatives, which in turn raises other issues regarding consent and the potential impact on families.

23andME has also recently purchased CureTogether, which allows users to share their 'experiences on the impact of prescription drugs on over 600 medical conditions across 110 countries'.[317] According to its press release, 23andMe hopes its acquisition of CureTogether will bring:

---

315 McGillivray (n 314) 244-245; citing Article 29 Data Protection Working Party, Opinion 05/2012 on Cloud Computing, European Commission 27 (1 July 2012) <http://ec.europa.eu/justice/data-protection/article-29/documentation/opinion-recommendation/files/2012/wp196_en.pdf> accessed 15 May 2016; and Peter Hustinx, Opinion of the European Data Protection Supervisor on the Commission's Communication on "Unleashing the Potential of Cloud Computing in Europe" Eur Data Protection Supervisor (16 November, 2012) <https://secure.edps.europa.eu/EDPSWEB/webdav/site/mySite/shared/Documents/Consultation/Opinions/2012/12-11-16_Cloud_Computing_EN.pdf> accessed 12 May 2016.

316 SS Lee and L Crawley, 'Research 2.0: social networking and direct-to-consumer (DTC) genomics' (2009) 9 The American journal of bioethics : AJOB 35, 37;VG Koch, 'PGTandMe: social networking-based genetic testing and the evolving research model' (2012) 22 Health Matrix Clevel 33.

317 Allison Proffitt, 'Deals center on self-reported patient data services' (2012) 30 Nature biotechnology 1016; 23andMe, '23andMe Acquires CureTogether, Inc.' (*Press Release,* 12 July 2012), <https://www.23andme.com/about/press/curetogether/> accessed 6 January 2013;

> to 23andMe additional tools and systems for gathering data from health-based communities that are complementary to the existing 23andMe platforms, allowing customers to share quantitative information on more than 500 medical conditions, talk about sensitive symptoms and compare which treatments work best for them as they track their health.[318]

23andMe has claimed that its service allows for the democratisation of research and together with other DTCGT companies, innovations in this area may indeed lead to improvements in medical research.[319] Part of this stems from the opportunity which web-based interfaces provide for people to take on a more active role in research. However, the activities of DTCGT companies in this regard do need to be considered and there is a need to ensure that web-based interfaces are being established in a manner affording sufficient protection for consumers' rights in their genomic sequence data as well as other types of personal data they disclose to the company. Where consumers participate in research focussed on serious psychiatric diseases, addiction susceptibility, or late-onset diseases, which may be untreatable, different standards, may need to be developed and adhered to.[320] While web-based interfaces can be beneficial for consumers, they need to be used carefully. It might be advisable for DTCGT companies to look to web-based models used in the research context such as HeLEX's dynamic consent model.[321] It might be particularly helpful if online genetic counselling services were made available to consumers.

CureTogether Inc, <https://www.23andme.com/about/press/curetogether/> accessed 6 January 2013.

318 23andMe, '23andMe Acquires CureTogether' (n 317.)

319 Koch, (n 105) 43,48-52; 23andMe, '23andMe Democratizes Personal Genetics' (*Press Release,* 9 September 2008) <https://www.23andme.com/about/press/20080909b/> accessed 2 January 2013.

320 R Mathews, W Hall, and A Carter, 'Direct-to-Consumer Genetic Testing For Addiction Susceptibility: A Premature Commercialisation of Doubtful Validity and Value (Dec 2012) 107(12) Addiction 2069-74; CA Bellcross, PZ Page, and D Meaney-Delman, 'Direct-to-Consumer Personal Genome Testing and Cancer Risk Prediction' (Jul 2012) 18(4) Cancer J 293-302.

321 J Kaye et al, 'Dynamic consent: a patient interface for twenty-first century research networks' (2015) 23 Eur J Hum Genet 141

(k) Marketing of DTCGT

The primary way that DTCGT companies market their services is by means of their website content. It is common for DTCGT websites to make emotional appeals in their marketing. The promise of empowerment is a very common feature used in the marketing of DTCGT tests and in their study of the marketing of DTCGT tests Liu and Pearson found that 60.9% of websites appeal to warmth and empowerment.[322] Nordgren also highlights the frequency of references to empowerment.[323] Having examined numerous DTCGT websites and drawing upon other studies, such as Nordgren, Liu, Lachance, Lewis et al's,[324] it is clear that there is a need for greater transparency, as many company are making statements on their websites, which often are in direct contradiction to the terms in their contracts. It is also important to keep in mind that DTCGT, as an industry is not yet impacting upon a significant proportion of the population. The findings of Lachance et al in their study of informational content and literacy demands of DTCGT websites lend support to observations made in chapter three regarding the content of DTCGT websites in the present study.[325] Lachance et al note that with the lowering cost of sequencing and the lowering of DTCGT prices mean that 'DTC genetic testing is becoming increasingly affordable and accessible to broader segments of the population.' As in the USA a significant portion of the population has 'limited health

322 Yuping Liu and Yvette E Pearson, 'Direct-to-consumer marketing of predictive medical genetic tests: assessment of current practices and policy recommendations' (2008) 27 Journal of Public Policy & Marketing 131

323 A Nordgren, 'Neither as harmful as feared by critics nor as empowering as promised by providers: risk information offered direct to consumer by personal genomics companies' (2014) 5 J Community Genet 59, 62

324 Norman P Lewis et al, 'DTC genetic testing companies fail transparency prescriptions' (2011) 30 New Genetics and Society 291-307; Christina R Lachance et al, 'Informational content, literacy demands, and usability of websites offering health-related genetic tests directly to consumers' (2010) 12 Genetics in Medicine 304–312

325 Lachance et al (n 324)

literacy', and many are likely to have 'limited genetic literacy'[326] and as DTCGT becomes more widely available it is likely to be accessed by people with limited health literacy. In light of this their study sought:

> to examine whether DTC companies present web-based information that can be understood and used by consumers with a range of health literacy skills. One way to assess the appropriateness of such information is to examine the content, reading level, and usability of DTC websites.[327]

Their study analysed the content of 29 DTCGT websites and they found that:

> In assessing the literacy demand of the sites, very few (7%) used mostly common language and consistently explained technical terms. About one-half (52%) used mostly active voice and 31% used mostly simple sentences, although this varied across site type. The sites had a very high level of reading difficulty. The mean SMOG score was 14.7 (range, 12–18) and the mean Fry score was 15.2 (range, 10.5–17), which can be interpreted as the sites required college-level reading skills, on average.[328]

Furthermore, they found that regarding companies descriptions of the benefits of testing:

> Almost all of the sites (90%) listed at least one benefit to consumers of undergoing testing, although this was less common among sites offering testing for known mutations (57%). Of those sites that stated a benefit, the one most frequently stated (76%) was that the results of a test can inform a health decision (data not shown). Other commonly stated benefits were that there would be a benefit to the consumer in the future (35%); being tested could be beneficial to one's family or children (24%); information itself is beneficial (24%); and there would be a benefit to scientific research (21%).[329]

Finally, they stated that:

> Overall, most sites presented health conditions and at least some markers for which they offered testing, described their process of collecting and analyzing DNA samples, and stated their privacy policy. Privacy policies were often filled with jargon and, although most sites identified the people who ran the company, there was far less transparency regarding the role of scientific collaborators (whether academic or private industry). The standard of clearly describing which collaborators would have access to

326 ibid (n 324) 304
327 ibid (n 324) 305
328 ibid (n 324)307
329 ibid (n 324)306

> consumer data at which points in the testing process and their relationship to the testing company was largely unmet. As described above, the recommendations from professional bodies are for consumer privacy policies to be clearly stated and for consumer data to be highly guarded. This is clearly an area in need of improvement.[330]

(l) Cross-Jurisdictional Issues for the Law

As the majority of DTCGT companies operate on an international basis, issues regarding what law should govern the interaction between company and consumer arise. Many UK citizens who utilise DTCGT services will purchase tests from companies based in other jurisdictions, most commonly the USA. 55 of the 102 companies identified, which offer health related testing, are based in the USA. Consumers' samples will often be sent overseas for analysis. Consequently, jurisdictional issues are very important, but discussion of issues herein will be only be in relation to choice of law clauses included in DTCGT contracts, other issues of Private International Law will not be considered here. While several areas of law have bearing on this situation, it is contract law that is currently being relied upon by DTCGT companies to govern their interaction with consumers and this is why this thesis primarily considers mechanisms of redress available under contract law. In the conclusion, it is argued that contract law may not be the best mechanism for addressing some of the issues raised in the context and that it is important for regulators to take action here and that greater reliance on data protection and medical devices legislation is advisable.

The DTCGT contractual setting is worthy of critical review as it is a one sided scenario, where the consumer has little or no power to negotiate with the company, and while it is common practice for companies to attempt to limit their liability and draft

---

330 ibid (n 324) 308

contracts in their own favour, it may not be entirely appropriate in the context of DTCGT, especially where services are carried out for health purposes. Consequently, a large component of this thesis will consist of a comparative document analysis of DTCGT companies' online contracts in order to ascertain what rights consumers currently possess in the DTCGT context. The review will consist of two chapters.

DTCGT companies often have quite broad disclaimers seeking to limit almost all possible liability.[331] If DTCGT is framed as an industry solely dealing with consumers and not patients, even without the extra duties, which would be imposed on a physician in a medical context, it seems that it might not be justifiable to restrict liability in this manner. It is also very likely that many disclaimers commonly included in DTCGT contracts would be unenforceable under UK law. Although some tests offered by DTCGT companies may not have clinical validity or utility, the majority of the other information provided on many DTCGT companies' websites is likely to give consumers the impression that they will receive health-related information. [332] An interesting issue to be explored in subsequent research is whether website content could be deemed 'labelling' and the potential consequences that this could have on the interpretation of contracts both in the US and the UK.

(m) Challenges for Regulation – Different Heads of Law

Chapter four will discuss the regulatory framework and policy response to date in detail, but it is useful to touch upon this briefly here. There are several areas of law, which can be drawn upon in considering how to improve the regulation of the DTCGT industry.

---

331 23andMe, 'Terms of Service' <https://www.23andme.com/about/tos/> accessed 8 January 2013; Lumigenix, (2012) <lumigenix.com> accessed 20 October 2012; DNA Traits, 'Terms and Conditions' <http://www.dnatraits.com/terms-and-conditions.aspx> accessed 7 January 2013.

332 Howard and Borry (n 295) 111-12

These are: contract law; consumer protection law; product liability and medical device regulation; tort law; medical law; data protection; and human rights. There are a variety of opinions regarding the regulation of DTCGT and the respective possible benefits and harms of allowing such testing. What follows is a discussion of some of the issues raised by commentators in this area. In suggesting reform, the main focus in subsequent chapters will primarily be on: contract law and applicable consumer protection law. However, the issues raised by medical devices regulation, data protection, and human rights will be considered in chapter four.

DTCGT tests for health are not necessarily useful diagnostics as yet and for most complex diseases this technology is not a reliable predictor of disease on its own. Concern has also been expressed over the possible strain on health services if DTCGT were to become particularly popular.[333] The central issue here is that consumers might seek out unnecessary medical consultations or treatment. There is also concern about disease mongering in the marketing of DTCGT.[334] At present, consumers seeking out unnecessary treatment may not be a significant problem. However, it will only be possible to correctly estimate how much impact DTCGT will have on the healthcare system if a larger proportion of the population begins to utilise it. It is possible that if individuals choose to seek out extra medical services, which are not offered by the public health system more private medical services may need to be developed. One of the ways that unnecessary treatment of the 'worried well' may be avoided is by requiring DTCGT companies to only conduct their tests and scans through accredited laboratories, as then

333 AL McGuire and W Burke, 'Health System Implications of Direct-to-Consumer Personal Genome Testing' (2011) 14 Public Health Genomics 53–58

334 Kaye, 'The Regulation of Direct-to-Consumer Genetic Tests'

their results should be of a higher standard and it may then be possible to minimise the risk of contradictory or clinically or analytically invalid results.

It is also possible that an appeal to property law may prove useful in strengthening the protection of genetic data, but this will not be addressed herein. While the law has had difficulty recognizing property rights in excised tissue and DNA, and even though the nature of genomic data entails some degree of shared information, it may be possible to allow for a type of property right in DNA. This could be akin to a copyright in the sense that a person may own a copyright to a work, which no longer remains in their possession and still exercise some degree of control over how that work is used. DNA is not a creative work, but it is analogous to a body part in some senses and to those who are knowledgeable in genetics your genomic sequence data may reveal much personal information about you, which you might not wish disclosed.

3 Issues Raised by the DTCGT Industry

While the issues of genetic privacy and genetic discrimination will be discussed in chapter four in the context of discussion of human rights and data protection law, the following section provides an overview of scientific and ethical issues raised by commentators regarding DTCGT industry. Genetic tests are different from other types of laboratory tests because of several features of genetic information. Namely, genetic test results have implications not only for the individual tested, but for their family members; genetic information can also have implications for future generations; a genetic test can be carried out at any stage of an individual's life; test results can indicate risk for future ill health; and genetic information with some exceptions stays relatively static over time,

meaning that a test result conducted early on in an individual's life can be stored and used to identify her at a much later date.[335]

(a) Predictive or determinative

While testing for some single gene disorders can be highly predictive, the development of many diseases is complex, depending on a variety of factors, including how genes interact with each other and with the environment. Concerns have been raised about the marketing practices of some DTCGT companies and about the clinical utility and validity of some tests.[336] For example, it has been suggested that much marketing of genetic tests is designed to encourage consumers to believe that the results they receive from a DTCGT test are likely to be deterministic, rather than predictive of their risk of developing particular diseases or conditions.[337]

It is possible that DTCGT could provide benefits for consumers and scientific research. However, in the short term many companies are making claims, which are exaggerations at best, and utterly misleading at worst.[338] While it may be possible one day to calculate a person's absolute or relative risk factor for developing particular diseases or traits with some degree of accuracy, as several studies have shown, this is not yet possible and there is a tendency for DTCGT companies to overstate the role of

---

335 JK Mason and Graeme Laurie, *Mason and McCall Smith's Law and Medical Ethics* (8th edn, OUP 2011) 210-11; Naveed et al (n 312) 4-6.

336 Pascal Borry and Lidewij Henneman, 'Debating the clinical utility of direct−to−consumer genetic testing for addiction susceptibility' (2012) 107 Addiction 2076; SD Adams, JP Evans and AS Aylsworth, 'Direct-to-consumer genomic testing offers little clinical utility but appears to cause minimal harm' (2013) 74 N C Med J 494

337 McGuire et al, 'Social networkers' attitudes toward direct-to-consumer personal genome testing'

338 Timothy Caulfield, 'Predictive or Preposterous? The marketing of DTC Genetic Testing' (2011) 10 JCOM 3;Jessica Gabel, 'Redeeming the Genetic Groupon: Efficacy, Ethics, and Exploitation in Marketing DNA to the Masses' (2012) 81 Mississippi Law Journal363-438;Melanie F Myers, 'Health Care Providers And Direct-To-Consumer Access And Advertising Of Genetic Testing In The United States' (2011) 3 Genome Medicine 81;Williams-Jones Bryn, ''Be ready against cancer, now': direct-to-consumer advertising for genetic testing' (2006) 25 New Genetics and Society 89-107; Lewis et al (n 324) 291–307

genetics in human health.[339] One significant problem with DTCGT testing companies' reports of risk factors is that:

> the majority of frequent diseases involve a combination of numerous genetic variations (…)each conferring a very slightly increased risk, usually in the magnitude of 1.2, as measured by the numerous GWAS studies published over the last years.[340]

Researchers have found that much genomic data does not play a determinative role in our health. Whether or not a person develops a particular disease is very dependent on their environment and familial history.[341] All of this means that is questionable whether many disease risk tests should in fact be offered as direct-to-consumer services.

(b) Clinical Validity and Clinical Utility

One major area of concern is that DTCGT services are not held to the same standards as clinical geneticists, and that their tests do not have clinical validity and utility. If DTCGT companies do not operate in accordance with the same guidelines and standards as clinical geneticists, then the clinical utility and validity of their tests is called into question. If results are unreliable then it is possible that individual consumers will make important decisions based on flawed information. It is possible that such testing may result in psychological harm for individual consumers, who will worry unnecessarily

---

339 Timothy Caulfield et al, 'Direct−to−consumer genetic testing: good, bad or benign?' (2010) 77 Clinical Genetics 101-105; David J Kaufman et al, 'Risky business: risk perception and the use of medical services among customers of DTC personal genetic testing' (2012) 21 Journal of genetic counseling 413 1-10; KAB Goddard , et al, 'Health-Related Direct-to-Consumer Genetic Tests: A Public Health Assessment and Analysis of Practices Related to Internet-Based Tests for Risk of Thrombosis' (2009) 12 Public Health Genomics-104; T Frebourg, 'Direct-to-consumer genetic testing services: what are the medical benefits?' (2012) 20 Eur J Hum Genet 483; GenomeWeb Staff Reporter, 'Study Finds Clinical Worries over DTC Tests in Europe' *GenomeWeb Daily News* (31 May 2011) <genomeweb.com/dxpgx/study-finds-clinical-worries-over-dtc-tests-europe> accessed 10 December 2012{GenomeWeb Staff Reporter, 2011 #3110}

340 Frebourg (n 339) 483

341 ibid 483; WG Feero and AE Guttmacher, 'Genomic Medicine — An Updated Primer' (2010) 362 N Engl J Med 2001, 2003-10

about developing diseases or traits, which they may in fact never develop.[342] For less well-understood, often complex polygenic diseases, there is as yet no standardised testing procedure, meaning that different laboratories will analyse different SNPs in order to assess an individual's level of risk for the same condition, which can produce widely divergent results. An American report conducted by the Government Accountability Office (GAO) in 2010 proves enlightening in this context.[343] While limited study has been done on this so far, this is an area of interest to researchers and the literature on this is growing.[344] It is also important to keep in mind that DTCGT as an industry is not yet impacting upon a significant proportion of the population. However, even in the research community there is disagreement over how to interpret the same results. The ClinVar database was created in order for researchers to share their research findings in genetic research and a recently published study looking at how the variants recorded in ClinVar are understood highlights the problems here. Briefly:

> More than 118,000 of these variants have an effect on the risk for a disease — and 11 percent have been analyzed by more than one lab so results can be compared. In 17 per cent of those cases, labs interpreted the findings differently, as either raising the risk of a disease, having no effect on it or having an unknown effect.[345]

There is much promise in genomic research more generally, but DTCGT companies are not necessarily providing the same level of service as a genetics clinic. Furthermore, if

---

342 Graeme Laurie, *Genetic Privacy : A Challenge To Medico-Legal Norms* (reprint edn, Cambridge University Press 2002)90-95; Lindsay Dohany et al, 'Psychological Distress With Direct-To-Consumer Genetic Testing: a Case Report of an Unexpected BRCA Positive Test Result' (2012) 21 Journal of genetic counseling 399–401

343 US Government Accountability Office, *Direct-To-Consumer Genetic Tests: Misleading Test Results Are Further Complicated by Deceptive Marketing and Other Questionable Practice* (GAO-10-847T, 2010) 1–8 <http://www.gao.gov/assets/130/125079.pdf> accessed 5 January 2013

344 Frebourg (n 339); Heald Brandie, Edelman Emily and Eng Charis, 'Prospective Comparison Of Family Medical History With Personal Genome Screening For Risk Assessment Of Common Cancers' (2012) 20 EJHG 547–551.

345 Marilynn Marchione, 'Study reveals shortcomings in gene testing; results on estimating disease risk often conflict' *The Associated Press* (27 May 2015) – the original study is reported in Heidi L Rehm et al, 'ClinGen — The Clinical Genome Resource' (2015) 372 N Engl J Med 2235

the research community are also not united in their understanding of genetic risk information then it is questionable whether many tests offered are of real use to consumers.

(c) Uncertain Standards

One major area of concern is that DTCGT services are not held to the same standards as clinical geneticists, and that their tests do not have clinical validity and utility. This will be explored in more detail in chapter two. If DTCGT companies do not operate in accordance with the same guidelines and standards as clinical geneticists, then the clinical utility and validity of their tests is called into question. If results are unreliable then it is possible that individual consumers will make important decisions based on flawed information. It is possible that such testing may result in psychological harm for individual consumers, who will worry unnecessarily about developing diseases or traits, which they may in fact never develop.[346] For less well-understood, often complex polygenic diseases, there is as yet no standardised testing procedure, meaning that different laboratories will analyse different SNPs in order to assess an individual's level of risk for the same condition, which can produce widely divergent results. An American report conducted by the Government Accountability Office (GAO) in 2010 proves enlightening in this context.[347] While limited study has been done on this so far, this is an area of interest to researchers and the literature on this is growing.[348] Finally, 'the human

346 Laurie, *Genetic Privacy* (n 342) 90-95; L Dohaney et al, 'Psychological Distress with Direct-to-Consumer Genetic Testing: A Case Report of an Unexpected BRCA Positive Test Result' (2012) 21 J Genet Counsel 399–401

347 US Government Accountability Office1-8 <http://www.gao.gov/assets/130/125079.pdf> accessed 5 January 2013

348 Frebourg (n 339); Brandie, Emily and Charis 547–551

genome contains more than 10 million SNPs',[349] but DTCGT companies only sequence hundreds of thousands of SNPs, this all means that the value of test results may be limited at present.

Many clinical geneticists are concerned about DTCGT testing because of the lack of 'adequate clinical guidance.'[350] They especially highlight the lack of genetic counselling. There is also concern amongst clinical geneticists regarding the standard of knowledge and understanding regarding genetic testing generally within their own profession. Ordinary medical practitioners need further training in genetics in order to be able to assist their patients and the general public also needs further education in genetics in order to have a better understanding of the services being offered by DTCGT companies and the respective benefits, limits and risks associated with such testing. A recent study conducted with members of the Human Genetics Society of Australasia found that only 7% of the geneticists surveyed 'were confident in accurately interpreting and explaining DTC-GT results.'[351] This study was confined to genetic health professionals in Australia and New Zealand, but it does highlight a possible need for further education in genetics for medical practitioners. Furthermore, another study by Powell et al, which surveyed primary care physicians in North Carolina found that 'of the 381 respondents, 38.7% (n=148) were aware of and 15% (n=59) felt prepared to answer questions about DTC genetic tests'. The authors highlight the need for further education in genetics for primary care physicians.[352] While the demand for genetic testing in both

349 Ajai Raj, 'Soon, It Will Cost Less To Sequence A Genome Than To Flush A Toilet — And That Will Change Medicine Forever' (*Business Insider*, 2014) <businessinsider.com/super-cheap-genome-sequencing-by-2020-2014-10?IR=T> accessed 31 July 2015

350 Annes (n 433) 1100-01

351 Gemma R Brett et al, 'An Exploration Of Genetic Health Professionals' Experience With Direct-To-Consumer Genetic Testing In Their Clinical Practice' (2012) 20 EJHG 825.

352 KP Powell et al, 'Primary Care Physicians' Awareness, Experience And Opinions Of Direct-To-Consumer Genetic Testing' (2012) 21 Journal of Genetic Counseling 113–126; KP Powell

these studies was not high, it is likely to increase in the near future and with DTCGT companies operating online, it may be necessary for clinicians in many countries to up skill before real problems arise.

There is also a statistically significant probability that DTCGT companies will produce results that are false positives or false negatives.[353] While risk calculations have not as yet been found to be of highly predictive value, they will be of much greater value to the consumer and to scientists, if they are accurate. A person who receives a false negative result, but who in fact has a heightened risk of a particular condition, may be falsely reassured.

While recreational genomics may not be seriously harmful, testing companies offering tests for diseases or late onset disorders ought to be monitored more carefully. Those who offer tests for psychiatric or neurological disorders should be held more accountable and adhere to stricter guidelines than those who offer tests for relatively minor conditions.[354]

While DTCGT has the potential to be useful, it is not acceptable for companies to distort the scientific facts and mislead consumers regarding the potential risks and benefits of their services. This is something that has been stressed in policy documents,

---

et al, 'Educational Needs Of Primary Care Physicians Regarding Direct-To-Consumer Genetic Testing' (2012) 21 Journal of Genetic Counseling 469.

353 Feero and Guttmacher (n 341) 2009.

354 Ruth Saunders and Richard E Ashcroft, 'Consumer Genetics And Addiction Susceptibility Testing—Just What The Consumer Ordered' (2012) 107 Addiction 2075–2076; Lynn Rew, et al,, 'Systematic Review Of Psychosocial Benefits And Harms Of Genetic Testing' (2010) 31 Issues in Mental Health Nursing 631–645; Alex Wilde et al, 'Implications Of The Use Of Genetic Tests In Psychiatry, With A Focus On Major Depressive Disorder: A Review' (2013) 30 Depression and Anxiety 267; Rebecca Mathews, Wayne Hall and Adrian Carter, 'Direct−To−Consumer Genetic Testing For Addiction Susceptibility: A Premature Commercialisation Of Doubtful Validity And Value' (2012) 107 Addiction 2069–2074

including the European Society of Human Genetics' (ESHG) Statement on DTCGT for Health Related-Purposes, which will be discussed in chapter three.

DTCGT is an industry with a broad spectrum of services available and due to the number of companies identified it does seem to be a growing industry. It is possible that DTCGT services may be beneficial to consumers, but at present there is much inconsistency in the services provided and the standards followed. Also, several companies do make claims, which are exaggerations at best, and utterly misleading at worst.[355]

Commentators argue that genomic science has been seized upon by companies wanting to build on the hype and make a profit. In a recent article Professor Caulfield classified such companies operating on the Internet into three categories: clearly preposterous; marginally pertinent; and vaguely predictive.[356] While he acknowledged that his categorisation is rough, he does highlight many of the problems, which arise in this area. While the focus of this thesis will be primarily on the work of companies who operate in the 'vaguely predictive' sphere, it is important to note the misuse of genomic science in the less reputable pseudoscientific industry.

The media has also contributed to misconceptions about genetic information with many DTCGT marketing claims being taken at face value. While your genetic information is important, it is not the only factor governing your life. It is very unlikely that people can find a romantic match based purely on their genomic sequence data, at least not any time soon. There may be a need for geneticists to keep a stricter watch on

355 Caulfield, 'Predictive or Preposterous' (n 338); Jessica D Gabel, 'Redeeming the Genetic Groupon: Efficacy, Ethics, and Exploitation in Marketing DNA to the Masses' (2012) 81 Mississippi Law Journal363–438; Myers (n 338); Lachance (n 338) 304–312; Williams-Jones (n 338) 89–107; Lewis et al(n 324) 291–307

356 Caulfield (n 338) C02; Caulfield and McGuire, 'Direct-to-consumer genetic testing: perceptions, problems, and policy responses'

the claims being made about their discipline in the media and by commercial organisations and their colleagues. 23andMe's slogan on its website 'knowledge is power' may be true. However, in the context of DTCGT, knowledge of a person's genomic makeup will only be empowering if it is based on the truth and analytically valid results.[357]

Zawati et al have highlighted the need for more oversight of the accepted processes for closure of DTCGT companies, as well as biobanks.[358] Currently, there has been very little scholarship addressing this topic. Zawati et al's study focussed on the policies of four DTCGT companies as case studies, together with some biobanks. The companies they considered were DeCODEme, 23andME, Navigenics and Pathway Genomics. They were interested in what processes the companies had in place for dealing with issues, including the collapse of the company and transfer of ownership. Part of this thesis in its review of company policies will build upon their work. This review will attempt a broader study, focussing on these companies, together with other DTCGT companies. It seems that while the four companies studied generally destroy their consumers' samples, they do in fact store the data obtained from their GWAS. This does not sit well with the claims for protection of anonymity made by these companies. The mechanisms for the provision of informed consent for storage of such data also need to be examined.

---

357 23andMe previously used this phrase on its American website and still uses it on its Canadian website (as of August 2015) Taryn O Hall et al, 'Risk Prediction for Complex Diseases: Application to Parkinson Disease' (2012) 15 Genetics in Medicine 361; Heidi C Howard and Pascal Borry, 'Direct-to-consumer genetic testing: more questions than benefits?' (2008) 5 Personalised Medicine 317 (n 357)

358 Ma'n H Zawati, Pascal Borry and Heidi Carmen Howard, 'Closure of Population Biobanks and Direct-To-Consumer Genetic Testing Companies' (2011) 130 Human genetics 425–432.

Previously, research biobanks comprised the majority of databases storing genetic information. However, although many DTC companies claim to be primarily working to empower consumers with knowledge of their genetic selves, and also to help consumers avoid discrimination in employment and insurance by protecting their anonymity, a number of these companies have begun to move into the research arena. The 23andMe website claimed to have the world's largest DNA database.[359] Furthermore, the provision of social networking functions on DTC companies' websites should arouse some degree of concern regarding consumers' privacy and the validity and extent of their consent.

A useful comparison can be made here with the regulation of DTCGT marketing of prescription drugs. One problem, which has occurred in the context of countries that allow DTCGT advertising of prescription drugs is a lack of bias amongst medical practitioners. In this context, medical practitioners often appear to display similar behaviour to their patients in terms of giving credence to the marketing claims of these companies.[360]

(d) Genetic Discrimination

The advances in genetics and genomics have also renewed concern about possibilities for genetic discrimination and eugenics. At present, the main area in which this concern is articulated is in relation to insurance. It is possible that companies might share genetic data with insurance companies or with pharmaceutical companies. At present, while companies are not yet sharing with insurers, they are sharing with pharmaceutical companies and this could lead to targeting of population groups. One possibility here is

359 23andMe, 'Journey Through Your DNA' <23andme.com/fyr/> 10 December 2012
360 Howard and Borry (n 295) 108–111.

that pharmaceutical companies might engage in direct marketing to consumers based on an individual's genetic makeup.

In the DTCGT context there are companies that will conduct tests on minors and such practice needs to be scrutinised more carefully. The different types of testing will be covered in more detail in chapter four. However, it should be noted that in conducting research for this thesis 85 companies were identified that provided paternity testing, while 29 were identified that specifically offer tests to identify athletic ability or child talent and 24 companies were identified that conducted carrier testing. There has also been concern expressed regarding the retention of DNA profiles of innocent persons in criminal databases, most notably the UK's NDNAD and the USA's CODIS. Given that the age of criminal responsibility can actually be very low in some states, for example, the age of criminal responsibility in the UK is ten, it does seem advisable to restrict such retention of DNA profiles of minors or at least to place time limits on such retention. If this is so, perhaps there also needs to be time limits on DTCGT companies' retention of DNA profiles.

4 What Can Go Wrong?

Various commentators have raised concerns about the DTCGT industry[361] and the need for improving regulation of the industry. This is primarily because of concerns over the lack of clinical validity and utility of many tests currently offered, the ambiguous nature of test results and legal and ethical issues raised by the industry, and the potential risks

[361] Howard and Borry, 'Direct-to-consumer genetic testing: more questions than benefits?'; European Society of Human Genetics, 'Statement of the ESHG on direct-to-consumer genetic testing for health-related purposes' (2010) 18 Eur J Hum Genet 1271

that the industry poses to consumers. Given the ambiguous nature of many genetic tests results Howard and Borry have in fact suggested that:

> most DTC genetic tests being sold at the present time can be seen as an uninformative waste of consumers' money and time. Moreover, they have the potential to cause concrete and extensive harm to consumers' health and wellbeing.[362]

Two of the most significant areas of concern in this context are genetic privacy (as well as general concern over privacy of personal data) and information security.

Briefly, when a person orders a genetic test online she is giving up both a physical sample of herself and personally identifiable and potentially sensitive information. Once the physical sample is processed by the DTCGT company, the genetic data can serve as a unique identifier for the individual tested and can also be used to identify related individuals. This has implications where a company might sell or share the information with third parties including law enforcement agencies. While it was previously believed that complete anonymization of personal data was possible, there is growing recognition that it is not possible to truly anonymize genetic data. Even the best encryption of data can only be guaranteed for between 30 and 50 years.[363] There have been several recent efforts by researchers which have demonstrated that it is possible to re-identify research participants in large genetic studies. The best examples being the work of Gymrek et al[364] and Erlich et al.[365] It has even been demonstrated that identification is possible through reliance on research statistics.[366] While in the US, the

---

362 Howard and Borry, 'Direct-to-consumer genetic testing: more questions than benefits?' 319-20

363 This is based on discussion with Professor Emiliano De Cristofaro at UCL, who is an expert in cryptography.

364 Melissa Gymrek et al, 'Identifying personal genomes by surname inference' (2013) 339 Science 321

365 Yaniv Erlich and Arvind Narayanan, 'Routes for breaching and protecting genetic privacy' (2014) 15 Nature Reviews Genetics 409

366 Rui Wang et al, *Learning your identity and disease from research papers: information leaks in genome wide association study* (ACM 2009)

Genetic Information Non-discrimination Act (GINA) affords some level of protection against discrimination in the context of employment and insurance, it does not cover all types of insurance. Meanwhile, in the UK although there is currently a Moratorium between the British Association of Insurers and the Government on the use of predictive genetic tests, this is only an agreement and there is no statute currently in force prohibiting genetic discrimination.

As the dominant method of DTCGT companies involves self-sample collection by consumers there is also 'no way of controlling for the identity of the sample provider'.[367] What this means is that consumers can use DTCGT for fraudulent or criminal purposes. Consumers may choose to send in the samples of third parties without their consent. They may also send in samples belonging to their children or the samples of third parties who have agreed to help them engage in some form of identity fraud, such as sending in another person's sample in order to receive test results indicating the individual is not the father when in fact he is, in order to avoid maintenance payments.

Several companies offer a 'family finder' service, which connects consumers with individuals likely to be related to them. As falsely attributed paternity is relatively common sometimes companies are providing consumers with unexpected information that might have serious consequences. For instance, J Trevor Hughes wrote recently about this risk as by signing his parents up to 23andMe's service they learned that his father had another son and subsequently his parents divorced.[368] This is a phenomenon that will likely increase.

---

367 Howard and Borry, 'Direct-to-consumer genetic testing: more questions than benefits?' 319

368 J Trevor Hughes, 'Consent and Forgetting: What Privacy Pros Can Learn From One Family's Unexpected Experience' (2014) <https://privacyassociation.org/news/a/consent-and-forgetting-

There is also the possibility that companies will provide inaccurate test results. An older example of Cellmark Diagnostics illustrates this point, as the company provided a man with an inaccurate test result, indicating he was not the father of the child in question, when in fact he was.[369] Such errors can result in serious harm to family relationships.

As the DTCGT industry grows companies will accumulate more data and it is vital that such data is stored securely, as potential attackers could target DTCGT companies in order to engage in identity theft or perhaps create synthetic DNA, which might be planted at a crime scene. As Ayday et al note due to the shared nature of genetic data potential data leakage is not a matter that will only affect the individual concerned, but their family and genetic data stored in DTCGT databases if leaked could actually impact upon a large family group. As biometric identifiers are increasingly used in banking security and home security systems there may be an increased incentive for criminal organisations to attempt to gain access to both DTCGT databases and biobanks. While some of this concern may seem futuristic some recent examples can illustrate the potential problems in this area. MasterCard has recently announced that it will be using face-scanning technology on phones at checkouts in order to validate purchases. This technology will take a photo of the cardholder's face and translate that into an algorithm, which will be sent back to the bank.[370]

---

what-privacy-pros-can-learn-from-one-familys-unexpected-experience/> accessed 14 September 2014

369 Macer Hall, 'False DNA test led father to reject daughter' *The Telegraph* (11 February 2001) <telegraph.co.uk/news/uknews/1322077/False-DNA-test-led-father-to-reject-daughter.html> accessed 11 February 2015

370 Erman Ayday et al, 'Whole Genome Sequencing: Revolutionary Medicine or Privacy Nightmare?' (2015) 2 Computer 58, 62; Jose Pagliery, 'MasterCard will approve purchases by scanning your face' *CNN Money* (1 July 2015) Cyber-Safe <money.cnn.com/2015/07/01/technology/mastercard-facial-scan/>

Fingerprint recognition is also being used to validate payments with Apple Pay's Touch ID being the most prominent example, although Samsung and banks such as RBS and NatWest are using similar technology, while EyeLock has developed an iris scanner.[371] The Touch ID was successfully hacked one day after its launch.[372] A German hacking group has also claimed to be able to recreate fingerprints based on photographs. If genetic data is not stored securely this may lead to as yet unforeseen harms. It is therefore desirable that companies utilise encryption technology and also have rigorous policies in places on data storage, sharing, access, and destruction of data.

More recently, it has been demonstrated that hacking medical devices is a real possibility with the FDA publishing an alert regarding the Hospira drug pump.[373] Security experts demonstrated that it would be possible for a person with access to the hospital network to alter drug dosage remotely meaning that it would be possible for a hacker with malicious intent to cause a patient's death.[374]

Another area of concern is in the context of pharmacogenetic testing, as consumers may self-manage their dosage of particular medications without appropriate medical advice. While pharmacogenetic testing is probably one of the most promising

---

371 P Belton, 'In your irises: The new rise of biometric banking' *BBC News* (20 March 2015) Business <bbc.co.uk/news/business-31968642> ; Nicholas Yeap, 'Your finger is about to replace your bank password' *CCN Money* (9 June 2015) <money.cnn.com/2015/06/05/technology/bank-fingerprint-reader/index.html?iid=EL>

372 Belton,

373 FDA, *Cybersecurity Vulnerabilities of Hospira Symbiq Infusion System* (FDA Safety Communication, 31 July 2015)

374 Guneet Bhatia, 'FDA Fears Hacking Risks In Medical Devices; Says Hospira Pump Should Not Be Used' *International Business Times* (5 August 2015) Technology <ibtimes.com/fda-fears-hacking-risks-medical-devices-says-hospira-pump-should-not-be-used-2039898> accessed 11 August 2015; William Brady and Emma Glazer, 'Cybersecurity in Hospitals: Protecting Electronic Patient Devices from the Risk of Hacking' *MD News* (7 August 2015) Legal Technology <mdnews.com/news/2015_08/cybersecurity-in-hospitals-protecting-electronic-patient-devices-from-.aspx> accessed 11 August 2015; Darlene Storm, 'MEDJACK: Hackers hijacking medical devices to create backdoors in hospital networks' *Computerworld* (8 June 2015) <computerworld.com/article/2932371/cybercrime-hacking/medjack-hackers-hijacking-medical-devices-to-create-backdoors-in-hospital-networks.html> accessed 11 August 2015

areas of genetic research for personalised medicine, it also entails the greatest potential risk of real harm and it is important that consumers accessing pharmacogenetic testing are provided with sufficient information to understand the test results and the potential risks of altering dosage. Furthermore, as many tests currently offered lack clinical validity and utility concern has also been expressed regarding the possibility of people undertaking unnecessary medical treatment and putting unnecessary strain on public health resources.[375]

Social networking functions of DTCGT websites also pose potential risks to consumers, as they are encouraged to share potentially sensitive health information, which could be used against their interests. Furthermore, as some companies, such as 23andMe, AncestryDNA, and Gene By Gene are partnering with third parties it is possible that user content may be shared more widely than consumers might anticipate.

When thinking about consumer vulnerability in this context, it should be noted that vulnerability is something that can affect everyone. It is also not a constant state and people can move in and out of it. It may also vary according to the nature of goods and services purchased. A consumer is more likely to be vulnerable and experience detriment if they are less familiar with the nature of the products or the services are complex.[376] In the context of DTCGT for health purposes the information provided in test results is of a complex nature. While some consumers may have sufficient competence to understand these results if DTCGT becomes widespread, as it will reach a larger proportion of the population this in turn will mean that a larger number of ordinary consumers will access these services. This may then increase the likelihood of issues arising regarding

375 Su (n 222)

376 FCA (n 279) 22, citing Office of Fair Trading, *Vulnerable consumer groups: quantification and analysis* (Office of Fair Trading, Research Paper 15 1998, 1998).

consumers' levels of understanding and it is also possible that specific vulnerable groups of consumers are more likely to access these services and experience detriment. Much of the research conducted to date on the experiences, motivations and overall behaviour of DTCGT consumers has been focussed on early adopters.[377] If DTCGT is to become more widely accessible the potential for it to negatively impact upon vulnerable consumers will increase and as Lachance et al have noted 'there is no evidence that even the early adopters of these services understand the information being given to them by' DTCGT websites.[378]

5 Conclusion

This chapter has discussed the challenges the DTCGT industry raises for regulation and society more generally. Genomic sequencing technology (which will be considered in more detail in the next chapter) is presently in a state of constant progression. The costs and time required to sequence an entire genome are falling rapidly, and the accuracy of sequencing technology is also improving rapidly. Scientific understanding of the meaning of genomic sequence data is also changing and improving, but not at the same rate and implementing these advances in a comprehensive and reliable manner will require further work.[379] At present the technology has been seized upon by DTCGT companies, who offer tests to the public that are often not ready for the market in the

377 J Scott Roberts and Jenny Ostergren, 'Direct-to-Consumer Genetic Testing and Personal Genomics Services: A Review of Recent Empirical Studies' (2013) 1 Current Genetic Medicine Reports 182; TMD Finlay, 'UK Users' and Genetics Clinicians' Experiences of Direct-to-Consumer Genetic Testing' (PhD thesis, Cardiff University 2015); P Saukko, 'State of play in direct-to-consumer genetic testing for lifestyle-related diseases: market, marketing content, user experiences and regulation' (2013) 72 The Proceedings of the Nutrition Society 53

378 Lachance et al (n 338) 311.

379 Frebourg (n 339) 483; MJ Murtagh, et al, 'Navigating the Perfect [Data] Storm' (2012) 21(2) Norsk Epidemiologi 203-9.

sense that the nature of the information provided by such tests is inherently ambiguous and the tests lack utility and validity.

The industry is growing with companies emerging constantly and there is a trend of companies merging or partnering with others and engaging in health research. It is likely that for most companies their main source of profit is not the sale of tests, but the value of biobanks and databases, which can be used for research. This is a matter of concern for many policymakers, such as the Human Genetics Commission, the European Society for Human Genetics, and the Association for Molecular Pathology, whose work in this area will be considered in chapter three.

The next chapter will provides an overview of the recent developments in genetic and genomic science, which have enabled the DTCGT industry to develop and it will also discuss the nature of genomic sequence data and explain the nature of the different types of tests currently available. It will also demonstrate that the science does not provide the answers that DTCGT companies need to justify their claims, as many findings are ambiguous.

CHAPTER TWO – THE SCIENCE BEHIND THAT CLICK OF THE MOUSE

1 Introduction

The DTCGT industry is centred around the online sale of genetic tests and the industry has emerged and has been able to develop because of rapid advances made in two technological areas: genetic and genomic science; and computing. The rate of technological advances in genetics and genomics is continuing on an almost unprecedented scale. This chapter is concerned with the scientific advances that have enabled the DTCGT industry to develop, the variety of tests available, and the nature of genetic information. It will begin with a discussion of the nature of genetic information and genetic exceptionalism. It will then define some key terms and consider the recent history of genetic and genomic science. It will then highlight the variety of tests available with descriptions of the nature of the different categories of DTCGT tests available. The issues raised by these different categories of testing will then be considered in more detail in chapter three, which provides an overview of the industry. It is suggested that as most companies only perform tests on a portion of an individual's genome their utility for individual consumers is inherently limited. DTCGT services should be viewed with caution due to the ambiguous and complex nature of many genetic test results and the lack of clinical validity and utility of many tests. Furthermore, as genetic information can serve as an identifier not only for the individual tested, but also for their family the importance of protection of privacy and security in this context should not be underestimated.

In the space of less than two decades there has been a dramatic fall in the cost of this technology and the 'price of sequencing an average human genome has plummeted

from about US$10 million to a few thousand dollars in just six years'[380] with the price of sequencing an individual genome dropping below $1000 in 2014. However, the process of sequencing while vital is only one part of the genetic testing process. Sequencing allows for the generation of an individual's genetic data, but the value of such data to individuals and to scientific research is dependent on the quality of interpretation and analysis of the data. At present, while costs of sequencing continue to fall, the cost of interpretation and analysis is not dropping at the same rate.[381] Largely due to the gap between the power to generate data and the challenges of analysis and interpretation there is still more uncertainty in the field of genomic research than was previously expected.[382] This gap means that many tests currently offered by DTCGT companies may at present offer consumers little benefit.[383]

Even without the issues posed by interpretation and analysis of genomic data, DTCGT services are also challenging merely because they do allow individuals to purchase genetic tests without medical involvement and prior to the advent of this industry genetic tests were not available in this manner.

380 Erica Check Hayden, 'Technology: The $1,000 genome' (2014) 507 Nature 294; Raj (n 349)

381 Raj (n 349); Naveed et al (n 312); Pollack, (n 262); Nordgren, 'Neither as harmful as feared by critics nor as empowering as promised by providers: risk information offered direct to consumer by personal genomics companies'

382 Nordgren, 'Neither as harmful as feared by critics nor as empowering as promised by providers: risk information offered direct to consumer by personal genomics companies'; RR Kalf et al, 'Variations in predicted risks in personal genome testing for common complex diseases' (2014) 16 Genet Med 85; A Lindblom and PN Robinson, 'Bioinformatics for Human Genetics: Promises and Challenges' (2011) 32 Hum Mutat 495; Caulfield et al, 'Direct−to−consumer genetic testing: good, bad or benign?'

383 Andrea Sboner et al, 'The real cost of sequencing: higher than you think!' (2011) 12 Genome biology 125

2 The nature of genetic information and genetic exceptionalism

(a) What is genetic information?

Genetic information can be defined as 'the information carried in a sequence of nucleotides in a molecule of DNA or RNA'.[384] For present purposes, genomic sequence data can be understood as the data generated by sequencing technology. It has recently been suggested by Raymond McAuley that the cost of sequencing a genome will be less than the cost of flushing a toilet by 2020.[385] 'As of January 2014, sequencing a human genome cost just under $1,000 — less than the cost of a chest X-ray' and 'genome scanning is dropping in cost faster than computers can keep up. Moore's Law observes that computing power doubles every two years, but the cost of sequencing a genome drops by 5 or 10 times per year'.[386]

DTCGT services normally only sequence a portion of an individual's genome, rather than the entire genome sequence. However, this may change, as more companies begin to offer whole genome sequencing. Currently Gene By Gene is the most prominent example of this. In the context of DTCGT, the focus herein is on sequenced data, which is generated by analysing an individual's DNA sample. This is normally a saliva sample collected by the consumer and sent to the company and in the context of DTCGT the sample gains value for the company once it has been sequenced and interpreted, (although it is also possible that some companies may also conduct research on the stored physical sample, especially in metabolics). Some companies offer data only services, which means that they only provide their customers with the raw sequenced data, which they have not subjected to interpretation. Gene By Gene's DNA DTC and 23andMe's

384 Richard Cammack et al (eds), *Oxford Dictionary of Biochemistry and Molecular Biology* (Oxford University Press)
385 Raj (n 345)
386 ibid

American website are good examples of this. Other companies supply their customers with results that have been interpreted and it should be noted that 23andMe does in fact still offer interpretation services for its UK and Canadian consumers. If this were to be done in a clinical setting, there would normally be pre and post test genetic counselling, but while some DTCGT companies offer counselling, the majority do not and there are questions around the adequacy of genetic counselling services offered by these companies.[387]

(b) Is genetic information special?

DTCGT companies provide genetic sequencing services and through the provision of these services they are collecting and often storing sequenced genetic data from consumers. Several of the most prominent DTCGT companies also have research branches and are using consumers' data for a variety of purposes. There is debate over whether or not genetic information should be treated differently from other types of personal information.[388] It is possible to argue that genomic sequence data should be treated as special on the grounds that it can reveal important information on a variety of matters. Most significant here is its ability to serve as an unique identifier for the individual tested, which means that where companies store genetic information and share it with third parties such information has the potential to be used against an individual's interests. This is largely due to other features of genetic information. For instance, genetic information can be used to reveal an individual's level of risk of developing a particular disease or condition or their carrier status. In the DTCGT context, when consumers purchase genetic tests, they may find information of this type personally

387 HC Howard and P Borry, 'Survey of European clinical geneticists on awareness, experiences and attitudes towards direct-to-consumer genetic testing' (2013) 5 Genome Med 45

388 ELSI Contributor, 'Genetic Exceptionalism and the Precautionary Principle' Genomics Law Report <genomicslawreport.com/index.php/2009/10/06/genetic-exceptionalism-and-the-precautionary-principle/> accessed 10 December 2012; James P Evans and Wylie Burke, 'Genetic exceptionalism. Too much of a good thing?' (2008) 10 Genet Med 500

useful, but when shared it could be used by insurance companies or employers in a discriminatory manner.

It should be noted that genetic information is also to a large extent immutable and can be preserved for a significant period of time, meaning that secure storage is not an issue that decreases in importance over time. A person can change her passwords and even her name. However, she cannot change her genome and as genetic information can also be used to identify family members the issue of privacy in this context continues after death.[389]

Other features of genetic information include: revelations about traits that are not health-related, but which might be fun, such as eye colour or bitter taste perception; information about a person's family, ancestry and personal identity. While learning about eye colour and ancestry information might seem relatively innocuous, ancestry testing can be used to reinforce notions of race,[390] which could result in an individual being discriminated against. Furthermore, as this information can also be used to identify family members DTCGT companies' databases could be used against consumers' interests for the detection of criminal activity where companies share data with government agencies or law enforcement. It could also be used for targeted marketing of family or large population groups that possess certain genetic traits. For instance, a pharmaceutical company might develop a particular drug for a specific group and then market directly to consumers through a DTCGT company's website. As there is growing recognition that it is not possible to completely de-identify or anonymize genetic data, the risks of misuse due to data sharing should not be underestimated.[391] Two of the most

389 Ayday et al, 'Whole Genome Sequencing: Revolutionary Medicine or Privacy Nightmare?' (n 366)

390 Kim TallBear, 'The Emergence, Politics, and Marketplace of Native American DNA1' (2014) Routledge Handbook of Science, Technology and Science 21

391 Naveed (n 312); Gymrek (n 364)

prominent early DTCGT companies, DeCODE and Navigenics, have since been sold on to life sciences research companies and while they are no longer offering DTCGT services their stored consumer data is being used in on-going research.[392]

Genetic exceptionalism 'is the concept that genetic information is inherently unique and should be treated differently in law than other forms of personal or medical information.'[393] The term was coined by Thomas Murray.[394] Some argue strongly for the special treatment of genetic and genomic sequence data, as it can be connected with notions of personal identity. There are several important international documents supporting the special treatment of genetic information. Firstly, the *International Declaration on Human Genetic Data* sets out the 'special status' human genetic data in article 4.[395] UNESCO's *Declaration on the Human Genome and Human Rights* states in article 1 that:

> The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity.

It also prohibits genetic discrimination in article 6. Meanwhile, the Council of Europe's *Convention on Biomedicine* prohibits 'discrimination against a person on grounds of his or her genetic heritage'. The provisions of some of these documents will be considered in chapter four in the context of discussion of genetic discrimination and human rights.

---

392 D Vorhaus, 'Implications of Amgen/deCODE Deal for Genetic Testing Consumers' (2012) <www.genomicslawreport.com/index.php/2012/12/10/implications-of-amgendecode-deal-for-genetic-testing-consumers/> accessed 10 December 2012; T Ray, 'With Decode Purchase, Amgen Gains Genetics Expertise, Consumers Lose DTC Testing Option' *GenomeWeb* (12 December 2012) <genomeweb.com//node/1163376?hq_e=el&hq_m=1432031&hq_l=1&hq_v=654c94516e> accessed 12 December 2012;Navigenics, 'How It Works' <navigenics.com/visitor/what_we_offer/how_it_works/international_orders/> accessed 2 April 2012 ;Navigenics, *Our Acquisition by Life Technologies*; Navigenics, *Find a Physician*

393 ELSI Contributor (n 388)

394 Mark A Rothstein, 'Epigenetic Exceptionalism' (2013) 41 The Journal of Law Medicine & Ethics 733 citing TH Murray, 'Genetic Exceptionalism and 'Future Diaries': Is Genetic Information Different from Other Medical Information?' in MA Rothstein (ed), *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* (Yale University Press 1997)

395 See Health Law Institute (n 244) 11; UNESCO, 'International Declaration on Human Genetic Data' <portal.unesco.org/en/ev.php-URL_ID=17720&URL_DO=DO_TOPIC&URL_SECTION=201.html> accessed 6 January 2013.

The genetic exceptionalist approach has been criticised. One of the main criticisms levelled at the genetic exceptionalist approach is that genetic information differs from other forms of personal data in that much of it is shared between people.[396] For example, if Mary has a test for the gene variants associated with Huntingdon's Disease and has a positive test result, it does significantly increase the likelihood that other family members will also possess this mutation. With Huntingdon's and some other monogenic conditions, if one possesses the specific gene variant associated with the condition, they will actually develop the disease. At present, Huntingdon's is untreatable and so tests of this kind often do not have clinical utility in the sense that physicians cannot offer the individual any treatment options. Because of this, sometimes a person may choose not to be tested, where they have a known family history of this type of disease.[397] Where individuals are tested for diseases of this type, they may suffer psychological harm and where some family members choose to be tested, while others do not, this can cause division within families and also the question of how to balance rights. How should one person's right to be tested (or right to know) be balanced against another's right not to know. The answer is still unclear at present. Some individuals choose to take the test and use the knowledge they gain to make life choices.

An interesting suggestion is that it might be desirable to protect genetic information more strongly, where it has limited clinical utility and afford it less, where it has strong clinical utility.[398]This approach seems to deal with competing interests quite well.

---

396 Trevor Woodage, 'Relative Futility: Limits to Genetic Privacy Protection Because of the Inability to Prevent Disclosure of Genetic Information by Relatives' (2010) 95 Minnesota Law Review(n 426) 683

397 Rhona MacLeod et al, 'Experiences of predictive testing in young people at risk of Huntington's disease, familial cardiomyopathy or hereditary breast and ovarian cancer' (2014) 22 EJHG 396

398 James P Evans and Wylie Burke, 'Genetic exceptionalism. Too much of a good thing?' (2008) 10 Genetics in Medicine 500; James P Evans, Wylie Burke and Muin Khoury, 'The rules remain the

However, even if one accepts that genetic information is not essentially different from any other type of personal information, the fact that it can be used to identify individuals and also give insights about their family members should urge caution. In the business context, many companies will do whatever they think is permissible under the law and will often take this to the limits of what the law allows. Given that in other contexts where information is less sensitive, there is regulation of how companies use it, it might be advisable to improve regulation of DTCGT. An analogy could be made with the financial services industry, which often has industry specific regulators in different countries (the UK's regulator is the Financial Conduct Authority) and it may be advisable that if the DTCGT industry continues to develop that such an industry specific regulator is created.

3 Recent Advances in Genetic and Genomic Science

The DTCGT industry has developed as a direct consequence of recent advances in genetics and genomics combined with the exponential decrease in the cost of genetic sequencing.[399] This section will outline the recent advances in genetics and genomics that have made DTCGT possible and in so doing will define some key terminology.

Over the course of the 20th Century and now at the dawn of the 21st, scientific understanding of the nature of the human body and genetics has greatly improved. Watson and Crick identified the structure of DNA (deoxyribonucleic acid) in 1953 and it is their model, which has facilitated developments in genetic and subsequently genomic science.[400] The Human Genome Project began in 1990 and by 2003 the first complete

same for genomic medicine: the case against "reverse genetic exceptionalism"' (2010) 12 Genetics in Medicine 342

399 Raj (n 349)

400 AJF Griffiths et al, *Introduction to Genetic Analysis* (10th edn, GH Freeman and Company 2012) 279–80, 84–89

genome had been sequenced.[401] Since that time major technological advances have been made and the cost of sequencing has been drastically reduced. What used to take months can now be done in a fraction of the time and at a greatly reduced cost. Since 2003 technology has evolved so rapidly and the cost of sequencing has reduced so much that there has been a shift from genetic testing to whole genome scanning.

The current genetic testing technologies used by DTCGT companies have their origins in the methods developed by Sanger and the Human Genome Project. Many DTCGT companies utilise Next Generation Sequencing methods to conduct their tests, but the technology is continuing to change rapidly. The majority of DTCGT companies only sequence part of a person's genome, focussing on testing for specific single nucleotide polymorphisms (SNPs) and not the whole genome. While this may change in the near future, sequencing only part of the genome means that some of the tests offered, especially those for predictive purposes, may in fact have limited predictive value.[402]

Furthermore, scientific understanding of the human genome is still progressing and the implications that a person's genomic data have on their health and well being are still being deciphered. Although much progress has been made, scientific understanding of how genes function and their role especially in the development of complex diseases has not advanced as rapidly as once hoped. Our understanding of how epigenetic factors contribute to health is also continuing to develop. There is also growing interest in the impact of the microbiome on human and animal health and researchers have also found that a person's genetic makeup may in fact vary in different organs of their body, a

401 Human Genome Project, 'History of the Human Genome Project' <ornl.gov/sci/techresources/Human_Genome/project/hgp.shtml> accessed 2nd April 2012; Laurie, *Genetic Privacy* (n 342) 86–87

402 Luke Jostins and Jeffrey C Barrett, 'Genetic Risk Prediction in Complex Disease' (2011) 20 Human Molecular Genetics R182–R188

phenomenon known as mosaicism.[403] This is more common in individuals suffering from cancer, but there are examples of women and men who are chimeras and have more than one genome. For instance, 'a woman needing a kidney transplant did not genetically match her children' and a kidney was grown for her 'from the cells of her lost twin brother'.[404] As Field and Davies write 'the new dogma could be 'one human, multiple genomes'.[405]

Consequently some of the information that DTCGT companies offer to their consumers may currently have little practical application for the individuals tested.[406] Where companies offer health-related tests without proven utility or validity the nature of the product they are in fact selling is worthy of consideration. As noted in chapter one, there is some evidence suggesting that some consumers believe that the test results they receive from DTCGT companies constitute a medical diagnosis.[407] This is problematic because while many companies do offer health-related tests, they also commonly have quite broad exemption clauses indicating that these tests should not be viewed as medical tests.[408] Whether such disclaimers are enforceable will be considered in subsequent chapters.

(a) Genetics and Genomics

The terms genetics, genome, gene, and genomics, are used widely and sometimes interchangeably without strong definitions. Genetics as a science can be defined as the:

403 Maeve O'Huallachain et al, 'Extensive genetic variation in somatic human tissues' (2012) 109 PNAS 18018; Carl Zimmer, 'DNA Double Take' *The New York Times* (New York, 16 September 2013)

404 Dawn Field and Neil Davies, *Biocode The New Age of Genomics* (OUP 2015) 33

405 ibid 33

406 Dreyfuss; Kraft and Hunter, 'Genetic risk prediction: Are We There Yet?'1701-3; Kraft et al, 'Beyond odds ratios—communicating disease risk based on genetic profiles' 264;Prudente et al (n 307) 929-936

407 McGuire (n 286)

408 Howard and Borry, 'Personal genome testing: do you know what you are buying?'

> the scientific discipline dealing with
>
> **1.** the study of inheritance and variation of biological traits, and
>
> **2.** the study of genes, including their structure, function, variation, and transmission.[409]

The genome can be defined as 'an organism's complete set of genetic information, encoded in its DNA'.[410] Thus, the human genome is an individual's complete set of genetic data. The genome consists of units known as genes. A more comprehensive definition of the genome sequence is that it is:

> the linear order of nucleotide sequences in a genome. The genome sequence is a sequence map with the highest resolution, in which each nucleotide is a landmark. Determining the sequence of a genome is important for many reasons, including identifying genes and regulatory regions, deciphering gene function, understanding genome structure, and determining the degree of sequence similarity between species.[411]

The definition of the term 'gene' has been changing over time, [412] but for present purposes, it can best be understood as both 'a unit of heredity' and 'a segment of DNA encoding a protein'.[413] The exact number of genes, which exist in humans, is not yet known, but current estimates vary between 20,000 and 25,000. The human genetic code at its simplest is a series of four base nucleotides. These are Adenine (A), Cytosine (C), Guanine (G), and Thymine (T). These bases form pairs of T and A and C and G. There are around 3 billion base pairs in the human genome. The genome also consists of 46 chromosomes, which also normally form pairs, but in this case usually only 23 pairs.

Meanwhile, genomics can be defined as the:

> field of genetics concerned with the study of the structure, function, and evolution of whole genomes. This field has its origins in recombinant DNA technology (*q.v.*) and has evolved rapidly due to significant technical advances in large-scale cloning, sequencing, and analyses of sequence data using computational means. Genomics represents a major advance in

409 Robert C King, Pamela Mulligan and William Stansfield (eds), *A Dictionary of Genetics* (8th edn, OUP 2013) 189.
410 Griffiths et al (n 400) 4
411 King, Mulligan and Stansfield189
412 ibid 182
413 Feero and Guttmacher (n 341) 2002

> genetics, shifting the focus from identifying and studying single genes and genetic elements to discovering and studying coding and noncoding genetic components on a much larger, genome-wide scale. The term is often used broadly to include not only the study of genomes, but also transcriptomes and proteomes.[414]

(b) Causes of genetic variation

There are three main categories, which are the main causes of genomic variation and the reason why one person will be different to another, even though so much of our DNA is shared. These categories are: Single Nucleotide Polymorphisms (SNPs); insertions and deletions of nucleotides from the DNA; and 'structural rearrangements that reshuffle the DNA.'[415] What happens when a SNP occurs in a person's genomic sequence is an alteration in the order of base nucleotides at a single site, so for example, a person may have a guanine base present at a particular point in their genome, where many other people have a cytosine base. These small genetic variations can sometimes result in significant changes in an individual's phenotype (or visible trait).[416] Scientific understanding of these categories and their effects on human health has changed over time and should improve with more research and emerging technologies.

(c) Genetic sequencing

Sequencing technology allows for the analysis and deciphering of the human genetic code. Genomic sequence data provides a blueprint for the human condition. Humans are all essentially made up of long strings of code. This code does play an important role in causing individuals to possess certain traits (or phenotypes) and in whether or not they may develop particular diseases or conditions, or possess particular abilities, but it is not the only determining factor. Some conditions, which are monogenic, are particularly heritable and if a person possesses the gene associated with that particular condition, they

414 King, Mulligan and Stansfield (n 409) 190
415 ibid 2003
416 Griffiths (n 400) 610-12

will normally develop that disease. A good example is Huntingdon's disease.[417] However, there are many conditions which individuals might have a genetic predisposition to, but which they may avoid if they take precautionary measures. The environment in which people live, their lifestyle choices (for instance whether they smoke or exercise regularly), and their family history will often also play an influential role in determining whether or not they develop breast cancer or heart disease.[418] There is also growing interest in the role of the microbiome[419] and its impact on human health, so while genetics may be important to an individual's health it is very important that the benefits of testing are not overstated.

First generation sequencing technology was developed by Sanger in 1977 and was the technique used predominantly for the next thirty years. Then in 2005, second generation sequencing technology (or next generation) was introduced. Today, there is now third generation and now fourth generation sequencing technology with the very recent developments which include the use of nanopores and it may be possible soon to sequence a whole genome in less than an hour.[420] While each generation of technology brings significant improvements, second, third and fourth generation techniques have not superseded each other and all techniques continue to be used in different contexts.[421]

Next-generation sequencing technologies allow for the sequencing of 'millions of fragments in parallel' and the generation of more than 100Gb of data in days or hours.

---

417 Susanne B Haga et al, 'Public knowledge of and attitudes toward genetics and genetic testing' (2013) 17 Genetic testing and molecular biomarkers 327

418 Feero and Guttmacher (n 341) 2002-2006

419 Timothy R Sampson and Sarkis K Mazmanian, 'Control of Brain Development, Function, and Behavior by the Microbiome' (2015) 17 Cell host & microbe 565; Sahil Khanna and Pritish K Tosh, *A clinician's primer on the role of the microbiome in human health and disease* (Elsevier 2014); Peter Kramer and Paola Bressan, 'Humans as Superorganisms How Microbes, Viruses, Imprinted Genes, and Other Selfish Entities Shape Our Behavior' (2015) 10 Perspectives on Psychological Science 464

420 Steven McGinn and Ivo Glynne Gut, 'DNA sequencing–spanning the generations' (2013) 30 New Biotechnology 3661-7; Patrik L Ståhl and Joakim Lundeberg, 'Toward the single-hour high-quality genome' (2012) 81 Annual review of biochemistry 359-78; GF Schneider and C Dekker, 'DNA sequencing with nanopores' (2012) 30 Nature biotechnology 326-328; Sboner et al1.

421 McGinn and Gut 1-7

Traditional sequencing prior to this could only 'sequence about 100 fragments in parallel' and generate 0.1Mb of data per 'run'.[422] The advents of exome sequencing and genome-wide association studies (GWAS) are causing further improvements in researchers' ability to analyse and process data.[423] Both these new technologies should help lead to improvement in understanding heritability and the development of complex diseases and traits. Furthermore, the cost of sequencing the whole genome or the whole exome (which can be understood as the functional part of the genome) is continuing to fall rapidly. A new company DNA DTC has recently entered the market place offering whole exome sequencing for $795.00(US) and whole genome sequencing for $5495.00(US).[424]

Scientific understanding of how individuals differ from one another genetically has been greatly improved through research in Population genetics and Genome-Wide Association Studies (GWAS). Roughly 99.6 per cent of the human genome is the same from one person to another [425] and an individual may share even more of their genome with their blood relatives.[426] Population genetics 'analyses the amount and distribution of genetic variation in populations and the forces that control this variation',[427] and GWAS:

> is an approach that involves rapidly scanning markers across the complete sets of DNA, or genomes, of many people to find genetic variations associated with a particular disease. Once new genetic

422 Feero and Guttmacher (n 341) 2010

423 Michael J Bamshad et al, 'Exome sequencing as a tool for Mendelian disease gene discovery' (2011) 12 Nature Reviews Genetics 745–755.

424 DNA DTC, 'Products' <dnadtc.com/products.aspx> accessed 11 December 2012; D Vorhaus, 'DNA DTC: The Return of Direct to Consumer Whole Genome Sequencing' *Genomics Law Report* (29 November 2012) <genomicslawreport.com/index.php/2012/11/29/dna-dtc-the-return-of-direct-to-consumer-whole-genome-sequencing/> accessed 11 December 2012

425 Feero and Guttmacher (n 341); Hon-Cheong So et al, 'Risk prediction of complex diseases from family history and known susceptibility loci, with applications for cancer screening' (2011) 88 The American Journal of Human Genetics 548548–565; and P Barry, 'Seeking Genetic Fate Personal genomics Companies Offer Forecasts of Disease Risk, but the Science behind the Packaging Is Still Evolving' (2009) 176 Science News 17, <www.sciencenews.org/view/feature/id/44786/description/Seeking_genetic_fate> accessed 10 December 2012

426 Woodage (n 396) 683

427 Griffiths (n 400) 610

> associations are identified, researchers can use the information to develop better strategies to detect, treat and prevent the disease.[428]

It is GWAS in particular which has contributed greatly to the development of the DTCGT industry, as many companies rely on published GWAS studies. These studies have identified 'hundreds of gene variants that contribute to disease', but research has shown that many common genetic variations 'in the majority of studies confer only very small relative risks (ranging from 1.1 % to 1.5 %) and account for only a small part of the known inheritability of the condition studied'.[429] Also, while GWAS has been very useful many GWAS studies have concentrated on 'common variants with modest effect size in a scenario where a large proportion of disease risk is under the control of environmental factors', although further study may improve this.[430]

In the context of DTCGT, one problem with GWAS testing is that while the person tested may receive a great deal of information as a result of such analysis, much of that information is currently of little practical use. While many companies use the promise of empowerment through knowledge of a person's genome in their marketing much information offered by testing companies may not be truly empowering for the ordinary consumer at this point.

(d) From SNP based sequencing to whole genome sequencing

It was primarily the work of the Human Genome Project that showed that whole genome sequencing (WGS) was possible, although advances since that time have greatly reduced its cost. In fact the speed of technological change is almost unprecedented. The dramatic reduction in the cost of sequencing technologies means that large numbers of the population in developed countries are likely to have their genomes sequenced in the near

428 National Human Genome Research Institute, 'Genome-Wide Association Studies' <genome.gov/20019523> accessed 9 December 2012

429 Meyer, 'Personalized medicine: a personal view', 374; Kraft and Hunter, 'Genetic risk prediction: Are We There Yet?'

430 Prudente et al (n 307) 934

future. In the research and clinical context interest is shifting from SNP based tests to whole genome scans. It is the promise of the availability of whole genome sequencing at an affordable price which may ultimately revolutionise healthcare, [431] but at present as most DTCGT companies are not providing whole genome sequences much of the information they provide to consumers may have little value for the individual tested.

(e) Analytical validity, clinical validity, and clinical utility

In order for a test to become part of clinical practice, it ultimately needs to have analytical validity, clinical validity and clinical utility.[432] A test will have analytical validity where its results are 'positive when a particular sequence is present and negative when it is absent'.[433] It will have clinical validity where the test results in a positive finding 'in people with the disease and negative in those without'.[434] Finally, it will have clinical utility where its 'benefits outweigh its risks'.[435] At present many tests offered by DTCGT companies lack clinical validity and utility and this means that the nature of product that DTCGT companies are selling is questionable. Given the growing trend of companies entering into partnerships with third parties or merging with other companies and the growth in the research activities of these companies it is becoming clear that while companies are selling a service to consumers the main source of value for the company is not the sale of tests, but the use to which sequenced genetic data from consumers can be put.

---

431 Ayday et al, 'Whole Genome Sequencing: Revolutionary Medicine or Privacy Nightmare?' (n 366)

432 HGC, *More Genes Direct*, 23, para 2.1

433 Justin P Annes, Monica A Giovanni and Michael F Murray, 'Risks of presymptomatic direct-to-consumer genetic testing' (2010) 363 New England Journal of Medicine 1100

434 Annes (n 433) 1100–1

435 ibid 1100; Martina C Cornel, Carla G van El and P Borry, 'The Challenge Of Implementing Genetic Tests With Clinical Utility While Avoiding Unsound Applications' (2014) 5 J Community Genet 7

4 Types of tests currently available

The DTCGT industry is also notable for its diverse variety of services with companies offering tests for a wide variety of purposes, most of which have not been validated in the research community. This section will provide brief explanations of the nature of the different types of test available. It should be stressed that the vast majority of tests currently availability have not been well validated in the research community and as there is debate within the research community regarding the impact of particular genetic variants on human health, the wide availability of these tests should cause some degree of concern.[436] As will be discussed further in chapter three some types of DTCGT testing may be in breach of UK and EU law already and it might be beneficial for consumers for the Human Tissue Authority, the Competition & Markets Authority, and the Information Commissioner's Office to take on a more active role in regulating this industry.

(a) Pre-symptomatic Testing

(i.) *Nature of this type of testing*

This tests for whether a healthy asymptomatic individual 'has a high probability of developing a condition'.[437] In pre-symptomatic testing, 'a positive result indicates that the patient will develop the condition but does not indicate when this will occur',[438] which means that sometimes receiving such information can be distressing for the individual, especially where there are no treatment options available. Good examples are tests for Huntingdon's Disease or BRCA1 and 2, which are associated with breast

436 Howard and Borry, 'Personal genome testing: do you know what you are buying?'
437 HGC, *A Common Framework of Principles* (n 232) 2, Table 1,
438 Elizabeth McPherson, 'Genetic diagnosis and testing in clinical practice' (2006) 4 Clinical Medicine & Research 123, 124.

cancer.[439] This form of testing can be useful for monogenic disorders, which have a high level of penetrance. A gene will have high penetrance if the majority of people who possess it, will develop the condition. Thus, it is not as useful for complex multigenic disorders and as the European Academies of Science Advisory Council (EASAC) and the Federation of European Academies of Medicine, (FEAM) have noted it can be difficult to distinguish between 'high-and low- penetrance genes'.[440] While some of these tests are better validated than many others offered by DTCGT companies, given the serious impact with test results may have on a person if she is at high risk for a condition such as Huntingdon's it may be best to restrict the availability of such tests to a clinical setting.

(b) Susceptibility/ Predisposition Testing

(i.) *Nature of this type of testing*

This form of testing is 'intended to provide an indication of the absolute lifetime risk and/or relative risk of an individual developing a condition'.[441] Examples are testing for different types of cancer or heart disease.[442] There is some similarity between predisposition and pre-symptomatic testing. However, it 'differs from pre-symptomatic testing in that it informs individuals of an increased or decreased risk of developing the condition in question; however, the degree of certainty is unknown'.[443] Consequently, much predisposition testing is extremely probabilistic and at present will often lack both

439 HGC, *A Common Framework of Principles* (n 232) Table 1 (2); EASAC and FEAM, 'Direct-To-Consumer Genetic Testing For Health-Related Purposes In The European Union' EASAC Policy Report 18 <http://www.easac.eu/home/reports-and-statements/detail-view/article/direct-to-co.html> accessed 10 December 20126, 17; R Fears, V ter Meulen and and for the EASAC-FEAM Working Group, 'The perspective from EASAC and FEAM on direct-to-consumer genetic testing for health-related purposes' (2012) 21 Eur J Hum Genet 1

440 Fears, ter Meulen and and for the EASAC-FEAM Working Group 2

441 Human Genetics Commission, *Common Framework* (n 232) 2-3, Table 1

442 HGC (n 232) 2-3, Table 1

443 McPherson (n 299) 124

clinical utility and validity.[444] Thus, the usefulness or potential benefit of such tests for individual consumers is questionable.

(c) Pharmacogenetic Testing

(i.) Nature of this type of testing

This form of testing is concerned with assessing an individual's responsiveness to particular drugs or therapies.[445] As very few companies currently perform whole genome sequencing, the majority of tests provided by companies are pharmacogenetic, rather than pharmacogenomics. This is normally depicted as one of the most promising areas of genomic research largely due to the problems associated with drug responsiveness more generally. For many drugs, a large proportion of the population may be non-responsive or experience an adverse reaction.[446] The cost of treating patients suffering from adverse drug reactions in the UK alone has been estimated at 'up to £2 billion each year'.[447] Thus, if pharmacogenetic testing can assist in identifying individuals likely to respond well to treatment and also identify those likely to have an adverse reaction this should be beneficial for the general population. Researchers hope that pharmacogenetics will allow us to minimise the occurrence of these adverse events. However, providing pharmacogenetic tests without medical supervision does entail some risk of harm to the individuals tested, as they may be encouraged to alter their dosage, which could result in direct harm to their health. Thus, it is desirable that the availability of such tests is restricted.

---

444 Caulfield et al, 'Direct-to-consumer genetic testing: good, bad or benign?'; Hogarth, Javitt and Melzer (n 236)

445 HGC, *Common Framework* (n 232) 2-3

446 G Frazzetto, 'The drugs don't work for everyone. Doubts about the efficacy of antidepressants renew debates over the medicalization of common distress' (2008) 9 EMBO Reports 605

447 Kyla H Thomas et al, 'Reporting of drug induced depression and fatal and non-fatal suicidal behaviour in the UK from 1998 to 2011' (2014) 15 BMC Pharmacology and Toxicology 54

(d) Nutrigenetic testing

(i.) Nature of this type of testing

This deals with associations between nutrients and genes and attempts to identify which diet might be best suited to a person based on their genetic makeup. The Human Genetics Commission defined it as, 'intended to provide information about an individual's responsiveness to a particular nutrient or diet and how this affects metabolism, health status and risk of disease'.[448]This may be considered as recreational, but where companies also sell supplements or other products, it is likely that it would be considered to be an example of what the AMP dubbed 'business interest testing'.[449] As with the category of pharmacogenetic testing, most companies offering this type of service are engaged in nutrigenetics, rather than nutrigenomics. There is also some overlap between nutrigenetics and genetic tests for athletic ability. However, at present there is little evidence to support the studies conducted in this area.[450]

(e) Carrier Testing

(i.) Nature of this type of testing

This is aimed at identifying whether a person is a carrier for a particular condition, which might result in having a child affected by that condition. This type of testing has been used quite frequently by the Jewish community in order to identify carriers of Tay-Sachs and Canavan Disease, along with other diseases, which are common amongst people of

448 HGC, *Common Framework* (n 232) 3, Table 1

449 AMP, *Association for Molecular Pathology Position Statement: Direct Access Genetic Testing (Direct to Consumer Genetic Testing)* (Association for Molecular Pathology, 2015)

450 Lewis et al(n 324) 291–307; P Saukko et al, 'Negotiating the boundary between medicine and consumer culture: Online marketing of nutrigenetic tests' (2010) 70 Soc Sci Med 744; David Castle and Nola M Ries, 'Ethical, legal and social issues in nutrigenomics: the challenges of regulating service delivery and building health professional capacity' (2007) 622 Mutation Research/Fundamental and Molecular Mechanisms of Mutagenesis 138

Ashkenazi descent.[451] It is also becoming increasingly popular for other population groups, especially in those with a family history of certain autosomal recessive disorders, although carrier screening of the general population is still relatively uncommon.[452] While such testing is generally better validated than many other types of tests currently offered by the DTCGT industry, it may not be beneficial to offer it without medical intermediaries, especially genetic counsellors, given that undergoing such tests may mean that people make life changing reproductive decisions. [453]

(f) Companies offering services via physicians

(i.) Nature of this type of testing

In identifying DTCGT companies, companies that market their tests online either directly to consumers or directly to physicians, but only provide their services through physicians or other intermediaries were also included for the sake of comprehensiveness. This is in part due to the fact that certain companies which began as DTCGT companies have now shifted to models where testing can only be ordered via a physician and also to capture companies engaged in marketing directly to physicians or consumers Two of the most prominent examples of this are Navigenics and Pathway Genomics, which both shifted to this model. Some companies included are in fact academic laboratories. At present, companies that involve physicians offer many types of tests, including tests that may not be well validated, such as nutrigenetics and athletic ability tests.

451 Center for Jewish Genetics, 'Jewish Genetic Disorders' <http://www.jewishgenetics.org/?q=content/jewish-genetic-disorders> accessed 3 January 2013.

452 P Borry et al, 'Preconceptional genetic carrier testing and the commercial offer directly-to-consumers' (2011) 26 Hum Reprod 972

453 ibid

(g) Ancestry testing

(i.) Nature of this type of testing

This is 'intended to provide information about an individual's relatedness to a certain ancestor or ancestral group'.[454] This category of testing is likely to be the most popular type of testing over the coming years.[455] This type of testing is typically classed as recreational, but as certain ethnic groups can be more prone to particular diseases it can also reveal information that is health-related. It may also reveal unknown relatives and false paternity and given recent examples of ancestry testing companies moving into health research, it is important that these tests are monitored.

(h) Genetic Relatedness Testing

(i.) Nature of this type of testing

This is done for the purposes of determining genetic relationships. Two of the most significant examples of this are maternity and paternity tests.[456] This testing is generally well validated in the scientific community. It can also be particularly useful in the context of donor-conceived children, who want to ascertain that they are not related to their romantic partner. However, it can also reveal false paternity and given the mode of delivery of DTCGT tests it is also open to abuse, as consumers may send in samples belonging to others in order to avoid things, such as their maintenance commitments. A recent example, which did not involve a DTCGT company, is illustrative of the potential risks here. John Bullet wishing to avoid maintenance payments arranged for another man

454 HGC, *Common Framework* (n 232) 3

455 Spencer Wells of National Geographic's Genographic Project speaking at the Consumer Genetics Conference in Boston in 2013 suggested that the most likely growth area in the immediate future in consumer genetics would be in the field of ancestry testing.

456 HGC, *Common Framework* (n 232) 3

to take a DNA test in his stead.[457] Given the detrimental impact which such testing can have on families especially where it is abused, it is desirable that tests are of high quality and also that the availability of such tests is restricted. As will be shown in chapter four this type of testing has proliferated, but as the majority of companies offering this service currently offer a 'legal' and a 'peace of mind' option and will test minors without appropriate consent there is a need to monitor the industry and this supports the need for specific legal regulation.

(i) Testing for Athletic Ability

(i.) *Nature of this type of testing*

This type of testing is carried out in order to identify genetic predisposition to athletic ability. The most common example of this type of testing are services focussed on variants of the ACTN3 gene, which have been found to have some association with a person's ability to excel in endurance sports or to be a gifted sprinter.[458] However, the effects of these gene variants have not yet been shown to be the determinative factor in individual's potential for athletic success. There is some overlap in testing services in this category with the category of nutrigenetics and child talent testing, as companies engaged in this type of testing also commonly provide diet testing and will test children for athletic ability. It is often considered to be an example of lifestyle testing.[459]

---

457 Leon Watson, 'Father who didn't want to pay child maintenance sent another man in his place to give DNA for paternity test' *Mail Online* (5 June 2013) <dailymail.co.uk/news/article-2336469/Father-didnt-want-pay-child-maintenance-sent-man-place-DNA-paternity-test.html> accessed 25 August 2015; 'Shamed: Dad who tried to beat DNA paternity test' *Yorkshire Evening Post* (10 May 2013) <yorkshireeveningpost.co.uk/news/latest-news/top-stories/shamed-dad-who-tried-to-beat-dna-paternity-test-1-5660133> accessed 25 August 2015 the case was heard in the Leeds Crown Court and the number was S20130486, but the case does not seem to have been reported.

458 Roger Collier, 'Genetic tests for athletic ability: Science or snake oil?' (2012) 184 Canadian Medical Association Journal E43;

459 HGC *Common Framework* 3, Table 1

(j) Testing for child talent

(i.) Nature of this type of testing

Testing for child talent has not yet proliferated, but it is one of the most dubious types of testing currently available. It is also an area of genetic testing which has little credibility in the scientific research community and most tests currently offered lack analytical validity, clinical utility and clinical validity.[460] It is often categorised as lifestyle testing.[461] Child talent testing normally provides information on a wide variety of traits. Companies providing testing for talent encourage consumers that such tests will allow them to identify whether their child is best suited to playing particular sports, has good memory or high IQ or has emotional traits. As will be shown in chapter three, much policy guidance to date has been opposed to the offering of tests to children more generally and it is desirable that such testing is restricted.

(k) Surreptitious ('infidelity') testing

(i.) Nature of this type of testing

This testing is often dubbed infidelity or secret testing on DTCGT websites. The websites of such companies encourage consumers to submit samples of other individuals without their consent ostensibly for the purposes of ascertaining whether a person is being unfaithful to their partner.[462] The companies that provide such tests as their primary service may in fact be providing services of very dubious quality, partly due to their

460 Heidi Howard, Denise Avard and Pascal Borry, 'Are the kids really all right? Direct-to-consumer genetic testing in children: are company policies clashing with professional norms?' (2011) 19 EJHG 1122; Silvia Camporesi, 'Bend it like Beckham! The ethics of genetically testing children for athletic potential' (2013) 7 Sport, Ethics and Philosophy 175

461 HGC, *Common Framework*, 3, Table 1

462 Albert E Scherr, 'Genetic Privacy & the Fourth Amendment: Unregulated Surreptitious DNA Harvesting' (2012) 47 Ga L Rev 445; E E Joh, 'DNA Theft: Recognizing The Crime of Nonconsensual Genetic Collection and Testing' (2011) 91 B U L Rev 665; Gurwitz David and Bregman-Eschet Yael, 'Personal genomics services: whose genomes?' (2009) 17 Eur J Hum Genet 883

acceptance of samples of very poor quality, such as samples collected from bed sheets. It is desirable that such tests are legally prohibited.

(l) Match making testing

(i.) Nature of this type of testing

Fortunately, one category of testing, which has not yet proliferated is that of DNA based Dating services. This type of testing has been promoted as a means of match making based on two individuals' genetic compatibility.[463] To date, there is little scientific evidence to support this type of service and it is desirable that companies providing such tests are carefully monitored.

5 Conclusion

The DTCGT industry is engaged in the business of providing genetic sequencing services directly to the public. This technology has come to market very rapidly and without much oversight. Most companies only test for SNPs and not an individual's whole genome, meaning that the utility of test results is limited. Recent advances in genomics have made sequencing of an individual's whole genome possible at a greatly reduced cost and as the science continues to progress large numbers of people may have their whole genome sequenced and eventually included as part of their medical record. However, the utility of sequencing only a portion of an individual's genome without due consideration of other factors such as family history is questionable. It is important also to stress the ambiguous nature of some genetics research at present. If even in a research context the impact of particular variants upon human health is disputed, some services currently offered to consumers may not be useful to them. Given the ambiguity of the association of

463 Molly C Novy, 'Privacy at a price: direct-to-consumer genetic testing & the need for regulation' (2010) U Ill JL Tech & Pol'y 157; Caulfield, 'Predictive or Preposterous? The marketing of DTC Genetic Testing'

particular genetic variants with human health, many tests currently offered by DTCGT companies cannot perform in the manner described on DTCGT websites. Therefore, it is unclear what the consumer is really buying.

Given this ambiguity and the nature of testing services it was necessary to discuss the scientific background to the industry. As such testing can reveal a large amount of personally identifiable and potentially sensitive information about individual consumers and also because genetic information itself has several important features it is important that companies are transparent about the respective risks and benefits of their tests.

Genetic information by its very nature is different to many other forms of personal information and even if the genetic exceptionalist approach is not accepted, a cautious approach to the treatment of such information seems desirable, because of some of its most significant features. Namely, that genomic data serves as a unique identifier for an individual and can also provide information about those who are related to that individual. This means that testing on individual is in some ways essentially not an exclusively private act.

While some tests may not be particularly useful at present, DTCGT companies are continuing to grow, and if legal regulation may not be the only solution, involving the industry in developing standards which all DTCGT companies can adhere to seems a pragmatic strategy. In the UK, the now disbanded Human Genetics Commission did attempt to collaborate with companies in drafting its framework of principles and this could perhaps be a model for future work.

The next chapter will provide an overview of the DTCGT industry, highlighting the variety of tests available and the issues raised by the different types of tests available.

CHAPTER THREE – CONSUMING DNA – OVERVIEW OF THE DIRECT-TO-CONSUMER GENETIC TESTING INDUSTRY AND THE ISSUES IT RAISES

1 Introduction

The nature of sequenced genetic information means that it can be used for a wide variety of genetic testing purposes. The DTCGT industry is a novel industry as it is a web-based and centred on the sale of genetic tests as consumer services internationally, which represents an important shift, as previously these tests have been confined to a medical setting.[464] The present chapter provides an overview of the industry, discussing the various categories of tests available and the issues which different types of testing raise for consumers. It will begin with a description of some of the most prominent companies in the industry. As has been discussed previously, at present the industry is in a volatile state with companies entering the market and merging or partnering with others.[465] This chapter will highlight the issues, which the availability of such a wide variety of tests poses and suggest that there is a general need for greater oversight of the industry. It will use examples of claims made on DTCGT websites for each category of testing. These examples demonstrate that DTCGT tests are often sold in a manner that disregards existing governance mechanisms. (Advertising on some websites is also potentially misleading, although this is outside the scope of this thesis). Generally, companies engage in practices, which are at odds with most policy guidance to date (as will be discussed in chapter four), such as encouraging consumers to send in samples belonging to children, or encouraging consumers to send in the samples of other third parties

464 Margaret Curnutte and Giuseppe Testa, 'Consuming genomes: scientific and social innovation in direct-to-consumer genetic testing' (2012) 31 New Genetics and Society 159; Kayte Spector-Bagdady and Elizabeth R Pike, 'Consuming Genomics: Regulating Direct-to-Consumer Genetic and Genomic Information' (2014) 92 Neb L Rev 677

465 Sullivan, (n 246); Chafkin (n 247)

without appropriate consent. It is hoped that the examples provided in this chapter will show that there is a need for more oversight of the industry as a whole.

At the outset, it should be noted that in the UK, the Human Tissue Act 2004 (HTA) sets requirements for consent for tests involving the use of human tissue and DNA. DNA tests prior to the rise of DTCGT were previously only performed in a medical setting, as part of medical research, as part of legal proceedings for identification purposes (including to establish paternity) or by law enforcement agencies for identification purposes. Under the Act, it is an offence to conduct a DNA test without 'qualifying consent' with very few exceptions. It would appear from the guidance documents and information provided by the Human Tissue Authority (which enforces the HTA) that companies providing DNA test kits to UK based consumers come within the Act's remit. The Human Tissue Authority's *Analysis of DNA under the HT Act FAQs* states that: 'All companies providing DNA testing kits or DNA testing services must comply with the provisions of the Human Tissue Act 2004 relating to consent and the holding of bodily material with the intent to analyse DNA.'[466] Consequently, it seems that any DTCGT company regardless of the type of test they offer should be complying with the HTA. The offence of non-consensual DNA analysis under section 45 of the HTA carries with it penalties of fines or imprisonment, so it would be wise for DTCGT companies to work on improving their consent mechanisms and for the Human Tissue Authority to investigate compliance. (The requirements for what constitutes "qualifying consent" are set out in Schedule 4 of the HTA). Furthermore, the recent Supreme Court ruling in *Montgomery v Lanarkshire Health Board*[467] might indicate that some DTCGT companies providing tests of certain type, most especially health-related tests, may need

466 Human Tissue Authority, *Analysis of DNA under the HT Act FAQs <https://www.hta.gov.uk/faqs/analysis-dna-under-ht-act-faqs> accessed 12 May 2016.*

467 (Scotland) [2015] UKSC 11; Mark Campbell, 'Montgomery v Lanarkshire Health Board' (2015) 44(3) Common Law World Review 222-228.

to provide their consumers with more information about the respective risks and benefits of undergoing testing and possible risks relating to potential misuse of data, especially in the context of ongoing health research using consumers' data.[468]

2 Overview of prominent companies

As part of this research a list was compiled of all the companies operating in the last three years with English language websites, which offered some form of genetic testing via the Internet. In total 229 companies were identified. The list categorised the companies according to services type. Namely: health related testing; ancestry; genetic relatedness (primarily paternity); athletic ability; child talent; and non-consensual testing.

Chapters five and six will then discuss the actual terms included in DTCGT contracts used by companies providing testing for health purposes. It should be noted however that the contracts of companies providing other types of testing were also saved, but it was not possible to analyse all the data herein. However, in a preliminary analysis of the contracts of ancestry testing companies it was found that overall these contracts tended to be very similar to those of companies providing health testing. The choice was made to focus on testing for health purposes for the contractual analysis as a case study, because this category of testing is most representative of the challenges that DTCGT in general poses to regulation. It is also the category of testing which if it proliferates is

468 Jane Kaye, Jessica Bell, Linda Briceno, and Colin Mitchell, 'Biobank Report: United Kingdom' (2016) 44(1) The Journal of Law, Medicine & Ethics 96-105, 102; note: the recent case of *Spencer v Anderson* (Paternity Testing) [2016] EWHC 851 (Fam) suggested that the Human Tissue Act did not apply to DNA because "DNA does not contain human cells" – see Rosalind English, 'Judge allows paternity test for DNA disease analysis' UK Human Rights Blog (20th April 2016), <https://ukhumanrightsblog.com/2016/04/20/judge-allows-paternity-test-for-dna-disease-analysis/> accessed 11 May 2016; However, if this is correct it is limited to the very narrow situation of applying for post-mortem scientific testing and consequently does not seem likely to have bearing on whether or not DTCGT companies should be complying with the consent requirements set out in Schedule 4 of the Human Tissue Act and the code of practice issued by the Human Tissue Authority.

more likely to have an impact on a larger range of consumers and may also impact upon health service providers, such as general practitioners.

The DTCGT industry essentially began in 2007 when:

> deCODEme and 23andMe—began offering consumers genome scans. For a price of approximately $1,000, one could spit into a tube and mail the tube to a genetic analysis laboratory, which would genotype the sample at somewhere between 500,000 and 1 million SNPs, or approximately 0.03% of the genome.[469]

Since then the industry has continued to grow and due to the decrease in the cost of sequencing technology, the prices offered by DTCGT companies are continuing to fall and a UK based consumer can now purchase a test from 23andMe for £125.[470] At present there are several leading companies that offer specific tests and have amassed quite significant databases, which are being or are likely to be used for on-going health research.[471] Such databases might also be used for targeted marketing and broader surveillance. The industry has thus developed in the space of less than a decade as a direct consequence of advances in genetic and genomic science. This section will describe the activities of the most prominent companies identified. These are the companies, which have received the most attention from academics and the media and also have established the largest databases to date.

The most prominent companies originally were: DeCODE (which became DeCODEme); 23andMe; Navigenics; Pathway Genomics; and Knome.[472] However, Gene By Gene and Ancestry.com's AncestryDNA are also now very significant in this area. Each of these companies has been the focus of the majority of academic attention in

---

469 Leachman et al (n 222) 34

470 This price is accurate as of August 2015.

471 Jessica Cussins, 'Direct-to-consumer genetic tests should come with a health warning' The Pharmaceutical Journal <pharmaceutical-journal.com/opinion/comment/direct-to-consumer-genetic-tests-should-come-with-a-health-warning/20067564.article> accessed 3rd August 2015

472 Hogarth, Javitt and Melzer, 'The current landscape for direct-to-consumer genetic testing: legal, ethical, and policy issues'(n 236);Kalf et al (n 382)

this context and most early studies of DTCGT companies have focussed primarily on the activities of DeCODE, 23andMe, Navigenics, and Pathway.

DeCODE was really the first company to emerge, beginning its operations in 1996 and it gained the contract to conduct testing on the Icelandic population. It made a lot of advances in genetic research, but it subsequently declared bankruptcy in 2009 and was purchased by another entity and continued to operate under the name DeCODEme. It launched its direct-to-consumer service in 2007. Then in December 2012, DeCODEme was sold again to Amgen,[473] which led to it ceasing to offer DTCGT services, but at present it continues to operate,[474] as in 2014 they resumed operations in Iceland, going door to door and offering free T-shirts in exchange for an individual's DNA sample.[475] It previously offered a variety of services, but they specifically described their activity as a 'genetic health scan'. Their 'Complete Scan' (which it should be noted is not a whole genome scan) service tested an individual's risk susceptibility for 47 specific traits and conditions, including: gout; pancreatic cancer; breast cancer; and chronic kidney disease.[476] They offered the 'Complete Scan' service for the price of $1,100.00 (US). DeCODEme's website claimed that 'the total number of SNPs or genetic variants analyzed is the key to scientific accuracy. In analyzing nearly twice as many SNPs as any

473 Vorhaus, 'Implications of Amgen/deCODE Deal for Genetic Testing Consumers' (n 392); Ray, 'With Decode Purchase, Amgen Gains Genetics Expertise, Consumers Lose DTC Testing Option' (n 392)

474 Pete Shanks, 'Genomic Controversy in Iceland: Déja Vu All Over Again' (*Center for Genetics and Society*, 2014) <http://www.biopoliticaltimes.org/article.php?id=7778> accessed 30 May 2014; Alda Sigmundsdóttir, 'Privacy on Ice This company wants to collect DNA from one-third of Iceland's population.' (*Future Tense*, 2014) <http://www.slate.com/articles/technology/future_tense/2014/05/decode_genetics_wants_to_collect_dna_from_one_third_of_icelanders.html> accessed 9 June 2014; ALDA, 'Why I won't give a sample of my DNA to Decode Genetics' *The Iceland Weather Report* <http://icelandweatherreport.com/why-i-wont-give-a-sample-of-my-dna-to-decode-genetics/> accessed 7 June 2014

475 I checked their website again on 3 January 2013 and they are continuing to offer DTC services.

476 DeCODEme, 'Conditions Covered ' decodeme.com/conditions-covered 19 October 2012.

of its competitors, the deCODEme Complete Scan is by far the most comprehensive genetic health scan available today'.[477]

23andMe was founded in 2006, but it is probably the DTCGT testing company with the most prominent public profile, partly due to its co-founder, Anne Wojcicki's link with Google. Wojcicki was married to Sergey Brin, who has also invested in 23andMe (their divorce was finalised in June 2015).[478] From November 2013 to October 2015, 23andMe only offered ancestry testing in the USA. They ceased to offer health-related testing services in the US after the FDA sent the company a letter requiring it to cease marketing their health related testing service. The letter also classed 23andMe's test kit as a medical device.[479] They are also now facing multiple class action lawsuits. Prior to the FDA's action, 23andMe had offered a single service, Journey Through Your DNA, at the reduced price of $99 (US) with no subscriptions.[480] (As of December 11th 2012). Its website claimed that its company has: 'over 200 online health & traits reports'; 'the largest genealogical DNA database in the world'; [and will provide] 'updates on new genetic discoveries that are personalized for your DNA by our experts.'[481] Prior to this, it had offered two services, which both involved a one year subscription where you would receive updates on your genomic information throughout the year.

However, more recently, as of December 2014, 23andMe has launched a UK website and is marketing health related testing services to UK customers for £125. (It is also selling tests in Canada). Its UK service currently offers reports for more than a 100

477 DeCODEme, 'deCODEme Complete Scan' (DeCODEme, Jun., 2011) <decodeme.com/complete-genetic-scan> accessed 20 October 2012.

478 23andMe, '23andMe Raises More Than $50 Million in New Financing' (*Press Release*) <https://www.23andme.com/about/press/12_11_2012/> 3 January 2013; M Lewis, 'Sergey Brin's Wife Runs A Genetics Startup, 23AndMe, And It Just Raised $50 Million' (*Business Insider,* 12 December 2012) <http://www.businessinsider.com/sergey-brins-wife-runs-a-genetics-startup-23andme-and-it-just-raised-50-million-2012-12> accessed 4 January 2013

479 US Food and Drug Administration

480 23andMe, <www.23andme.com/store/cart/> accessed 10 October and then 13 December 2012

481 23andMe, <www.23andme.com/store/cart/> accessed 10 March 2013

health conditions and traits, as well as ancestry testing.[482] Also, as of March 2015 23andMe are also selling their test kits through Superdrug both via the Superdrug website and in their stores.[483] It should be noted that 23andMe is allowed to market their services in the UK because their test kits have a Conformité Européene (CE) mark meaning that the kit has been approved as safe for the purposes of collecting saliva. This certification though is only an assessment of the test kit's safety as a collection device. It does not provide an assessment of the quality of the sequencing service provided or of any accompanying analysis or interpretation services. Furthermore, 23andMe has also received approval in the US to market a test for Bloom syndrome, and in October 2015 it resumed health testing for US customers, although this is restricted to carrier testing.[484] As of June 2015, it has exceeded one million customers.[485]

Navigenics was also founded in 2006 and provided DTCGT services originally without the involvement of medical practitioners. It then shifted to a model, which required tests to be ordered via physicians.[486] In 2012 it was sold to Life Technologies and ceased offering DTCGT services, although the database it developed based on consumer data is being used in on-going research.

Knome was co-founded by George Church in 2007 as an offshoot of the Personal Genome Project and provided whole genome sequencing at a much higher cost than the

---

482 23andMe, <23andme.com/en-gb/> accessed 11 March 2015

483 Wallace, 'GeneWatch UK PR: Shoppers warned not to buy gene tests from Superdrug'; Meikle,

484 23andMe, '23andMe Granted Authorization by FDA to Market First Direct-to-Consumer Genetic Test Under Regulatory Pathway for Novel Devices' (23andMe, Press Releases, 19 February, 2015) <mediacenter.23andme.com/blog/2015/02/19/fdabloomupdate/> accessed 19 February 2015; Caroline Humer and Julie Steenhuysen, '23andME Launches New Consumer Test Service to Check for Genetic Disorders' (2015) Scientific American <http://www.scientificamerican.com/article/23andme-launches-new-consumer-test-service-to-check-for-genetic-disorders/> accessed 29 May 2016.

485 Wojcicki (n 255)

486 Howard and Borry, 'Personal genome testing: do you know what you are buying?'

other early companies' services. It charged $350,000 for a whole genome sequence.[487] It has since stopped offering DTCGT services.

Pathway Genomics was founded in 2008 and moved to a model requiring orders through physicians. It is still operating and provides a wide variety of testing services including pharmacogenomics, cancer, general health and wellness, and carrier testing.[488] It also now provides a mobile healthcare application for smartphones.

One of the other earliest companies, which has received less attention to date, is Gene By Gene, which is a Texas based company, which was founded in 2000 as Family Tree DNA. It initially specialised in ancestry testing and has a partnership with National Geographic to provide the testing for National Geographic's Genographic Project.[489] Then in 2011 it launched DNA Traits and DNA DTC,[490] which provide health testing and whole genome and whole exome sequencing.[491] These two have now been amalgamated under the one name Gene By Gene. They have also purchased other smaller ancestry companies including DNA Heritage[1] and DNA-Fingerprint.[2] To date, it has received less attention than the other leading companies, but it is worthy of greater attention due to its involvement in several different categories of genetic testing and its acquirement of other companies. Its database is growing and it seems likely to rival that of 23andMe in the near future.

Ancestry.com's AncestryDNA is one of the newest entries into the DTCGT space. Ancestry.com began as a genealogy company, which has been operating for several decades. It allows its customers to compile family trees and search for related

487 Misha Angrist, *Here Is a Human Being* (Harper Perennial 2011) 75-6; Personal Genome Project: Harvard, 'Sharing Personal Genomes' <personalgenomes.org/harvard> accessed 3rd August 2015

488 Pathway Genomics, <pathway.com> accessed 21 July 2015

489 Family Tree DNA, 'Surname & Geographical Projects' <familytreedna.com/projects.aspx> accessed 3rd August 2015

490 Vorhaus, 'DNA DTC: The Return of Direct to Consumer Whole Genome Sequencing'

491 Gene By Gene, <genebygene.com/pages/company> accessed 21 July 2015.

family members and also search archival documents. However, in 2012 it launched its AncestryDNA service and has now exceeded 1 million customers.[492] More recently the company announced its intention to transition into the field of medical research[493] and as of July 2015 they have begun their AncestryHealth division, which is as yet not using genetic information, but instead collecting consumers' health information via surveys. While AncestryHealth and AncestryDNA are currently separate entities, consumers who use AncestryHealth 'are asked upon accessing the service to consent to take part in an internal Ancestry project' and although:

> the information stored by customers in both is not currently accessible simultaneously to customers, the company in its privacy statement notes that by consenting to take part in its research project, a customer gives Ancestry permission to upload his or her AncestryDNA data for use in Ancestry's internal research.[494]

AncestryDNA has also acquired other ancestry companies including Relative Genetics, GeneTree, and Sorenson Molecular Geneology Foundation.[495]

As can be seen, several of the leading companies have entered partnerships, merged with others or have been sold on to other entities. This highlights the need for appropriate regulation of the industry, especially in relation to the protection of consumers' privacy, as often consumers' genetic data and other types of personal information are being shared more widely then consumers might anticipate. Given the privacy and data protection issues here, it may be beneficial for the ICO and the European Data Protection Supervisor to take on a more active role in regulating the industry and assessing compliance.

---

492 Justin Petrone, 'AncestryDNA Aims to Have 1.3M Genotyped by Year End' *GenomeWeb* (28 April 2015) <genomeweb.com/microarrays-multiplexing/ancestrydna-aims-have-13m-genotyped-year-end>

493 Hernandez, Petrone, 'Ancestry Sees AncestryHealth Offering as First Step in New Health-Focused Strategy'

494 Petrone, 'Ancestry Sees AncestryHealth Offering as First Step in New Health-Focused Strategy'(n 494)

495 Sorenson Molecular Geneology Foundation, <smgf.org> 22nd July 2015; International Society of Genetic Genealogy, 'Welcome to ISOGG!' <isogg.org> 3rd August 2015

3 Companies that Perform Health Related Testing

In total, 102 companies have been identified, which offer (or have offered in the past three years) some form of health-related testing service. Of these, 55 are located in the USA. The category of health-related testing itself covers a broad range of services and it is possible to further classify companies within this category into subcategories, namely: predisposition; pre-symptomatic; pharmacogenetics or pharmacogenomics; nutrigenetics or nutrigenomics; susceptibility; and carrier testing. At present, the majority of tests offered by DTCGT companies lack clinical validity and utility. Nutrigenetics is the area of health genetic testing with the least validation so far.[496] DTCGT companies providing genetic tests for health purposes can more readily be likened to clinical laboratories and research institutions, especially where they engage in health research using consumers' data. The Human Tissue Authority in its code of practice on consent sets out that in order for consent to be valid 'it must be given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question'.[497] Further it states 'that the person should understand what the activity involves and, where appropriate, what the risks are. When seeking consent, healthcare professionals or other suitably experienced people should ensure that it is appropriate for the intended purpose.'[498] Based on the review of companies' terms, which will be set out in chapter five, it seems that current practices regarding obtaining consent of many DTCGT companies may not be sufficient

496 Saukko et al, 'Negotiating the boundary between medicine and consumer culture: Online marketing of nutrigenetic tests'; Nola M Ries and David Castle, 'Nutrigenomics and ethics interface: direct-to-consumer services and commercial aspects' (2008) 12 OMICS A Journal of Integrative Biology 245; Cynthia Marietta and Amy L McGuire, 'Direct-to-consumer genetic testing: Is it the practice of medicine?' (2009) 37 The Journal of Law, Medicine & Ethics 369; Rehm et al (n 343); Sboner et al; A Adeyemo and C Rotimi, 'Genetic variants associated with complex human diseases show wide variation across multiple populations' (2010) 13 Public Health Genomics 72 ibid; Kalf et al (n 382); Marchione, (n 345)

497 Human Tissue Authority, *Code of Practice 1 – Consent* (Version 14.0, updated July 2014) para. 33, <https://www.hta.gov.uk/sites/default/files/Code_of_practice_1_-_Consent.pdf> accessed 12 May 2016

498 Human Tissue Authority, *Code of Practice 1 – Consent* para. 35.

to meet the requirements of the Human Tissue Act.[499] This does leave them open to the possibility of prosecution under the HTA for the offence of non-consensual DNA analysis and this could mean that the company could be fined or its employees subject to a term of imprisonment. Given that these are not insignificant penalties, if the industry continues to grow it would be wise for companies to improve their consent mechanisms. What follows is a discussion of the different subcategories of health related testing currently available and their implications for consumers.

(a) Pre-symptomatic Testing

(i.) Companies Operating

As there is some overlap between predisposition and pre-symptomatic testing companies that perform pre-symptomatic testing generally also offer predisposition testing. 64 companies have been identified which offer pre-symptomatic testing. 10 companies provide tests for Parkinson's disease. This includes: 23andMe's UK branch; Biotechnology Group Inc; Genetic Centre Company Limited; Map My Gene; and Matrix Genomics. 29 test for Alzheimer's risk. Examples include: 23andMe's UK branch; Map My Gene; Gene Planet; Genetic Healthcare Group; Gonidio; and Graceful Earth.

Companies often make claims on their websites that are somewhat imbalanced and do not represent the limitations of such testing appropriately.[500] Here are some examples. Gonidio offers its Health and Medical Care test for 409,50 € and next to the 'add to cart option' it makes the following statement:

> Discover your risk to disease and reduce it! A simple DNA test can now reveal significant information about your personal risks for several common, yet serious diseases, from Cardiovascular disease to Alzheimer's. Then a plan tailored to your needs will help reduce the risks!

---

499 Human Tissue Authority, *Code of Practice 1 – Consent*

500 Lewis et al(n 324) 291–307; Bryn William-Jones, ''Be ready against cancer, now': direct-to-consumer advertising for genetic testing' (2006) 25 New Genetics and Society 89

Graceful Earth provides the following endorsement of its Alzheimer's test:

> "Future peek Still, there's no question that many people find the chance to peek into the medical future irresistible… The Alzheimer's test by Graceful Earth of Honolulu examines the APOE gene. Once version is associated with an increased risk of Alzheimer's. "Knowing a person is at increased risk could prompt him or her to eat healthier."[501]

Another example is 23andMe's American website, prior to the FDA's warning letter, which stated, 'Knowledge is power. 23andMe empowers you to better manage your health and wellness'.[502] It should be noted that as of 24 August 2015, 23andMe's Canadian website still includes this statement on its ordering screen.[503]

(ii.) Implications for consumers

Pre-symptomatic tests often provide consumers with information about very serious diseases, which can result in psychological harm. Even in clinical settings there is debate over whether all patients should undergo such testing even where they have a family history of a particular disease. The best example is Huntingdon's disease, as this is a very debilitating illness and at present there are no treatment options. Some patients choose to undergo such testing as they feel the information provided by the test will allow them to make decisions about their lives.[504] However, some people also choose not to undergo such testing. In the DTCGT context if such tests are to be offered then as several commentators have suggested, there is a need for genetic counselling, the provision of adequate information and strong informed consent mechanisms. At present, the companies identified are not offering tests for Huntingdon's, but they are offering testing

---

501 Graceful Earth, 'Alzheimer's Genome Test' <gracefulearth.com/alzheimerstest.aspx> accessed 10 August 2013

502 23andMe, '23andMe Order Screen' accessed 5 September 2013

503 23andMe (Canada), <store.23andme.com/en-ca/cart/> accessed 24 August 2015

504 MacLeod et al (n 397)

for Parkinson's and Alzheimer's and several other serious conditions and while the Huntingdon's test is well validated, tests for Parkinson's and Alzheimer's are not standardised.

(b) Susceptibility/ Predisposition Testing

(i.) Companies Operating

64 companies have been identified, which offer (or have offered) some type of predisposition testing. 38 of these offer some form of testing for a person's risk of coronary heart disease. 9 offer tests estimating risk of Stroke. Many give people a risk estimate for different types of cancer with 39 testing for breast cancer. 23 offer tests for lung cancer. 27 offer tests for prostate cancer. 59 test for diabetes risk. 17 offer tests for Multiple Sclerosis risk. 15 companies provided tests for macular degeneration. 7 offer tests for migraines. 3 offer tests for bipolar disorder.[505] 3 offer tests for Attention-Deficit Hyperactivity Disorder. 3 test for Schizophrenia.[506]

Some examples of companies offering predisposition testing currently are: 23andMe's UK branch; Map My Gene; Genetic Center Company Limited; and Gene by Gene's DNA DTC. 23andMe's UK website offers a health test covering 100 conditions and traits, which includes the following: breast and ovarian cancer; hypertrophic cardiomyopathy; hereditary hemochromatosis; Antitrypsin Deficiency; Early-Onset Primary Dystonia; and Factor XI deficiency.[507] Meanwhile, Map My Gene's Disease Susceptibility Test covers 100 diseases, including: ovarian cancer; pancreatic cancer; renal cancer; diabetes; arthritis and many others.[508]

---

505 These were: 23andMe's previous USA website; C2DNA; and Genetic Center Company Limited.

506 These were: 23andMe's previous USA website; Map My Gene; myDNA.

507 23andMe, 'Health' <23andme.com/en-gb/health/reports/> accessed 19 July 2015

508 Map My Gene, 'Disease Susceptibility Test' <mapmygene.com/disease-susceptibility-gene-test.html> accessed 19 July 2015

Here are two examples of the types of claims made by companies regarding testing of this type. Map My Gene featured the following quote under the heading 'Success Story' on its homepage:

> being able to look into my DNA to realize my genetic make-up is amazing because I wouldn't want to find out years from now that I've developed a disease I could have avoided had I done a Genetic Test today. This powerful information empowers me to be in control of my destiny.[509]

While Genetic Center Company Limited made this statement on its website:

> Disease susceptible gene test is done to analyze the presence, absence, or risk of a specific disease and to predict the possibility of future illness. It is the scope of preventive medicine.
> Even if you carry the disease susceptibility genes, so long as it can be realized and taken care of in time, the disease can be deterred or avoided as it has always been quoted that 'PREVENTION IS BETTER THAN CURE', therefore it is beneficial to have a Disease Susceptibility Gene Test conducted without delay.[510]

(ii.) Implications for consumers

While such tests may provide some useful information, currently the majority of tests lack clinical utility and often also clinical validity. As the appropriate interpretation of the effects of gene variants on disease risk are disputed even in the research context,[511] if such tests are to be offered DTCGT, companies do need to provide sufficient information regarding the limitations of such testing. Also, if such information is to have any benefit for the consumer it is likely that the benefit is really to be realised in the future, when understanding of the role of certain gene variants is better understood. It is also likely

---

509 Map My Gene, 'About' <mapmygene.com> accessed 14 August 2013

510 Genetic Center Company Limited, 'Disease Susceptibility Gene Test' <genetic-center.com/index_moduleId-114_pageName-content_pId-31.html> accessed 13 August 2013.

511 Rehm et al (n 343); Barry, 'Seeking Genetic Fate Personal genomics Companies Offer Forecasts of Disease Risk, but the Science behind the Packaging Is Still Evolving';CS Bloss, NJ Schork and EJ Topol, 'Effect of direct-to-consumer genomewide profiling to assess disease risk' (2011) 364 N Engl J Med 524; Marchione, (n 345)

that consumers do not understand statistical information sufficiently in order for these test results to offer them real benefit.[512]

At present, the marketing claims made my many DTCGT companies regarding the benefits of their testing could potentially be construed as misleading[513] and in line with the various policy guidance previously mentioned, it is desirable that DTCGT companies begin to comply more with existing advertising regulation. There is a need for greater transparency in advertising such tests.[514]

(c) Pharmacogenetic Testing

(i.) *Companies operating*

24 companies have been identified which offer (or have offered) this type of testing. Some examples of companies offering this type of testing without medical intervention are: Matrix Genomics; Theranostics Lab; GenePlanet; and 23andMe UK.[515] There are others offering their services directly through physicians, and these include: Genelex; Pathway Genomics; and formerly Navigenics.[516] It should be noted that while 23andMe

512 Lachance (n 332); McGuire et al, 'Social networkers' attitudes toward direct-to-consumer personal genome testing'

513 BM Kuehn, 'Inconsistent results, inaccurate claims plague direct-to-consumer gene tests' (2010) 304 JAMA : the journal of the American Medical Association 1313

514 Lewis et al(n 324) 291–307; Rose Geransar and Edna Einsiedel, 'Evaluating online direct-to-consumer marketing of genetic tests: informed choices or buyers beware?' (2008) 12 Genetic testing 13

515 EA Chua and MA Kennedy, 'Current state and future prospects of direct-to-consumer pharmacogenetics' (2012) 3 Frontiers in Pharmacology 1; Theranostics Lab, <theranostics.co.nz/wawcs0143590/tn-how-it-works.html> accessed 2 January 2013; 23andMe, 'Drug Response' <23andme.com/health/drugs/> accessed 3 January 2013.

516 Chua and Kennedy (n 515); Navigenics; Pathway Genomics, 'Drug Response (Medication) Insight' <https://www.pathway.com/dna-reports/medication-response> 3 January 2013; GeneLex, 'YouScript' <youscript.com> accessed 3 January 2013; Who'z the Daddy?, <whozthedaddy.com/regions/UK/EN/?gclid=CMm44IbTzLQCFcbLtAodSWgALg> accessed 3 January 2013.

has ceased offering this testing in the USA, its UK and Canadian websites offer drug response tests for 12 drugs.[517]

14 companies test for Warfarin response. These companies are: 23andMe UK; Biotechnology Group; C2DNA; Genetic Center Company Limited; Genomic Express; GeneLex; Gene Planet; Gentle; Kimball; Matrix Genomics; myDNA; Pathway Genomics; Theranostics; and the Wellness Gene. There is a difference in terminology in how the test is described. Here are some examples. Gentle, C2DNA, myDNA, and Theranostics describe their test, as one for 'Warfarin sensitivity', while Biotechnology Group Inc and Genetic Center Company Limited use the term 'Warfarin metabolism'.

11 companies have tests for statins.[518] Three test for Clopidrogrel and this is normally described as being for Clopidrogrel Metabolism, although GenePlanet describes this as 'Prevention of blood clotting'.[519] Two companies test for responsiveness to particular types of pain medication. Both of these though are companies whose services are only available through physicians (Pathway and GeneLex).

Six companies test for response to anti-deppressants generally. These are: 23andMe UK; C2DNA; GeneLex; myDNA; Pathway Genomics; and the Wellness Gene.

---

517 23andMe (Canada), 'What You Can Expect' <23andme.com/en-ca/health/reports/> accessed 24 August 2015; 23andMe (UK), 'What You Can Expect' <23andme.com/en-gb/health/reports/> accessed 24 August 2015.

518 These are: 23andMe; BioLogis; Biotechnology Group; DNA Plus; DNA Testing Centres of Canada; Genetic Center; GeneLex; Gene Planet; myDNA; Theranostics; and the Wellness Gene.

519 Biotechnology Group Inc, <biotechnologygroup.com/index.html> accessed 22 January 2014. [Checked again 28 January 2014 and still operating]. [Checked again 1 May 2014]; Genetic Center Company Limited, <genetic-center.com> accessed 13 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 14 April 2014]; GenePlanet, 'Personal Genetic Analysis', <geneplanet.com/personal-genetic-analysis.html/> accessed 3 February 2014. [Checked again 14 April 2014].

Six companies test for Caffeine Metabolism. These are: Biotechnology Group Inc[520]; Genomic Express Inc[521]; Theranostics Lab[522]; Pathway Genomics[523]; 23andMe UK[524]; and GenePlanet[525].

The benefits of pharmacogenetic testing are often presented very positively on DTCGT companies' websites. What follows are some examples of the claims made by some DTCGT companies. 23andMe's American website previously included the statement, 'Arm your doctor with information on how you might respond to certain medications'.[526] BioTechnology Group's website includes the following statement:

> Drug Awareness Report can save you significant time, money and unnecessary suffering. Your genetics can determine how effective a particular drug is for you. Your genetics may place you at risk of side effects for some drugs. It is well noted that drugs do have unique effects on certain individuals and none for others.[527]

While MyDNA states:

> Knowledge on DNA variations can help your doctor determine if you need more or less of a medication, or whether you might be at increased risk for certain side effects.
> By knowing ahead of time, your doctors can optimise drug selection and dosing based on your unique genetic profile by maximizing effectiveness and minimising adverse reactions.[528]

---

520 Biotechnology Group Inc, <http://www.biotechnologygroup.com/index.html> accessed 22 January 2014. [Checked again 28 January 2014 and still operating]. [Checked again 10 April 2014].

521 Genomic Express Inc, <https://secure.genomicexpress.com/home.html> accessed 27 January 2014. [Checked again 28 January 2014 and still operating]. [Checked again 14 April 2014].

522 Theranostics Lab, <http://www.theranostics.co.nz/afawcs0143120/tn-products.html> accessed 5 January 2013. [Checked again 29 January 2014 and still operating]. [Checked again 24 April 2014].

523 Pathway Genomics, <https://www.pathway.com/about-us/management> accessed 11 February 2013. [Checked again 24 April 2014].

524 23andMe (UK), 'Health' <23andme.com/en-gb/health/reports/> accessed 2 July 2015.

525 GenePlanet, <http://www.geneplanet.com/personal-genetic-analysis.html/> accessed 2 January 2013. [Checked again 28 January 2014 and still operating]. [Checked again 14 April 2014].

526 23andMe, 'Living well starts with knowing your DNA' accessed 5 September 2013.

527 BioTechnology Group, accessed 15 January 2014.

528 MyDNA, accessed 14 August 2013.

(ii.) ***Implications for consumers***

The area of pharmacogenetic genetic testing has been presented as one of the most promising areas of genomic research.[529] However, in the context of tests offered directly to consumers, pharmacogenetics is in fact one of the most challenging types of testing. Pharmacogenetics is the category of health related DTCGT that poses the greatest risk of direct harm to consumers. For instance, if a consumer takes a test for drug responsiveness and on the basis of test results increases, decreases or ceases taking their medication without consulting a physician this could cause severe health consequences including potential death.

A very recent study by Bloss et al investigated consumer behaviour in the context of pharmacogenetic tests and whether this was associated with increased utilization of physicians. [530] The study involved the recruitment of:

> a sample of adults who purchased a DTC genomic test and had previously received their genomic test results for complex disease risk. All participants additionally underwent PGx testing. At follow-up, to assess the impact of PGx testing on consumer behaviour, healthcare utilisation and psychological status were compared between approximately a third of participants who had received their PGx results and the remaining two-thirds of participants who were still awaiting results. The PGx test included genetic testing for drug effectiveness or risk of side effects for 12 medications.[531]

They concluded that 'risk profiling among a selected sample of persons was associated with statistically significant increases in physician utilisation', and 'testing did not result

529 NK Gillis and F Innocenti, 'Evidence required to demonstrate clinical utility of pharmacogenetic testing: the debate continues' (2014) 96 Clinical Pharmacology & Therapeutics 655; Susanne B Haga and Wylie Burke, 'Pharmacogenetic testing: not as simple as it seems' (2008) 10 Genetics in Medicine 391; ACJW Janssens and PA Deverka, 'Useless until proven effective: the clinical utility of preemptive pharmacogenetic testing' (2014) 96 Clinical Pharmacology & Therapeutics 652; Matthew B Lanktree et al, 'Positive perception of pharmacogenetic testing for psychotropic medications' (2014) 29 Human Psychopharmacology: Clinical and Experimental 287

530 Cinnamon S Bloss, Nicholas J Schork and Eric J Topol, 'Direct-to-consumer pharmacogenomic testing is associated with increased physician utilisation' (2014) 51 Journal of Medical Genetics 83

531 ibid 83.

in any short-term changes in psychological health'.[532] However, they did recommend the need for further evaluation of utility and cost and they highlighted limitations on their study and the need for further research in this area. They observed that their 'sample consisted of a self-selected group of individuals, likely representative of the current population of consumers (…) who chose to undergo and pay out of pocket for testing', and that their findings were in contrast with a previous study which has involved a sample of 'young (…), healthy, insured population'.[533] It seems that physician involvement is something that is particularly desirable in the context of pharmacogenetic testing.

It is clear that companies will use their websites to induce consumers to purchase their products, but there is a need for more transparency regarding the limitations of some DTCGT services and it is possible that pharmacogenetic tests might need to be subject to more oversight than other types of health tests provided DTCGT. This need for transparency and the provision of sufficient information regarding the respective limitations of testing is something that has been stressed in the majority of policy guidance to date.

(d) Nutrigenetic Testing

(i.) Companies operating

49 companies have been identified which offer (or have offered) this type of testing and the number is likely to increase. As companies providing nutrigenetic testing often provide other services related to diet and fitness, they often have more in common with fitness, wellness, and nutrition companies than with clinical genetics. Some examples

532 ibid 89.
533 ibid (n 530) 88.

are: My Gene Diet (Natures Remedies Ltd)[534]; Pathway Genomics[535]; Smart DNA[536]; Inherent Health[537]; Halo Health; and Gene Planet.[538]

Companies that offer nutrigenetic testing often also offer tailored diet services or food supplements. Here are three examples of companies' claims. Halo Health describes its 'Personalised Gene Diet' as follows:

> The way you metabolize certain foods and nutrients is also written in your DNA. That is why excess body weight is the result of metabolic changes to fats, carbohydrates, and proteins, which are usually accompanied by an unhealthy lifestyle and poor nutrition. Each person is unique and requires different combinations of nutrients in order to function effectively. With your genetic profile information in hand we can adapt to your body with a new lifestyle and weight loss diet plan that will actually work.[539]

Gene Planet sells the NutriFit service for €399.00 and it states:

> The core of NutriFit is based on the fact that link exists between numerous genetic variants and individual dietary needs.
>
> NutriFit is undoubtedly one of the main steps in the process of discovering specific needs of each individual and is therefore a key to the optimal diet and a healthy life-style.
>
> The personal nutrigenetic guide therefore identifies specific characteristics of each of us and guides individuals on the path to optimal health and well-being.[540]

Meanwhile, DNAFit provides its DNAFit Diet tests for £179 and claims that:

> DNAFit™ Diet is a unique way to help you eat right for your body. We hope this is the last diet advise you will ever need, it's not a FAD it's all about YOU. The way you metabolize certain foods and nutrients is written in your DNA. Each person is unique and requires different combinations of nutrients in order to function effectively. While we can't change our

534 My Gene Diet, <http://www.my-gene-diet.com/products.php> accessed 13 August 2013. [Checked again 29 January 2014 and still operating]. [Checked again 23 April 2014].

535 Pathway Genomics, "Pathway Fit" <pathway.com/about-us/management> accessed 3 February 2014.

536 Smart DNA, <smartdna.net.au/howitworks.html> accessed 13 August 2013. [Checked again 29 January 2014 and still operating]. [Checked again 24 April 2014]

537 Inherent Health, <inherenthealth.com/our-tests.aspx> accessed 13 August 2013. [Checked again 29 January 2014 and still operating]. [Checked again 15 April 2014]

538 GenePlanet, 'NutriFit' <http://www.geneplanet.com/nutrifit-en.html> accessed 3 January 2013;

539 Halo Health, halohealth.com/item/home-4/ accessed 14 August 2013. [Checked again 29 January 2014 and still operating]. [Checked again 15 April 2014].

540 GenePlanet (n 538). Please note that the current listing on the website has not changed substantially and the price has remained the same for the past two years. (21 July 2015).

> genes but we can adapt to them with a new lifestyle and weight loss diet plan. Based on our analysis of your genes we will calculate a score to determine which of three possible diet plans (low fat, low carb and Mediterranean) is likely to be the most effective for you.[541]

(ii.) Implications for consumers

The category of nutrigenomics raises issues regarding clinical validity, as many tests currently offered have not been appropriately validated and consequently the consumer may be paying for something that is ultimately useless. Some have argued that this type of testing should not be offered by DTCGT companies, unless the tests offered are properly validated.[542] Often companies engaged in testing of this type also market supplements or meal plans. In the Association for Molecular Pathology's (AMP*) Updated Position Statement*[543] they included a category dubbed 'business interest', which they did not support and it seems likely that many nutrigenetic tests would come under this classification. It is possible that some companies in this category are more interested in selling additional products than in providing reliable testing. Again consumer privacy is a significant issue here and companies' policies regarding sale of data, data sharing and storage need to be carefully monitored.

(e) Carrier Testing

(i.) Companies operating

17 companies have been identified which offer (or have offered) carrier testing.[544] Some current examples of companies still offering it are: 23andMe's UK branch;

---

541 DNAFit, dnafit.com/uk/ accessed 15 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 11 April 2014].

542 EASAC and FEAM, *Report* (n 439)10; HGC, *A Common Framework of Principles* (n 232); 3.

543 AMP

544 These are: 23andMe; All About Truth; Asper Biotech; Biotechnology Group Inc; Boston Paternity; Center for Medical Genetics; Counsyl; DNA Connect; DNA Testing Centres of Canada; DNA Traits; Gentle; GeneLex; GenePeeks; Genetic Center Company Limited; Genex; HomeDNADirect; and Pathway Genomics.

Biotechnology Group Inc; Counsyl (offers services through a physician); GenePeeks; and Genetic Centre Company Limited.[545]

23andMe UK tests for 43 conditions. Counsyl offers testing for more than 100 conditions. Gentle offers carrier testing for 120 conditions. GenePeeks's Matchright service compares consumers' DNA with that of potential donors to minimise disease risk. Genetic Center Company Limited provides tests for 37 recessive conditions.

Here are two examples of the statements made by companies providing carrier testing. Counsyl states:

> Our carrier test includes up to 100 additional recessive conditions and genetic counseling at one flat price. Our scientific team carefully selected every disease on the Counsyl test to screen for clinically relevant and actionable disorders, including those identified by ACOG and ACMG. You can tailor disease panels based on your patient population and access our genetic counselors via telephone at no additional cost. The Counsyl Carrier Screen is supported by several peer-reviewed publications and has been named one of Scientific American's "Top 10 World-Changing Ideas."[546]

Whereas, Genetic Center Company Limited states:

> When planning to start or expand a family, DNA testing will help you, your significant other learn what mutations you and your partner may carry and the chances of your children inheriting mutations or variants that cause genetic diseases. While family history can be an important indicator, it alone cannot confirm whether a recessive genetic condition exists in you and your family. Recessive genetic conditions can be carried silently in a family for generations, with no one being affected. Genetic testing can tell you whether you are a carrier of a gene mutation, which could mean a risk for passing the associated condition to your children.[547]

(ii.) Implications for consumers

As many of the carrier tests offered by DTCGT companies have been approved and used in clinical settings, there are less issues around clinical utility and validity. However, as

---

545 23andMe, 'Carrier Status' <https://www.23andme.com/health/carrier/> accessed 3 January 2013; Counsyl, <https://www.counsyl.com> accessed 29 May 2014

546 Counsyl

547 Genetic Center Company Limited,

undergoing carrier testing generally is intended to allow individuals to understand whether they are at heightened risk of having a child affected by a serious illness or disability and may impact upon their reproductive decision making, it is vital that such tests are of the highest quality.[548] In terms of reproductive decision making, undergoing carrier testing may allow couples to decide whether to use 'prenatal diagnosis followed (or not) by termination of the pregnancy in case of an affected fetus', allow them to understand and 'come to terms with the risk' and also decide whether to use 'pre-implantation genetic diagnosis', 'donor sperm or oocytes'.[549] It may also mean in some communities that couples may choose to adopt or not to have children or may mean that an individual will choose another partner.[550] None of these decisions is trivial and in a clinical setting patients would normally have genetic counselling and receive extensive information regarding the consequences of such testing.

In EASAC and FEAM's Report, they highlight the need for counselling and adequate information in this context. They stress that if DTCGT companies offer this service they should follow guidelines for quality control, which apply to other medical tests carried out in a clinical context.[551] As learning that a person is a carrier of a serious condition may actually be distressing and might be a factor in reproductive decision making, it is important that companies do in fact provide sufficient information about the nature of testing so that consumers can make informed decisions.[552]

548 Borry et al, 'Preconceptional genetic carrier testing and the commercial offer directly-to-consumers' (n 452)

549 ibid (n 452) 972.

550 ibid (n 452) 972.

551 EASAC and FEAM, *Report* (n 439)10; Fears (n 439); Borry et al, 'Preconceptional genetic carrier testing and the commercial offer directly-to-consumers' (n 439) 972-977.

552 Borry et al, 'Preconceptional genetic carrier testing and the commercial offer directly-to-consumers' (n 439) 972-977

(f) Companies offering services via physicians

(i.) Companies operating

41 companies were identified that offer genetic testing services that require orders to be made by physicians.[553] Some of these companies are more traditional laboratories, which market to physicians. However, several of these have websites that might be construed as advertising directly to consumers or which might be construed as advertising to physicians.

For instance, Genosense Diagnostics, has a page of its website entitled 'Genes & You'. Meanwhile, Map My Gene proclaims 'YOUR DNA IS YOUR BOOK OF LIFE!! "Using genomics to make predictions about your health is a powerful paradigm"'.[554] Finally, while Pathway has been operating through physicians for some time now its website seems to be aimed more at consumers, rather than doctors. It describes Pathway Fit as follows:

> Pathway Fit analyzes over 75 genetic markers known to impact metabolism, exercise and energy use within the human body. Through the examination of these genetic markers, which are expressed in various organs such as the brain, stomach, gut, muscle, pancreas, as well as directly in fat tissue, we are able to gain an insight into how a person's body processes sugars, fats, and nutrients and vitamins. What's more, our report includes detailed analysis on how a patient's body responds to exercise and performance, and provides strategies to help a patient reach an optimal potential to maintain a healthy weight based on that specific patient's genetics.[555]

---

553 The companies offering testing through physicians are: AccuraScience; American International Biotechnology, LLC (AIBioTech); ARUP Lab; Athleticode; Bio Logis; Bio Wellness Inc; Cancer Genetics Inc; CD Genomics; Center for Medical Genetics; Counsyl; Diagnomics; DNADirect; DNA Traits; Foundation Medicine Inc; GATC Biotech AG; GeneLex; GeneNews Ltd; Genetic Testing Laboratories Inc (GTL); Genewiz; Genomic Express Inc; Genomic Health Inc; Genosense; Gentle; Kimball; Knome; LabCorp; Map My Gene; MEDomics; Molecular Diagnostic Services (PTY) LTD; Myriad ; Navigenics; Pathway Genomics; Pediatrix Medical Group; Perkin Elmer Genetics ; Personal Genome Diagnostics Inc; Progenika Inc; Remede; Signal Genetics Inc; Smart DNA; Toldot Genetics; Transnetyx Inc.

554 Map My Gene, <mapmygene.com> accessed 24 August 2015.

555 Pathway Genomics, *'Pathway Fit'*

(ii.) Implications for consumers

While companies that only allow testing to be ordered through a physician are to some extent engaging in more responsible practices overall, their activities still need to be monitored carefully. While the provision of genetic counselling and supervision of physicians is desirable in DTCGT more generally, companies which began as DTCGT without the involvement of medical practitioners and have since shifted to a model involving practitioners have been criticised on the grounds that having a physician on staff or links to company approved physicians may provide a level of false reassurance.[556] Furthermore, as there are problems generally with general practitioners' understanding of DTCGT and genetic testing more generally the involvement of general practitioners does not necessarily overcome concerns about certain kinds of DTCGT.[557] Several commentators have also highlighted the need for further education for general practitioners in genetics.[558]

Clinical utility and validity, informed consent, and provision of adequate information are still important in this context. Some companies also still have websites that are targeted towards attracting consumers and they also market to physicians, which raises similar issues to the direct-to-consumer marketing of pharmaceutical drugs in terms of whether advertising has an impact on physicians' perceptions of testing.[559]

---

556 Howard and Borry (n 295)

557 Howard and Borry (n 295)

558 Powell et al, 'Educational needs of primary care physicians regarding direct-to-consumer genetic testing' (n 352) Powell et al, 'Primary Care Physicians' Awareness, Experience And Opinions Of Direct-To-Consumer Genetic Testing' (n 352)

559 Catherine A Womack, 'Ethical and epistemic issues in direct-to-consumer drug advertising: where is patient agency?' (2013) 16 Medicine, Health Care and Philosophy 275; Sanjo Adeoye and Kevin J Bozic, 'Direct to consumer advertising in healthcare: history, benefits, and concerns' (2007) 457 Clinical orthopaedics and related research 96

4 Companies that Perform Ancestry Testing

(a) Companies operating

68 companies have been identified which offer (or have offered) this type of testing.[560] Companies will normally have several options and many ancestry testing companies, will perform other types of testing for genetic relatedness including tests for paternity, maternity, grandparents and siblings. Some of the most prominent companies in this category are: AncestryDNA; AncestrybyDNA; Family Tree DNA; 23andMe; easyDNA; Britain's DNA; National Geographic's Genographic Project; and Nimble Diagnostics.[561]

32 companies offer testing for both maternal and paternal lineage. 13 companies specifically test for African ancestry and 15 test for Native American ancestry.[562] It is also common for companies to offer a 'family finder' function, which allows people to connect with others to whom they may be related.

Here are some examples of the types of claims made regarding ancestry testing services. AncestryDNA states, 'Your DNA has a story. It's time to discover it'. It then

---

560 These are: 23andMe; Accu-metrics Viaguard; Advanced Healthcare Inc; African Ancestry; African DNA; All About Truth DNA Services; Alpha Biolabs; Ancestry DNA; AncestrybyDNA; Any Lab Test Now®; ARCpoint Labs; BritainsDNA; Cambridge DNA; Services DDC, DNA Diagnostics Center; DDC, DNA Diagnostics Centre; Determigene; DNAme; DNA Ancestry Project; DNA Ancestry & Family Origin DNA; Clinics; DNA Consultants; DNA Dimensions; DNA DTC; DNAForce; DNA Heritage; DNA Identifiers; DNA Print Genomics; DNA Services of America; DNA Spectrum; DNA Solutions; DNA Test; DNA Testing Center of America; DNA Testing Centre Inc DNA; Testing Centres of Canada DNA Tribes; DNA Worldwide; easyDNA; Family Tree DNA; Full Genomes Corporation; Genebase; Genetic Testing Laboratories Inc (GTL); Gensys; Genetica DNA Laboratories Inc; Genex Diagnostics Inc; Genomic Express Inc; GFI Lab; Health Street; HomeDNAdirect; iGENEA; Indian Biosciences; International Biosciences Lumigenix; Merrimack Valley Paternity Testing (MVP Testing); MyHeritage National Geographic's Genographic Project; Nimble Diagnostics; North American DNA Testing; Oxford Ancestors; Paternity Testing Corp; Relative Genetic;s Roots for Real; Scotlands DNA; Test Country; Test Diagnostics; YSEQ DNA Origins Project; Who'z the daddy?

561 23andMe, 'Understand the Story of Your Past' <https://www.23andme.com/ancestry/> 3 January 2013; Family Tree DNA, <http://www.familytreedna.com> 3 January 2013; Nimble Diagnostics, 'Ancestry DNA Testing' <http://www.nimblediagnostics.com/home/anc.html> 3 January 2013; easyDNA, 'DNA Testing for Ancestry - Find Your Origins Here!' <http://www.easydna.co.uk/dna-ancestry-test.html> accessed 3 January 2013.

562 These are: Accu-metrics Viaguard; African DNA; Alpha Biolabs; AncestryByDNA; DDC; DNA Consultants; DNA Dimensions; DNA Services of America; DNA Spectrum; Genex; Genomic Express; North American DNA Testing; Genetica; Genebase; and Universal Genetics.

provides a quote from an apparently happy customer, Arlene O who comments "AncestryDNA connected me to a 2nd cousin I never knew. And through our family trees we were able to see how we were related. A cousin once lost to time and distance is now reunited through the use of DNA".[563] The latest version of the AncestryDNA website now says 'Discover your one in a million story with AncestryDNA'.[564]

Meanwhile, African Ancestry is extremely positive about its services, stating:

> The African Ancestry benefits are unparalleled:
> ANCESTRY FOUND BY COUNTRY AND ETHNIC GROUP African Ancestry is the ONLY company that traces your ancestry back to a specific present-day African country of origin and often to a specific African ethnic group when African ancestry is found.[565]

It also has a variety of slogans including 'Find the African in Your American' and 'Find the African in Your Brazilian'.

(b) Implications for consumers

It is becoming clear that in practice the lines between the activities of DTCGT companies which perform ancestry testing and those which perform health-related tested are very much blurred. Many companies are not limited to offering merely one type of genetic testing and may offer ancestry together with paternity and health testing. AncestryDNA and Gene By Gene are good examples of this. This also raises the question of whether it is possible to apply different regulatory regimes to ancestry testing and health related testing. Perhaps, it could be argued that while a company is engaged only in ancestry testing it should be subject to less regulatory oversight, but that if it subsequently moves into health research it should then be subject to more oversight. However, this would be very difficult to implement and it might be desirable to require ancestry companies to at

563 AncestryDNA, <dna.ancestry.com> accessed 28 August 2013.
564 AncestryDNA, <dna.ancestry.com> accessed 24 August 2015.
565 African Ancestry, <africanancestry.com> accessed 8 September 2013.

least have more rigorous mechanisms for informed consent and stronger security mechanisms to ensure protection of consumer privacy. It is also possible that in the UK ancestry testing companies may also come under the remit of the HTA and if that is the case then they would need to provide similar consent mechanisms to companies that provide health tests.

While it is possible for ancestry testing to be conducted as a 'recreational activity' ancestry testing is not necessarily innocuous. Firstly, the accuracy of ancestry testing in terms of its ability to identify an individual's ancient origins is questionable and while as more research is performed on different ethnic groups ancestry testing will become more accurate, notions of ethnicity and race have historically not generally been used in beneficial ways. So it is possible that an increase in ancestry testing focussing on ethnic origins may serve to fuel further racial divisions, which people have been trying to overcome for some time.[566]

Several DTCGT companies that perform ancestry testing also offer a family finder service, which connects individuals with others to whom they may be related. This sometimes leads to unexpected discoveries including false paternity and unknown siblings. While this information might be beneficial for some people it can also cause distress and have a serious impact on families.

Ancestry is also often linked with notions of identity and sometimes when a person learns unexpected information about their origins this may have a significant impact on their conception of their own identity. In terms of accuracy, it will also be of more use to consumers in the future, when more research has been conducted on all population groups, as at present, due to the lack of study of some ethnic groups the

[566] Mark Popovsky, 'Exaggerated Benefits and Underestimated Harms: The Direct-to-Market Consumer Genetic Test Market and How to Manage It Going Forward' (2010) 8 Dartmouth LJ 65; TallBear

reliability of some ancestry testing may be questionable.[567] Although with the research conducted by the 1000 Genomes Project and the 100,000 Genomes Project, there are likely to be significant improvements in this area in the near future.[568]

Another area of concern is the increasing number of companies that specifically offer testing for Native American ancestry testing. Historically, indigenous people in many countries have been marginalised and exploited in many ways, including through their involvement in health research.[569] It is desirable that companies providing testing of this type are subject to more scrutiny.

5 Companies that Perform Genetic Relatedness Testing

(a) Companies operating

In this category the most common type of testing is paternity testing with 83 companies offering this service.[570] 96% of the companies offering paternity testing offer both a 'legal' and a 'peace of mind' option. 60% of these companies offer both paternity and

567 E Callaway, 'Ancestry Testing Goes For Pinpoint Accuracy' (2012) 486 Nature 17; JK Wagner et al, 'Tilting at windmills no longer: a data-driven discussion of DTC DNA ancestry tests' (2012) 14 Genet Med 586593.

568 1000 Genomes Project, <http://www.1000genomes.org/about> 3 January 2013.

569 Mello and Wolf;

570 The companies identified that offer paternity testing are: 23DNA; Accu-metrics Viaguard; Accurate Paternity Testing; Advanced Healthcare Inc; Alpha Biolabs; American Paternity; Any Lab Test Now®; Any Time Lab; ARCpoint Labs; Asper Biotech; AssureDNA; Beta Paternity; Boston Paternity; BRT Labs Inc; Cellmark; Checkmatetest.com; Consumer Genetics; Dadchecksilver; DDC, DNA Diagnostics Center; DDC, DNA Diagnostics Centre; Definite DNA; Determigene; DNAForce; DNA Clinics; DNA Connect; DNA Diagnostics Ltd; DNA Dimensions; DNA Findings; DNA Genie; DNA Identifiers; DNA Ireland; DNA Labs; DNA Services of America; DNA Solutions; DNA Test; DNA Test.ie; DNA Testing Center of America; DNA Testing Centre Inc; DNA Testing Centres of Canada; DNA Worldwide; DNAQ owned by Genomics For Life Pty Ltd; easyDNA; Eurofins Medigenomix GmbH; EuroPaternity; Fairfax Identity Labs; Forensics Genetics Center; Genebase; GeneLex; Genetic Profiles; Genetica DNA Laboratories Inc; Gensys; Genetrack Biolabs; Genetic Profiles; Genetic Testing Laboratories Inc (GTL); Genetic Technologies; Genex Diagnostics Inc; GFI Lab; HealthCheckUSA; HomeDNAdirect; Home DNA Inc; Identigene Inc; Independent Forensics; Indian Biosciences; IDNA Systems; International Biosciences; iTest DNA; LabCorp; Medigenomix; Molecular Diagnostic Services (PTY) LTD; MVP Testing; Nimble Diagnostics; North American DNA Testing; Northgene; Paternity Testing Corp; PaternityUSA; Priority Investigations; Prophase Genetics; Serotech Laboratories LTD; Silbase Genetics; Sorenson Genomics; SwabTest; Test Country; Test Diagnostics; That DNA Company; Who'z the daddy?

maternity testing. 35% of the companies identified also offer prenatal paternity testing. 41% of the companies offering paternity testing also offer non-consensual (infidelity) testing.

Some examples include: Who'z the Daddy?[571]; Test Country[572]; Gensys[573]; Prophase Genetics[574]; International Biosciences[575]; and Genetic Profiles[576].

Who'z the Daddy makes the following statement regarding its 'peace of mind' testing:

> Establishes the paternal link between an alleged father and a child, without the need to test the mother. This level of test offers peace of mind and can be conducted solely by the applicant at home. These tests are 100% conclusive for exclusion and greater than 99.99% for inclusion.[577]

Meanwhile, DNA People Diagnostics states:

> We understand that all DNA paternity tests are not created equal. Our DNA paternity tests are 100 times more discriminating than the industry standard. Typical positive results exceed 99.99%. We will test up to 19 markers to assure you reliable paternity test results. Most labs run less than 10 markers, greatly increasing the chance for inaccurate results.[578]

---

571 Who'z the Daddy?, 'Court Approved DNA Tests' <whozthedaddy.com/regions/UK/EN/courtApprovedDNAtests.asp> accessed 5 January 2013. [Checked again 24 April 2014]; Who'z the Daddy?, 'Peace of Mind DNA Tests' <whozthedaddy.com/regions/UK/EN/peaceOfMindDNAtests.asp> accessed 5 January 2013. [Checked again 24 April 2014].

572 Test Country, 'Paternity DNA Testing' <testcountry.com/categories.html?cat=152&left> accessed 10 August 2013. [Checked again 24 April 2014].

573 Gensys, 'Do you need a legal or in-home paternity test?' <paternity-answers.com/paternity-test.html> accessed 12 August 2013. [Checked again 14 April 2014]

574 Prophase Genetics, <prophase-genetics.com/home_legal_paternity2.html> accessed 13 August 2013. [Checked again 24 April 2014]

575 International Biosciences, 'DNA Testing Services and Prices' <ibdna.com/regions/UK/EN/?page=services#PM_Paternity> accessed 2 February 2013. [Checked again 16 April 2014]

576 Genetic Profiles, <geneticprofiles.com> accessed 27 January 2014. [Checked again 28 January 2014 and still operating]

577 Who'z the Daddy? <whozthedaddy.com> accessed 13 August 2013.

578 DNA People Diagnostics, <dnapeoplediagnostics.com/paternitytestingservices.htm> accessed 11 September 2013.

(b) Implications for consumers

The majority of companies offering paternity testing will sell two versions of the test, which will normally be described as 'legal' or 'court approved' on the one hand and 'peace of mind testing' on the other. The 'legal' option is usually more expensive. The fact that it is common practice to provide these options calls for careful scrutiny of company practices in this context, as sample collection by individual consumers without witnesses does pose a substantial risk of sample contamination or misuse. The potential for abuse in this context was also highlighted in the Article 29 Data Protection Working Party's Opinion 03/2012 on developments in biometric technologies in which it stated that 'Insufficient identity checks could allow individuals or entities to submit samples from other individuals and getting sensitive personal data about other people as a result'.[579] A recent UK case that attracted media attention demonstrates this potential for misuse, as John Bullet wishing to avoid his maintenance commitment organised for another person impersonate him and take a paternity test in his stead. The mother discovered the imposter when she was shown a photo of the man who took the test. Bullett also lied to the Child Support Agency. He was then forced to have a second test, which proved he was the father.[580] While this case did not involve a DTCGT company it would be easier for a person to send in someone else's sample in the DTCGT context. Of course anyone who did in fact send in another sample's claiming it was theirs or that they had obtained appropriate consent would be committing the offence of non-consensual DNA analysis set out in the HTA and it is also possible that companies that do not have rigorous systems in place to check consent could also be prosecuted under the Act.

---

579 Article 29 Data Protection Working Party, Opinion 03/2012 on developments in biometric technologies (27th April 2012) 4.4.5, p 26, <http://ec.europa.eu/justice/data-protection/article-29/documentation/opinion-recommendation/files/2012/wp193_en.pdf> accessed 29 May 2016

580 Watson, ; 'Shamed: Dad who tried to beat DNA paternity test' the case was heard in the Leeds Crown Court and the number was S20130486, but the case does not seem to have been reported.

Companies providing paternity testing will often perform tests on children's DNA samples, which at odds with most of the policy guidance to date, as generally this guidance has recommended that testing of minors should not be offered direct-to-consumer. The wide range of paternity testing services raises issues in criminal law and family law, such as: the nature and adequacy of consent; the reliability of testing; and potential harm to individuals, which would be fascinating to investigate, but which cannot be addressed herein. It is hoped that future research will explore the issues raised by DTCGT paternity testing.

If DTCGT companies continue to offer this kind of testing, it would seem advisable that they improve consent mechanisms and adhere to higher standards, as unreliable parental testing could potentially result in significant harms to families. Companies offering prenatal paternity testing may need to be especially careful.

6 Companies that Perform Athletic Ability Testing

(a) Companies operating

This is a growing area, as while 29 companies were identified in this category, as of July 2015 it appears there are several new companies, which were not discovered in my previous searches. Some of the most prominent companies in this area are: Athleticode[581]; Atlas Sport Genomics[582]; Asper Biotech[583]; Genetic Sports Performance; and DNA Fit.

What follows are three examples of the types of tests available and the claims made by such companies. DNA Fit's slogan on its website is '[L]et your DNA work for

581 Athleticode, <athleticode.com> accessed 10 August 2013. [Checked again 22 January 2014 and still operating]. [Checked again 9 April 2014].

582 Atlas Sports Genetics, <atlasgene.com> accessed 28 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 9 April 2014]

583 Asper Biotech, 'Athletic Gene Test' <http://www.asperbio.com/asper-biotech-varia/athletic-gene-test> accessed 9 April 2014.

you' and it provides tests for diet and what it dubs 'ideal training'.[584] Regarding its athletic testing it makes the following claim, '[W]e test your DNA for 20 key genes to help you truly understand your body, and how best to train for your genetics'.[585] It also allows consumers who have already purchased a genetic test from 23andMe to link their data to DNA Fit.

Meanwhile, Athleticode, which may not be operating anymore[586] focussed on concussion management. It provided testing for the APOE gene and had a physician network. It featured the following testimonial on its website, 'Athleticode's ApoE test is a game changer for concussion management'.[587]

The Makings of Me also offers a Speed vs Endurance test for $39(USD). It makes the following claims regarding this test:

> Test yourself to learn about your athletic potential
> Test your children to get invaluable information about the sports that are best for them.
> Learn more about how to train to excel.
> Are you a natural marathon runner or a 100 meter sprinter?[588]

(b) Implications for consumers

Tests for athletic ability are generally not well validated and even those that have been validated are often of little predictive value.[589] In fact companies selling such tests have been compared with snake oil merchants.[590] While an individual's genetic makeup may

---

584 DNAFit

585 DNAFit, 'Fitness' <dnafit.com/fitness/> accessed 20 July 2015.

586 Its website is not functioning as of 20 July 2015.

587 Athleticode, <http://athleticode.com> accessed 10 August 2013. [Checked again 22 January 2014 and still operating]. [Checked again 9 April 2014].

588 The Makings of Me, 'Speed vs Endurance' <themakingsofme.com/dna-test-running.html> accessed 20 July 2015.

589 Patenaude; Howard, Avard and Borry, 'Are the kids really all right? Direct-to-consumer genetic testing in children: are company policies clashing with professional norms?'; Holly K Tabor and Maureen Kelley, 'Challenges in the use of direct-to-consumer personal genome testing in children' (2009) 9 The American Journal of Bioethics 32; Amy L Fletcher, 'Field of genes: the politics of science and identity in the Estonian genome project' (2004) 23 New Genetics and Society 3.

590 Collier

play a role in whether she is able to excel in sports it is only one factor and at present it does not seem that this role is determinative, as some successful athletes do not possess the ACTN3 variants. Where companies offer testing for children this raises further issues about the adequacy of consent and the privacy and security of sequenced genetic data, as well as other personal information.

7 Companies that Perform Child Talent Testing

(a) Companies operating

So far, only four companies have been identified that specifically market tests for child talent in a general way. However, the other 25 companies identified that market testing for athletic ability will also often test children.

Map My Gene's DNA Innate Talents service (this is now called Inborn Talent Genetic Test) tests for 46 talents and traits, which it divides into different categories. It is currently priced at $1,500(USD). The division of character traits includes: optimism; risk-taking; shyness; depression; hyper activeness; and adaptability. The category of IQ includes: intelligence; creativity; reading ability; memory; and comprehension. The artistic category includes predisposition for: performance; music; drawing; dancing; literature; and linguistics. While the EQ category includes: affection; faithfulness; propensity for teenage romance; self-control; self-reflection; and sentimentality. There is also a sports category, which covers: endurance; sprinting; tendency of sport injuries; and sport psychology. The test also covers certain health traits, including obesity and predisposition to addiction covering alcoholism, smoking, and general addiction.[591]

[591] Map My Gene, 'Inborn Talent Genetic Test' <mapmygene.com/inborn-talent-genetic-test.html> accessed 20 July 2015

Meanwhile, the Makings of Me currently provides its My Child's DNA Insights Kit for $79(USD)[592]. Its website claims:

> Take the TheMakingsofMe My Child's DNA Insights Unlock the secrets of how your children's genes influence who they are and what they can become, with this affordable DNA test kit. Gain valuable, scientific information about everything from your child's cognitive capacity to their athletic capabilities and physical attributes. This kit will enable you to make better decisions that will allow your children to reach their genetic potential.[593]

Genetic Center Company Limited also offers a Child Talent Gene Test. This also covers several categories including: intelligence quotient; emotional quotient; focussing potential; and sports potential. The company claims that, the 'Test for Child Talent is carried out to find the Gene that determines the life function and also basic elements to analyze the strengths and weaknesses of a child's capacity in life'.[594]

Genetic Healthcare Group (geneLAB) offers the Inborn Talent and Behavioural (DNA) Test and makes the following claims:

> Traditionally, persistence and industriousness allows one to achieve more in life - but with the arrival of genetic testing and analysis, we now have access to foreknowledge of the child's natural abilities and inner talents.
>
> Just as sports champions have sports-enhancing genes, and entrepreneurs have genes that enable greater emotional intelligence, so your future winners have personal genes of excellence which must be nurtured for the child's greater future success.
>
> (…) By understanding natural potentials and limitations, we are now able to focus on the right development areas rather than stumbling over the wrong areas. With the right guidance and motivation, we can now influence and cultivate a child's natural learning inclinations which give a higher guarantee of excellence for him. This saves parents from unnecessary disappointment and frustration; allowing money, time and

592 Price as of 20 July 2015.

593 The Makings of Me, 'My Child's DNA Insights Kit' <themakingsofme.com/dna-test-kit-for-kids.html> accessed 20 July 2015.

594 Genetic Center Company Limited, 'Genetic Center Company Limited' <genetic-center.com/index_moduleId-114_pageName-content_pId-30.html> accessed 13 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 14 April 2014]

> effort to be channeled into truly fruitful development regimes for the child.
>
> Ultimately, the child who possesses the advantage of cultivating his genetically predisposed talents has the clear upper hand. So know your child's innate talents and gain this indispensable advantage for them. You will be able to optimize your child's academic, vocational and social competency development - by maximizing their inherent abilities through the power of, and the knowledge from, our patented geneKIDS testing.[595]

(b) Implications for consumers

As previously noted, most policy guidance to date has opposed DTCGT companies offering tests to children, consequently the availability of this testing requires greater oversight and should ideally be restricted. Generally, tests for child talent are also not well validated and are not used widely in clinical settings. Clinical geneticists and physicians often discourage testing of children for late onset conditions.[596]There is again a need for greater transparency and fair advertising practice in this context, as companies marketing such testing often present genetics in a very deterministic way, which does not reflect the respective risks and benefits of testing in an honest way.

8 Companies that Perform Non-Consensual Testing

(a) Companies operating

Currently 34 companies offer non-consensual testing services. These tests are often marketed as 'infidelity' tests. Some examples of companies specialising in testing of this

---

595 Genetic Healthcare Group, 'Inborn Talent & Behavioural (DNA Test)' <genetic-healthcare.com/gh_services.html> accessed 30 April 2014.

596 Jeffrey R Botkin et al, 'Points to Consider: Ethical, Legal, and Psychosocial Implications of Genetic Testing in Children and Adolescents' (2015) 97 The American Journal of Human Genetics 6; L Jackson, L Goldsmith and H Skirton, 'Guidance for patients considering direct-to-consumer genetic testing and health professionals involved in their care: development of a practical decision tool' (2014) Family practice

type include: All About Truth DNA Services; Any Lab Test Now; Infidelity Testing; She Cheated; and Test Infidelity.[597]

However, when examining websites of many seemingly more reputable companies, it becomes apparent that they will sometimes also conduct tests without consent. Overall, 41% of companies that offer paternity testing also offer 'infidelity testing'.[598]

Some companies engaged in health testing or ancestry testing also encourage customers to purchase tests as gifts (for instance, 23andMe allows customers to purchase additional test kits as gifts and currently offers a 20 per cent discount if they purchase multiple kits[599]). Yet others also specifically offer tests for infidelity alongside their other services. For example, Advance Healthcare Inc, (which despite its name does not in fact offer health testing, but instead specialises in various tests for genetic relatedness), also offers an infidelity test for 9800 Rupees. [600]

Furthermore, companies often make claims on their websites in this context, which could be deemed misleading advertising and they also encourage customers to send in samples of dubious quality. One example is North American DNA Testing, which states:

---

597 Any Lab Test Now®, <mylabsa.com/index.html> accessed 28 August 2013; Infidelity Testing, <infidelitydnatesting.com> accessed 8 September 2013; All About Truth DNA Services, <allabouttruthdna.com/other-testing-services/infidelity-dna-testing/> accessed 28 April 2014;She Cheated, <shecheated.net> accessed 2 February 2013. [Checked again 24 April 2014]; Test Infidelity, <testinfidelity.com> accessed 20 January 2014. [Checked again 24 April 2014].

598 These include: Accu-metrics; Advanced Healthcare; All About Truth; Any Lab Test Now; Any Time Lab; Arcpoint; Boston Paternity; Checkmate; DNA Connect; DNA Findings; DNA Identifiers; DNA Q; DNA Services; DNA Test; DNATest.ie; DNA Testing Centre; easyDNA; EuroPaternity; Faifax; Forensics Genetics; GTL; IDNA; International Biosciences; ITest; Labcorp; Medigenomix; MVP; North American; Paternity Testing; PaternityUSA; Serotech; SwabTest; Test Diagnostics; and Universal.

599 23andMe, <23andme.com/store/cart/> accessed 23 May 2014.

600 Advanced Healthcare Inc, <advanceddna.in> accessed 28 August 2013, checked again 20 August 2015 – price is current as of 20 August 2015.

> Do you suspect your spouse or significant other is cheating? In a study conducted by the Journal of Marital and Family Therapy in 2012, it was discovered that 41% of marriages have at least one cheating spouse.
>
> Infidelity DNA Testing can help you get the answers and confirmation that you deserve so you can move forward with your life.[601]

Another example is All About Truth DNA Services, which states:

> Statistically, approximately 60% of husbands and 40% of wives will have an affair at some point in their marriage or relationship.
>
> DNA testing typically provides a conclusive way to find out if someone is cheating on you. We are able to confirm or deny the presence of male and/or female DNA on suspicious items such as undergarments, sheets, clothing, condoms and so on. Once we have confirmed that the item does contain DNA we can run a powerful DNA comparative analyses to identify the DNA source (was it yours or someone elses).
>
> The DNA testing we do is accurate, reliable, and strictly confidential. Get the peace of mind you need to take the next step in your life. Call us now to speak confidentially with a trained DNA testing case manager to discuss your suspected infidelity issue.[602]

Meanwhile, She Cheated claims its 'tests are a superior Infidelity testing method'[603] and its website features quotes from supposedly satisfied customers. One example attributed to Wyatt is 'I live in sin city. My girlfriend didn't seem like the cheating kind. You proved my girlfriend was cheating, and that it was with my best friend. Thanks for the proof. I'm not with her anymore, and now I hear she's cheating on him too'.[604] Although, the company does make a rather dubious attempt to be even handed with another quote entitled Saving Jeff's Marriage, which claims:

> I hired a private investigator. He followed my wife for three weeks and never gave me real proof. My wife was out late every weekend. I took a pair of her black lace panties. I sent it in, and you gave me proof that she wasn't cheating. Thanks for saving my marriage.

---

601 North American DNA Testing, <northamericandnatesting.com> accessed 7 April 2014.
602 All About Truth DNA Services, <allabouttruthdna.com> accessed 28 April 2014.
603 She Cheated, <shecheated.net> accessed 20 January 2014.
604 ibid accessed 20 August 2015.

(b) Implications for consumers

Surreptitious testing is probably the most concerning type of DTCGT testing, primarily due to the dubious nature of these services and also companies' marketing practices. Often the content of websites providing testing of this type seems open to challenge on the grounds that it is misleading. Companies often encourage consumers to send in samples of dubious quality belonging to other individuals without their consent and it is possible that some of the services advertised cannot perform in accordance with their claims.[605] Companies offering these services to UK consumers are also most clearly in breach of the HTA and are likely to be deemed to have committed the offence of non-consensual DNA analysis set out in section 45. Where the content of the website clearly encourages consumers to send in samples belonging to third parties without their consent the company should be liable to prosecution, but the consumer may also be committing an offence.

It seems that testing of this a type is worthy of more scrutiny and is desirable that regulators take action against these companies. However, enforcing the legislation in relation to this particular type of testing is likely to be difficult due to its very nature in that companies are encouraging people to send in samples without appropriate consent clearly in breach of the law.

605 Albert E Scherr, 'Genetic Privacy & the Fourth Amendment: Unregulated Surreptitious DNA Harvesting' (2012) 47 Ga L Rev 445; Eriq Gardner, 'Gene Swipe: With More DNA Labs, Few Know Whether Those Chromosomes are Yours-Or You Stole Them from Someone Else' (2011) 97 ABAJ 50;

9 Companies that Perform Match Making Testing

(a) Companies operating

Only three of these have been identified and one of these is no longer operating. The three companies are: GenePartner; Instant Chemistry; and Scientific Match.[606] Here are two examples of the claims made by such companies. The main page of GenePartner's website claims that 'Your perfect match is just one click away' and that:

> the GenePartner formula determines the level of genetic compatibility with the person they are interested in. The probability for successful and long-lasting romantic relationships is greatest in couples with high genetic compatibility. (…)
> Why is genetic compatibility important?
> With genetically highly compatible people we feel that rare sensation of perfect chemistry. This is the body's receptive and welcoming response when immune systems harmonize and fit well together. Genetic compatibility results in:
>
> - An increased likelihood of forming an enduring and successful relationship (…)

It also states that:

> GenePartner's biological matching method is designed as a complementary service for matchmakers and online dating sites. Based on the genetic profile of the client, the GenePartner formula determines the level of genetic compatibility with the person they are interested in. The probability for successful and long-lasting romantic relationships is greatest in couples with high genetic compatibility.[607]

Meanwhile, Instant Chemistry claims:

> The beginning of love is easy. We offer scientific solution to make it last.
>
> Scientific research has shown that relationship markers – a combination of genetics and psychology – strongly affect who we are attracted to and how successful our relationships are. Learn what makes your relationship tick and where strengths and weaknesses may lie.[608]

And also:

---

606 GenePartner, <genepartner.com> accessed 10 February 2013; Instant Chemistry, <instantchemistry.com> accessed 10 April 2014; Dating DNA, <datingdna.com> accessed 10 February 2013; Scientific Match – is no longer operating.

607 GenePartner, <genepartner.com> accessed 8 September 2013.

608 Instant Chemistry, <instantchemistry.com> accessed 12 April 2015.

> A long-term relationship is important to you. Science has a lot to say about that, especially if you want to ensure your unceasing compatibility. Relationships grow, but your DNA and core personality stay constant. Find out the underlying compatibility between you and your partner to help your relationship grow.[609]

(b) Implications for consumers

While this type of service has not yet proliferated, it is one of the most dubious services offered by DTCGT companies. There is very little evidence to support the claims made by companies and the few companies engaged in it often make exaggerated claims about the benefits of testing, which could are potentially misleading. Companies providing these tests to UK consumers are also likely to come within the HTA's remit. Based on the review of website content and companies' contracts, again it seems advisable that companies work to improve their consent mechanisms.

10 Conclusion

This chapter has discussed the wide variety of genetic tests currently offered by the DTCGT industry and the issues that different types of testing raise for consumers. It has demonstrated that the DTCGT industry is a diverse industry that is growing rapidly with companies taking advantage of new technologies that are not necessarily ready for the market. At present, the industry is continuing to grow and is not subject to specific legal regulation. However, companies offering services to UK consumers should be complying with the provisions of the Human Tissue Act and based on review of website content and companies' contracts, it seems likely that several companies' consent mechanisms are not adequate and that some companies may be committing an offence under the HTA.

[609] Instant Chemistry, 'How it works' <instantchemistry.com/#how-it-works> accessed 20 July 2015.

In light of this together with the concerns expressed by policymakers it is clear that the industry does need to be monitored. At present, the adequacy of consent mechanisms and the provision of sufficient information to enable informed decision-making, including sufficient information regarding the respective risks and benefits of testing, the utility and validity of tests, and overall transparency are issues that are raised by all types of DTCGT tests.[610] It seems that most companies are not engaging in practices that are in accordance with policy recommendations, especially in the context of the provision of test results. Consumers do need to be provided with sufficient information in order to be able to understand the limitations of test results. This is especially important where companies provide disease risk tests or carrier testing.

For most types of genetic tests offered by DTCGT companies, the results provided to consumers are probabilistic in nature. This means that their level of usefulness to the individual tested is inherently limited.[611] There is also a greater risk that there will be false positives and false negatives. Furthermore, the results and risk information provided to consumers of DTCGT companies are of a complex nature and it is quite possible that many consumers will have difficulty in understanding the implications of genetic test results. There are also risks associated with being falsely reassured or unnecessarily worried by such results and it is morally questionable whether allowing companies to sell consumers such tests is something that society should condone. The work of Eric Giannella is relevant here. Giannella questions the idea of

610 Lewis et al(n 324) 291–307; Geransar and Einsiedel, 'Evaluating online direct-to-consumer marketing of genetic tests: informed choices or buyers beware?'; BM Knoppers, 'Consent to 'personal' genomics and privacy. Direct-to-consumer genetic tests and population genome research challenge traditional notions of privacy and consent' (2010) 11 EMBO Rep 416;

611 Nordgren, 'Neither as harmful as feared by critics nor as empowering as promised by providers: risk information offered direct to consumer by personal genomics companies'; Saukko, 'State of play in direct-to-consumer genetic testing for lifestyle-related diseases: market, marketing content, user experiences and regulation'; European Society of Human Genetics, 'Direct-To-Consumer Genetic Tests Neither Accurate in Their Predictions nor Beneficial to Individuals, Study Suggests' (2011) <http://www.sciencedaily.com /releases/2011/05/110530190344.htm> accessed 3 November 2011

progress, which currently dominates Silicon Valley and much of the technology industry. He suggests that '23andMe should have been a long-term research project'[612] rather than a start-up and this idea has appeal.

In the context of DTCGT companies, which have research divisions and market on the promises of patient centred and participatory research, it is possible that companies could in the future operate as cooperatives and provide opportunities for profit sharing with their customers. If consumers are required to give up their privacy to some extent and this is done in the name of genetic research being a public good, then there are also possibilities for more truly collaborative research. Companies that offer testing to indigenous groups could also allow customers to decide how a share of their profits are allocated. For instance, a company could provide choices in its contracts that allow consumers to specify that their share of profits are fed back to their tribal group or community.

It is important to note that all DTCGT companies regardless of the type of testing they offer are united by the fact that they are commercial entities and as such, regardless of the claims made by company representatives regarding their motivations, they are all to some extent driven by commercial interests. On the whole, companies strive to be profitable[613] and in the context of DTCGT, it is the sequenced genetic data that is the primary asset to companies and its main source of profit, as the actual sale of tests does not seem to be especially profitable.[614] As Offit has noted:

---

612 Eric Giannella, 'Morality and the Idea of Progress in Silicon Valley' Berkeley Journal of Sociology <http://berkeleyjournal.org/2015/01/morality-and-the-idea-of-progress-in-silicon-valley/> accessed 12 April 2015

613 David Shaywitz, 'Does 23andMe Deal Mean Medical Centers Are Sitting On Data Worth Millions?' *Forbes* (8th January 2015) Pharma & Healthcare <forbes.com/sites/davidshaywitz/2015/01/08/does-23andme-deal-mean-medical-centers-are-sitting-on-data-worth-millions/> ;B Williams-Jones, 'Where there's a web, there's a way: commercial genetic testing and the Internet' (2003) 6 Community genetics 46; Offit

614 Aaron Krol, '23andMe Pursues Health Research in the Shadow of the FDA' *Bio IT World* (24 March 2014) <bio-itworld.com/BioIT_Article.aspx?id=136445>

> the implicit marketing strategy of these companies is to involve the consumer in a "voyage of genetic self-discovery," even if some of the initial paths charted lead nowhere. In the worse-case scenario, the paths may lead to unnecessary medical interventions or false reassurances and missed diagnoses. The incentive for financial profit in such a journey is at fundamental odds with the skeptical nature of scientific inquiry and the conservative nature of clinical translation of new biomedical technologies.[615]

An illustrative example highlighting the commercial nature of DTCGT company endeavours is that of 23andMe's recent refusal to share data with Open Humans and also, 23andMe has recently been valued at a market cap of $1 billion.[616]

The research ventures of DTCGT companies are also valuable and the databases developed by several of the most prominent companies are being used for profit, as companies partner with pharmaceutical companies or are sold on to biomedical research companies. Examples include AncestryDNA's recent collaboration with Calico,[617] 23andMe's partnerships with Pfizer, Genentech, and Reset Therapeutics,[618] and the sales of DeCodeMe and Navigenics. It is also possible that physical samples of DNA may also have value for companies, but the focus herein is on the sequenced data, rather than the physical sample itself and the issues raised by companies' treatment of consumers' physical samples will be explored in subsequent research.

Overall, the examination of the content of various DTCGT websites together with the wide variety of tests available highlights the need for greater transparency by

615 Offit (n 613)1354.

616 Aaron Krol, 'Open Humans Aims to Be the Social Network for Science Volunteerism' *Bio IT World* (9th April 2015) <bio-itworld.com/2015/4/9/open-humans-aims-social-network-science-volunteerism.html> accessed 13 April 2015;Aaron Krol, 'What Comes New for Direct-to-Consumer Genetics?' (*Bio IT World*, 2015) <bio-itworld.com/2015/7/16/what-comes-next-direct-consumer-genetics.html> accessed 18 July 2015

617 (n 250)

618 (n247) and (n 248).

DTCGT companies. This is supported by the previous studies of Lachance et al and Lewis et al.[619]

The next chapter will consider the regulatory response to date, which has been primarily a policy response. It will begin with discussion of the areas of law, which might be applicable to DTCGT in the UK and consider the class actions in the USA and against 23andMe. It will then consider the various policy statements and guidance that have been released and make some suggestions for reform. Although the primary focus in this thesis is on the content of DTCGT contracts and their role in governance of the industry and how specific terms might be challenged on the grounds of their unfairness, this does not necessarily provide the best remedy for consumers. It is desirable that regulators draw upon the various policy documents issued to date and either develop specific legislation to govern the industry or alternatively, that the ICO, the Human Tissue Authority, and the MHRA take on a greater role in regulating the industry.

619 Lachance (n 338) and Lewis et al (n 324)

CHAPTER FOUR – REGULATING DTCGT – THE REGULATORY RESPONSE TO A DISRUPTIVE TECHNOLOGY

1 Introduction

The nature and mode of sale of DTCGT tests do not fit clearly into existing legal regulation in the UK, EU, USA or elsewhere[620]. The fact that it is also web-based also poses challenges for enforcing regulation of the industry. To date, much of the regulatory response has been a policy response, rather than a legislative response and this is reflective of the industry's disruptive nature, as regulators have not been able to keep up with the pace of technological change and have found it difficult to fit the industry into existing regulation. However, as with several other new technologies, such as wearable technology and the various devices that form the Internet of Things, there is a need for a wider discussion including all stakeholders and the public, so that existing law can be adapted and enforced, and new law cognisant of the various issues raised by new technologies can be developed. This chapter will begin with an overview of the existing areas of legal regulation, which might be applicable to DTCGT in the UK and EU, concentrating on the governance of medical devices, data protection, consumer protection, and human rights. It will then touch upon the American situation, due to the large number of American based companies. This will be followed by discussion of the various policy responses to date together with a summary of the commonalities across such guidance. It argues that while DTCGT is currently permitted as a consumer industry consumer protection law has direct applicability to the industry, but that these other areas of law may also have direct applicability to industry governance. This is due to the nature

620 While this thesis is primarily focussed on UK law, I have also read about the regulation of DTCGT globally.

of the services provided by DTCGT companies, that is, they are providing genetic tests previously confined to a medical setting, tests results are complex and may also be ambiguous, and it is desirable that legislation governing medical devices and data protection is drawn upon to improve industry governance.

It seems that the most likely area of existing law, which has direct applicability to DTCGT, is the regulation of medical devices. In both the EU and the USA DTCGT genetic tests have been viewed as capable of coming under this branch of regulation.[621] Currently, in the EU many DTCGT tests, as 'laboratory developed tests' (LDTs) are considered to be medical devices,[622] but they are not subject to premarket review, as they are classified as being low risk.[623] However, there is a growing level of concern regarding appropriate regulation of DTCGT in various member states.

Various policymakers have released guidance on the appropriate regulation of the industry. The most important documents in this area are: the reports and principles developed by the Human Genetics Commission (HGC); the European Council's 2008 Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for Health Purposes; the European Society of Human Genetics' (ESHG) Statement On Direct-To-Consumer Genetic Testing For Health Purposes; European Academies of Science Advisory Council and Federation of European Academies of Medicine's Report; the Association for Molecular Pathology's two statements; and the OECD Guidelines.

As a large number of DTCGT companies currently offering services to UK consumers are in fact based in the USA it is desirable that the USA does play a role in developing effective governance of the industry. In the USA, the majority of DTCGT

621 Hogarth, Javitt and Melzer (n 236)
622 ibid, 173
623 ibid 173

tests have also not been subject to premarket review, but since 2010 the FDA has altered its stance on the regulation of DTCGT testing somewhat,[624] although it is yet to take definitive action.

Overall there is a general lack of specific regulation for DTCGT globally.[625] DTCGT as an industry challenges legal regulation. It is challenging, as an example of disruptive innovation, which does not fit neatly into existing legal categories.[626] It is challenging because it provides genetic tests framed as consumer services. Such tests were previously restricted to a medical setting and subject to governance mechanisms, which sought to protect individuals undergoing such testing and also ensure standards in both clinics and scientific research.[627] Now DTCGT companies often offer these services outside the clinic and tests are often offered that have not been clinically validated and even where they are validated, they will often lack clinical utility, meaning that there are no treatment options, which a person can take on the basis of such results.

Consequently, it is questionable and also quite probable that for disease predisposition testing especially and also nutrigenetic testing, consumers will derive no real benefit from such testing or at least that any benefit that might be derived by the consumer is likely to occur only at some undetermined future date when the effects of genetics on human health are better understood. Although, the $1000 genome sequencing

624 Most notably with its letter to 23andMe of November 2013. B Patsner, 'New "Home Brew" Predictive Genetic Tests Present Significant Regulatory Problems' (2009) Hous J Health L & Pol'y 237-77;D Vorhaus and Guest Contributor, 'DTC Genetic Testing and the FDA: is there an end in sight to the regulatory uncertainty?' (16th June 2011) ; Felix W Frueh et al, 'The future of direct-to-consumer clinical genetic tests' (2011) 12 Nature Reviews Genetics 511; PJ Zettler, JS Sherkow and HT Greely, '23andMe, the Food and Drug Administration, and the future of genetic testing' (2014) 174 JAMA Intern Med 493

625 Borry et al, 'Legislation on direct-to-consumer genetic testing in seven European countries'; Hogarth, Javitt and Melzer (n 236)

626 Hogarth, Javitt and Melzer (n 236); S Schlanger, 'Filling in the Cracks: Improving the Regulation of Direct-to-Consumer Genetic Tests' (2011) 14 J Health Care L & Pol'y S1;Paula Boddington, 'The ethics and regulation of direct-to-consumer genetic testing' (2009) 1 Genome Medicine 71; Stuart Hogarth, D Melzer and R Zimmern, 'The regulation of commercial genetic testing services in the UK' (A briefing for the Human Genetics Commission, Cambridge)

627 Hogarth, Javitt and Melzer, 'The current landscape for direct-to-consumer genetic testing: legal, ethical, and policy issues' (n 236)

service is now a reality,[628] the cost of interpretation of that genome is still much higher than $1000 and unlikely to near that figure in the near future.[629]

DTCGT is also challenging because of the features of the DTCGT service in the sense that they do not qualify solely as services or products. The way that DTCGT services are provided means that consumers purchase a test online, but in order for the test to be carried out there are several steps, which must be taken. The consumer will receive a test kit (which might be construed as a medical device or consumer product). This kit is used to collect the consumer's DNA, normally in the form of saliva. The consumer collects their sample and then sends the kit back to the company. The company then carries out the sequencing service (which can be construed as a either a medical or consumer service). The company then provides the consumer with test results, either in the form of raw data or data with interpretation (which can be considered digital content) and finally if the company is engaged in on-going research they may also provide the consumer with on-going updates on their genetic information, also in digital form. These points are all significant because in law they trigger the application of different legislation or governance mechanisms.

2 Sources of law which might be applicable to DTCGT in the UK and EU

This section will consider the areas of existing law, which might be drawn upon to regulate DTCGT, namely, medical devices legislation, consumer protection legislation, and data protection.

In the EU many DTCGT tests are not subject to premarket review, as they are classified as being low risk.[630] In the UK, the DTCGT industry is growing, but the

628 Raj (n 349)
629 Naveed et al (n 312) 7

majority of companies offering services to UK consumers are based in the USA. 23andMe's recent entry into Superdrug has received much media attention[631] and while it does have a UK website, tests on UK consumers are still in fact carried out in laboratories in the USA.

(a) Consent – from the Clinic to the Home

As has been previously noted the DTCGT industry provides genetic tests in a new setting, a domestic setting. Individuals are now able to order a large variety of tests online without any involvement of the medical profession. This is challenging for legal regulation and also for professional organisations that have traditionally played a role in regulating the provision of these tests because such tests were previously confined primarily to a medical setting. [632] The provision of such tests in clinics has been subject to governance mechanisms, which were designed to protect those tested and ensure testing standards. A vital aspect to this governance was the requirement that testing subjects, whether they were patients or research participants provided adequate consent to testing. Such consent needed to be voluntary and informed. The recent decision in

630 Hogarth, Melzer and Zimmern, 'The regulation of commercial genetic testing services in the UK' (n 458) 12

631 I was interviewed by the Newsnight programme organisers in preparation for their episode on the launch of 23andMe in the UK (2nd December 2014).
James Meikle, 'Superdrug criticised by doctors for stocking genetic self-testing kits' *The Guardian* (31 March 2015) Genetics <theguardian.com/science/2015/mar/31/superdrug-criticised-doctors-genetic-self-testing-kits> accessed 31 March 2015; Samuel Gibbs, 'DNA-screening test 23andMe launches in UK after US ban' *The Guadian* (2 December 2014) <theguardian.com/technology/2014/dec/02/google-genetic-testing-23andme-uk-launch> accessed 4 December 2014; H Wallace, 'GeneWatch UK PR: Shoppers warned not to buy gene tests from Superdrug' (*GeneWatch UK*, 2015) <genewatch.org/article.shtml?als%5Bcid%5D=406259&als%5Bitemid%5D=575612> accessed 5 April 2015

632 Geransar and Einsiedel; Liam Curren and Jane Kaye, 'Revoking consent: A 'blind spot'in data protection law?' (2010) 26 Computer Law & Security Review 273; D Kishore, 'Test at Your Own Risk: Your Genetic Report Card and the Direct-to-Consumer Duty to Secure Informed Consent' (2009) Emory LJ; Eline M Bunnik, ACJW Janssens and Maartje HN Schermer, 'Informed Consent in Direct−to−Consumer Personal Genome Testing: The Outline of A Model between Specific and Generic Consent' (2014) 28 Bioethics 343; Jay Katz, 'Informed Consent-A Fairy Tale-Law's Vision' (1977) 39 U Pitt L Rev 137; Megan Allyse, '23 and Me, We, and You: direct-to-consumer genetics, intellectual property, and informed consent' (2013) 31 Trends in biotechnology 68

Montgomery v Lanarkshire[633] also stresses the need for the provision of adequate information to enable informed decision making. Consent in the clinic normally involves genetic counsellors who will meet patients or research participants in person and provide them with information regarding testing. This meant that undergoing testing in a clinic involved personal interaction with trained experts who were able to explain the complex nature of test results. More recently, initiatives, such as the HeLEX Centre's Dynamic Consent Project have been working to enhance consent mechanisms and allow individuals to have better understanding of the respective risks and benefits of testing while also enabling them to have a greater role in determining how their data is used in the context of medical research, including a right to withdraw consent.[634]

In contrast, at present the mechanisms for consent in the DTCGT context are not as rigorous as might be desired. Currently, most DTCGT companies use wrap contracts to govern all matters pertaining to the purchase of a genetic test, including consent. Furthermore, these documents often deem consent through use or viewing of a website, which means that the adequacy of consumer consent is open to challenge.

(b) Consumer Protection legislation

As DTCGT is currently framed as a consumer industry, rather than a medical service, consumer protection legislation may be a useful mechanism to draw upon in order to improve regulation. While there is a new Consumer Rights Act in the UK, which will be discussed in more detail in chapter six, there are several other pieces of legislation, which might be relevant to DTCGT. There is also now a new regulatory authority, the Competition & Markets Authority (CMA), which will also be discussed in chapter six.

---

633 (Scotland) [2015] UKSC 11; Mark Campbell, 'Montgomery v Lanarkshire Health Board' (2015) 44(3) Common Law World Review 222-228.

634 Kaye et al, 'Dynamic consent: a patient interface for twenty-first century research networks' (n 321)

UK consumer protection law has been influenced by EU legislation and case law. 'It is commonly recognized that EU law and the law of the Member States do not have a unique definition of the consumer'.[635] However, 'it is possible to identify common elements across several consumer directives, which may be used to delineate a common notion of the consumer'.[636] The European Court of Justice (ECJ) has also developed ideas about consumers. The conception of consumers promulgated by the Court depicts the consumer as 'a natural person, who, in transactions is acting for purposes which can be regarded as being outside his or her trade or profession'.[637] The Court also frequently makes reference to 'the average consumer', who is reasonably well informed and reasonably observant and circumspect'.[638] However, the ECJ also has 'recognised the 'vulnerable consumer', who requires a higher level of protection in particular circumstances'.[639]

(i.) The Directive on Consumer Rights

Firstly, the Directive on Consumer Rights[640] is significant in this context. The new Directive on Consumer Rights (2011/83/EC) came into force on 13 June 2014 and replaces the previous Directives (97/7/EC) and (85/577/EEC). The Directive is aimed at harmonising consumer protection across the internal market while also maintaining 'the competitiveness of enterprises'.[641]

The Directive defines consumer in Article 2(1) to mean 'any natural person who, in contracts covered by this Directive, is acting for purposes which are outside his trade,

635 Benöhr (n 275)16
636 ibid (n 275) 17
637 ibid (n 275) 17 citing Case C-269/95 *Francesco Benincasa v Dentalkit Srl* [1997] ECR I-3767,
638 ibid (n 275) 17
639 ibid (n 275) 17
640 (2011/83/EC) [17]-[19]
641 European Commission, 'The Directive on Consumer Rights' <ec.europa.eu/consumers/consumer_rights/rights-contracts/directive/index_en.htm> accessed 13 June 2014

business, craft or profession'. This definition has influenced the definitions of consumer used in both the new Consumer Rights Act and the previous Unfair Terms in Consumer Contracts Regulations 1999, which will both be discussed in chapter six. The Directive is intended to apply to all contracts between consumers and traders (article 3(1)).

The Directive provides for certain requirements in relation to distance and off-premises contracts. It is likely that these requirements are applicable to DTCGT contracts, which it seems, should be viewed as distance contracts. Distance contracts are defined in article 2 as:

> (7) 'distance contract' means any contract concluded between the trader and the consumer under an organised distance sales or service-provision scheme without the simultaneous physical presence of the trader and the consumer, with the exclusive use of one or more means of distance communication up to and including the time at which the contract is concluded.

Chapter III of the Directive in article 6 requires traders to provide consumers with information regarding a number of matters. For present purposes the most relevant sections are: (a) 'the main characteristics of the goods or services, to the extent appropriate to the medium and to the goods or services'; (b) 'the identity of the trader, such as his trading name'; (c) 'the geographical address at which the trader is established' and other contact information; (e) 'the total price of the goods or services inclusive of taxes (…)'; (h) 'where a right of withdrawal exists, the conditions, time limit and procedures for exercising that right in accordance with Article 11(1), as well as the model withdrawal form set out in Annex I(B)'; (k) 'where a right of withdrawal is not provided for in accordance with Article 16, the information that the consumer will not benefit from a right of withdrawal or, where applicable, the circumstances under which the consumer loses his right of withdrawal'; and (t) 'where applicable, the possibility of having recourse to an out-of-court complaint and redress mechanism, to which the trader is subject, and the methods for having access to it'. DTCGT companies ought to be

complying with these information requirements and currently; it is likely that many DTCGT companies are not satisfying these requirements.

(ii.) Consumer Protection from Unfair Trading Regulations 2008 (CPUTR)

Secondly, the CPUTR[642] could be drawn upon and utilized to improve regulation of DTCGT companies' advertising practices. In line with these regulations, it may be appropriate to develop an industry code of conduct for DTCGT services offered in the UK. This could involve collaboration with DTCGT companies and public consultation. Such a code could also draw upon the principles set out in the HGC's *Framework of Principles.* If the CPUTR were to be extended to apply to DTCGT, then the most relevant provisions are: regulation 3, which prohibits 'unfair commercial practices'; regulation 5, which sets out the matters relevant to ascertaining whether there has been a constitute misleading action; Part 3 which creates offences relating to unfair commercial practices; and Part 4 which deals with enforcement.

Regulation 3 defines 'unfair commercial practices' as follows:

> (3) A commercial practice is unfair if—
> (a) it contravenes the requirements of professional diligence; and
> (b) it materially distorts or is likely to materially distort the economic behaviour of the average consumer with regard to the product.
> (4) A commercial practice is unfair if—
> (a) it is a misleading action under the provisions of regulation 5; it is a misleading omission under the provisions of regulation 6;
> (b) it is aggressive under the provisions of regulation 7;
> (c) it is listed in schedule 1

Regulation 5 sets out the matters, which will constitute misleading actions. According to regulation 5 (1) 'A commercial practice is a misleading action if it satisfies the conditions in either paragraph (2) or paragraph (3)'. 5(2) provides that:

642 Consumer Protection from Unfair Trading Regulations 2008, SI 2008/1277.

> A commercial practice satisfies the conditions of this paragraph—
>
> (a) if it contains false information and is therefore untruthful in relation to any of the matters in paragraph (4) or if it or its overall presentation in any way deceives or is likely to deceive the average consumer in relation to any of the matters in that paragraph, even if the information is factually correct; and
> (b) it causes or is likely to cause the average consumer to take transactional decision he would not have taken otherwise.

In the context of DTCGT the most relevant provisions of Regulations 5(5) and 5 (4) are as follows. A trader's behavior may be misleading if it contains false information about 'the existence or nature of the product' (5(4)(a)); 'the main characteristics of the product (as defined in paragraph 5)' (5(4)(b)); or 'the consumers' rights or the risks he may face' (5(4)(k). According to Regulation 5 (5) 'In paragraph (4)(b), the "main characteristics of the product" include': 5 (5)(b) 'benefits of the product'; 5(5)(c) 'risks of the product'; 5(5)(l) 'fitness for purpose for the product'; 'results to be expected from use of the product'; 5(5)(r) 'results and material features of test or checks carried out on the product'. In examining the contracts of DTCGT companies and reviewing their websites, it seems likely that many DTCGT companies may potentially be engaging in practices that would qualify as misleading actions. As will be shown in chapters four and five companies often make exaggerated claims about the benefits of their tests, but their contracts often include broad disclaimers of liability, including disclaiming liability for fitness for purpose.

The development of a code of conduct seems particularly desirable in relation to DTCGT companies that provide tests for health purposes, as it might serve to help improve standards across the industry and afford greater protection to consumers. In Regulation 5 (3) (b) a commercial practice may also qualify as misleading where 'it concerns any failure by a trader to comply with a commitment contained in a code of

conduct which the trader has undertaken to comply with, if' 'the trader indicates in a commercial practice that he is bound by that code of conduct' (5(5)(b)(i)). Thus, if DTGCT companies were obliged to follow a code of conduct and it was clear that particular companies were not abiding by it, this provides another avenue of redress for consumers. It might also allow consumers to distinguish those DTCGT companies engaged in more responsible practices from those that are not.

Part 3 establishes offences relating to unfair commercial practice. Regulation 8 deals with the criteria for establishing when an offence has been committed. Accordingly under 8 (1) a trader will be guilty of an offence if (a) 'he knowingly or recklessly engages in a commercial practice which contravenes the requirements of professional diligence under regulation 3(3)(a)' and (b) 'the practice materially distorts or is likely to materially distort the economic behaviour of the average consumer with regard to the product under regulation 3(3)(b)'. Under 8 (2) a trader can be guilty of an offence where they engage in a practice 'without regard to whether the practice contravenes the requirements of professional diligence'. The penalty for such offences is set in regulation 13 and allows for those found guilty of an offence to be liable to a fine or imprisonment.

Part 4 deals with enforcement and it allows regulators certain enforcement powers, which might now include the Competition & Markets Authority and under regulation 20 an 'enforcement authority' is provided with a power to make test purchases. This could mean that the CMA could make sample purchases of DTCGT tests. Schedule 1 of the Regulations lists commercial practices, which should always be considered as unfair. Most relevant in this context are:

> 17. Falsely claiming that a product is able to cure illnesses, dysfunction or malformations.
>
> 18. Passing on materially inaccurate information on market conditions or on the possibility of finding the product with the intention of inducing the

> consumer to acquire the product at conditions less favourable than normal market conditions.

It is possible that the website content of some DTCGT companies might at present be deemed as an unfair commercial practice under these provisions.

(iii.) ***The Supply of Goods and Services Act 1982***

Thirdly, the Supply of Goods and Services Act 1982 may also be drawn upon in this context. This Act is the most significant enactment in the UK governing the provision of services. Part II of the Act applies to contracts for the supply of services and section 13 of the Act implies the following term into contracts for the supply of services:

> In a contract for the supply of a service where the supplier is acting in the course of a business, there is an implied term that the supplier will carry out the service with reasonable care and skill.

It seems likely that this Act ought to be applicable to the DTCGT industry and consequently, this should mean that an obligation to 'carry out service with reasonable care and skill' should be implied in DTCGT contracts. Section 16 of the Act prohibits companies from attempting to exclude this implied term. Consequently, this might have the result that clauses disclaiming liability for fitness for purpose in the context of DTCGT services provided for the purposes of health testing, (especially those companies providing disease predisposition or susceptibility testing, carrier testing, and pharmacogenetic testing) might not be enforceable. On this basis, clauses specifying that services are provided on an 'as is' basis may also be unenforceable.

It might also limit the enforceability of clauses attempting to limit the purposes of testing, such as those specifying that services are provided for 'educational', 'recreational' or 'informational' purposes. The Sale of Goods Act 1979 may also have relevance, but as it is concerned primarily with the sale of goods and the DTCGT industry is primarily engaged in selling genetic testing services, it seems that the Act may

not have direct applicability to the industry and generally, where consumer sales involve goods and services it is the Supply of Goods and Services Act which will govern.

(c) Medical Devices legislation - Directive 98/79/EC on In Vitro Diagnostic Medical Devices and the draft IVD Regulation[643]

One approach to regulating DTCGT relying on existing legislation is to draw upon the regulatory mechanisms governing medical devices and this is the area of existing regulation, which seems most likely to be utilised to regulate DTCGT. This relies on one aspect of how DTCGT services are provided, namely, the test kit, which is normally sent to consumers for them to collect their DNA sample in the form of saliva. Test kits as such are collection devices and the reason that 23andMe has been allowed to market through Superdrug in the UK is because it obtained a Conformité Européene (CE) mark for its test kit, which means essentially that the kit has been approved as safe for the purposes of collecting saliva.[644] This also means that the kit can be marketed throughout the EU, as CE certification is recognised reciprocally, so that if a company receives a CE mark in one Member State the mark will be recognised by others. This certification though does not provide for any additional assessment of the reliability or safety of the sequencing service itself or the interpretation or analysis performed.

The HGC did advocate for an increased role of the MHRA in regulating DTGCT.[645] Although, the Government did reject such a role, at present the MHRA does enforce the three current directives: Directive 93/42/EEC Regarding Medical Devices

643 Proposal for a Regulation 9770/15 of the European Parliament and of the Council on in vitro diagnostic medical devices of 12 June 2015. Interinstitutional File: 2012/0267 (COD)

644 Turna Ray, '23andMe Gets CE Mark, Launches PGS Offering in UK for £125' *GenomeWeb* (1 December 2014) <genomeweb.com/microarrays-multiplexing/23andme-gets-ce-mark-launches-pgs-offering-uk-125> accessed 20 August 2015; Samuel Gibbs, 'DNA-screening test 23andMe launches in UK after US ban' *The Guardian* (2 December 2014) <theguardian.com/technology/2014/dec/02/google-genetic-testing-23andme-uk-launch> accessed 30 August 2015

645 Human Genetics Commission, *More Genes* (n 258)16

(MDD); Directive 90/385/EEC Regarding Active Implantable Medical Devices (AIMD) and Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVD Directive).[646] The IVD Directive is most relevant in this context. Its scope, as set out in section 2 (a) was intended to apply to all 'medical devices':

> Intended by the manufacturer to be used for human beings for the purpose of:
>
> — diagnosis, prevention, monitoring, treatment or alleviation of disease,[647]

Much genetic testing for health purposes should be covered by such a definition, and it seems arguable that all test kits, which are to be used for health-related purposes, and especially those that are used for tests which are classed as either: predictive; predisposition; carrier; or pharmacogenetic ought to be considered as medical devices and regulated as such in both the UK and throughout the EU.

However, many predictive tests, which have an unclear medical purpose, and lifestyle tests have previously fallen outside the Directive's remit. This has meant that most lifestyle tests carried out in the EU have not required pre-market review. Furthermore, as most tests that have been deemed as within the Directive's remit have been classified as low risk they have also escaped pre-market review, as 'manufacturers usually self-certificate' and the regulation of medical devices is generally less rigorous than the regulatory regime governing medicinal products.[648]

While the primary focus herein is with DTCGT providers of health-related testing, it is suggested here that in light of the overlap between different categories of

---

646 Directive 93/42/EEC of 14 June 1993 concerning medical devices; Directive 90/385/EEC regarding active implantable medical devices; Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices; I have also discussed this with a representative of MHRA.

647 D Stynen, 'Revision of Europe's IVD Directive 98/79/EC Lessons and results from the Public Consultation document' (*IVD Technology*, 2011) <ivdtechnology.com/article/revision-europe's-ivd-directive-9879ec> accessed accessed 22 October 2012;

648 Nassim Parvizi and Kent Woods, 'Regulation of medicines and medical devices: contrasts and similarities' (2014) 14 Clinical Medicine 6

testing and the tendency of companies to offer testing of more than one type, broadening the scope for pre-market review of a significant number of lifestyle tests could significantly improve the quality of services offered to consumers and reduce the risks of harm. As the HGC noted in their *More Genes Direct* report, 'the Australian device regulators have recently issued guidance that states that nutrigenetic tests (regarded as 'lifestyle' tests in the UK) will be regulated as IVDDs' (that is, in vitro diagnostic devices).[649] Thus, it might be possible to draw upon the Australian guidance in developing regulation in the UK and EU.

In the EU, a review of existing medical device legislation is currently being undertaken and the existing directives are likely to be replaced by two Regulations of which there are draft versions. At present, the European Parliament and European Council are still negotiating, but a result is expected in 2015 or 2016.[650] It is the draft In Vitro Diagnostics Regulation (IVD Regulation), which is relevant to regulation of DTCGT testing.

It seems helpful to set out some of the IVD Regulation's provisions here. It defines medical devices broadly as follows in article 2 (1):

> 'medical device' means any instrument, apparatus, appliance, software, implant, reagent material or other article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific medical purposes of:
> — diagnosis, prevention, monitoring, treatment or alleviation of disease,
> — diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability,
> — investigation, replacement or modification of the anatomy or of a physiological ***or pathological*** process or state,
> — ***providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations.***

649 Human Genetics Commission, *More Genes* (n 258) 16, para 3.8

650 MHRA, 'New Legislation on Medical Devices' <http://www.mhra.gov.uk/Howweregulate/Devices/Legislation/NewLegislationonMedicalDevices/index.htm> 30 May 2014

— and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.[651]

Article 2 (4) then sets out that a 'device for self-testing' means any device intended by the manufacturer to be able to be used by lay persons'. This seems likely to cover test kits provided by DTCGT companies. The Regulation also covers consent, specifying in article 45a that:

> *'informed consent' means a subject's free and voluntary expression of his or her willingness to participate in a particular clinical investigation, after having been informed of all aspects of the performance evaluation study that are relevant to the subject's decision to participate or, in case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in the performance evaluation study*[652]

This means that if the Regulation is enacted in a form similar to the current draft and is used to govern DTCGT tests then explicit consent would be required from consumers in order for them to undergo DTCGT tests. Article 5 covers distance sales, which should include DTCGT services, given that they are offered online. It provides that:

> (1) A device offered by means of information society services as defined in Article 1(2) of Directive 98/34/EC to a natural or legal person established in the Union shall comply with this Regulation at the latest when the device is placed on the market.
>
> 2. Without prejudice to national legislation regarding the exercise of the medical profession, a device that is not placed on the market but used in the context of a commercial activity, ***whether in return for payment or free of charge***, for the provision of a diagnostic or therapeutic service offered by means of information society services as defined in Article 1(2) of Directive 98/34/EC or by other means of communication***, directly or through intermediaries,*** to a natural or legal person established in the Union shall comply with this Regulation.
> ***3. Upon request by a competent authority, the natural or legal person offering a device in accordance with paragraph 1 or providing a service in accordance with paragraph 2 shall make available a copy of the EU declaration of conformity of the device concerned.***

---

651 Proposal for a Regulation 9770/15 of the European Parliament and of the Council on in vitro diagnostic medical devices of 12 June 2015. Interinstitutional File: 2012/0267 (COD) – please note the italics and boldened text appear in this manner in the original, so these have been kept for the purposes of consistency with the draft text.

652 ibid

> ***4. A Member State may on grounds of protection of public health, require a provider of information society services as defined in Article 1(2) of Directive 98/34/EC to cease its activity.***[653]

The proposed IVD Regulation might be useful, as it would significantly restrict DTCGT for health purposes in the EU. Specifically, genetic tests for health purposes would only be accessible with a prescription, direct-to-consumer advertising of such tests would be prohibited, devices would need to be fit for purpose and as such tests would be classified as class C they would be subject to more premarket review and manufacturers would need to provide clinical evidence for their tests.[654] The requirements for clinical evidence are set out in article 47, which in the latest draft has been renamed 'Performance evaluation and performance studies:

> 1. The demonstration of conformity with the general safety and performance requirements set out in Annex I, under normal conditions of use, shall be based on clinical evidence.
> ***Confirmation of conformity with the requirements, in particular those concerning the performance characteristics referred to in Section I and Section II.6 of Annex I and where applicable relevant requirements of Annex IIa under the normal conditions of the intended use of the device, and the evaluation of the interference(s) and cross-reaction(s) and of the acceptability of the benefit/risk ratio referred to in Sections 1 and 5 of Annex I, shall be based on scientific validity, analytical and clinical performance data providing sufficient clinical evidence.***
> ***The manufacturer shall specify and justify the level of the clinical evidence necessary to demonstrate compliance with the relevant essential requirements on safety and performance which shall be appropriate to the characteristics of the device and its intended purpose.***
> ***To that end, manufacturers shall plan, conduct and document a performance evaluation in accordance with this Article and with Part A of Annex XII.***
> 2. The clinical evidence shall support the intended purpose of the device as stated by the manufacturer ***and be based on a continuous process of performance evaluation, following a performance evaluation plan***.[655]

The Regulation is also likely to make genetic counselling mandatory for genetic tests for health purposes and should also improve 'post-marketing surveillance and tracing of

653 ibid

654 Louiza Kalokairinou, Heidi Carmen Howard and Pascal Borry, 'Changes on the horizon for consumer genomics in the EU' (2014) 346 Science 296

655 Proposal for a Regulation 9770/15 of the European Parliament and of the Council on in vitro diagnostic medical devices of 12 June 2015. Interinstitutional File: 2012/0267 (COD)

medical devices'.[656] If this were to happen, as the Regulation would have direct applicability in the UK, it should hopefully lead to improvements in the regulation of DTCGT, although implementation of the new law will take a number of years.

Furthermore, as Borry et al have noted in relation to the requirement to provide clinical evidence, such evidence need 'only be limited to uses stated by the manufacturer' meaning that if a company claimed to test one gene variant for one purpose, but that variant might also reveal information regarding another disease it would not be caught by the Regulation.[657] Also, as the EU does not have a centralised regulatory authority equivalent to the FDA, enforcement would rely on national regulators and consequently, there may still be problems with enforcement and the issue of enforcement should not be underestimated. The potential impact of the Regulation will be dependant on whether regulatory bodies in EU Member States, such as the UK's MHRA have sufficient resources to devote to enforcement. Due to the international character of the industry it may also be difficult for nationally based regulators to take action against companies located in other jurisdictions.

(d) Human Tissue Act 2004

As was mentioned previously in chapter three, the Human Tissue Act governs the use of human tissue and organs in the UK. The Human Tissue Authority enforces the Act. The Act sets requirements for consent and makes it a criminal offence under section 45 to analyse DNA without appropriate consent. It would appear that the Act has direct application to the DTCGT industry. Although to date it would appear that DTCGT companies may not be complying with the Act, it might be possible for the Human Tissue Authority to work with the industry to create a code of conduct and improved consent

656 Parvizi and Woods 9.
657 Louiza Kalokairinou and Heidi Carmen, 'INSIGHTS' (2014)

mechanisms. This could draw upon the previous work of the Human Genetics Commission.

(e) Genetic Discrimination and Human Rights

Another area of law, which may be applicable to DTCGT is that of human rights. There has been concern regarding possible genetic discrimination,[658] especially in the context of insurance and employment. There is also increasingly some degree of overlap between human rights and consumer protection law.[659] It has been argued that some consumer rights can now be viewed as part of a third generation of human rights, which while not yet universally recognized have been 'approved by various organisations of the United Nations. These include the right to development and to peace, environmental rights, and cultural rights'.[660] There is also overlap with privacy and data protection law, so this section is more concerned with the law in this context that directly relates to genetic tests and genetic discrimination.

Taylor suggests that genetic discrimination can be divided into three different categories. Firstly, there is primary discrimination, which can be described as '[d]iscrimination that is informed by interpreted genetic data'.[661] There is then secondary discrimination, which is where assumptions can be made about a person's genetic makeup based on other types of information, that are not genetic.[662] Tertiary discrimination involves 'the act of expressing a preference for a characteristic that is disproportionately associated with a particular genetic variation' and can occur 'when a decision-making process is informed by the presence or absence of a property that is not

658 Iulia Voina Motoc, 'The International Law of Genetic Discrimination' in Thérèse Murphy (ed), *New Technologies and Human Rights* (OXFORD SCHOLARSHIP ONLINE 2009)
659 Benöhr (n 275) 45-9
660 ibid (n 275) 47
661 Mark Taylor, *Genetic data and the law: a critical perspective on privacy protection*, vol 16 (CUP 2012) 185
662 ibid187

uniformly shared across all genetic variations'.[663] Currently, there does not appear to be a large amount of discrimination occurring in fact,[664] but it is possible that as the science continues to progress and as the industry grows, insurers might require disclosure of DTCGT test results. Currently there is a lack of data and limitations on existing surveys, but genetic discrimination does seem a realistic possibility. Given the data sharing practices of several prominent DTCGT companies, such as 23andMe and AncestryDNA's partnerships with pharmaceutical companies, the risks of genetic discrimination on the basis of access to DTCGT companies' databases should not be underestimated.

There is also a real possibility of genetic discrimination for indigenous peoples and other isolated population groups, who may already be marginalized. It is also possible that in the future some DTCGT companies might sell their stored data. If such information was available to insurers, pharmaceutical companies, marketers, government agencies and others, it could lead to unforeseen harms.[665]

663 ibid 187

664 Timothy Caulfield, 'Direct-to-consumer testing: if consumers are not anxious, why are policymakers?' (2011) 130 Human Genetics 23

665 AL Morrison, 'A Research Revolution: Genetic Testing Consumers Become Research (And Privacy) Guinea Pigs' (2011) 9 J on Telecomm & High Tech L 573; MM Mello and LE Wolf, 'The Havasupai Indian Tribe Case — Lessons for Research Involving Stored Biologic Samples' (2010) 363 N Engl J Med 204; Elizabeth Adjin-Tettey, 'Potential for Genetic Discrimination in Access to Insurance: Is There a Dark Side to Increased Availability of Genetic Information?' (2013) 50 Alberta L Rev 577 A M Goh et al, 'Perception, experience, and response to genetic discrimination in Huntington's disease: the Australian results of The International RESPOND-HD study' (2013) 17 Genetic testing and molecular biomarkers 115 Y Joly, I Ngueng Feze and J Simard, 'Genetic discrimination and life insurance: a systematic review of the evidence' (2013) 11 BMC Med 25 M Otlowski, S Taylor and Y Bombard, 'Genetic discrimination: international perspectives' (2012) 13 Annu Rev Genomics Hum Genet 433 L Slaughter, 'Genetic Information Non-Discrimination Act' (2013) 50 Harvard Journal on Legislation 41 MJ Taylor, 'Problems of practice and principle if centring law reform on the concept of genetic discrimination' (2004) 11 European Journal of Health Law 365

(i.) Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (Oviedo Convention)

Article 11 of the Council of Europe's Oviedo Convention prohibits 'discrimination against a person on grounds of his or her genetic heritage' and article 12 of the Convention sets requirements for predictive tests. It reads as follows:

> Tests which are predictive of genetic diseases or which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counselling.[666]

The UK is not yet a signatory to the Convention, but if it were to become a signatory the Convention might be drawn upon in developing new regulation for the industry together with its Additional Protocol, which is mentioned below.

(ii.) Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes (Additional Protocol)

As the UK is not yet a signatory to the Oviedo Convention, it is not yet bound by the Additional Protocol. However, if the UK does sign and ratify the Oviedo Treaty and the Additional Protocol, this could provide a useful tool in assisting with regulation of the DTCGT industry, at least in the context of the companies offering tests for health-related purposes. The most significant provisions of the Protocol are as follows. Article 2 sets out the scope of the Protocol and states that:

> 2(1) This Protocol applies to tests, which are carried out for health purposes, involving analysis of biological samples of human origin and aiming specifically to identify the genetic characteristics of a person which are inherited or acquired during early prenatal development (hereinafter referred to as "genetic tests").

---

666 Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine

Article 6 states that 'Clinical utility of a genetic test shall be an essential criterion for deciding to offer this test to a person or a group of persons'. Article 7(1) requires individualised supervision for all genetic tests that are performed for health purposes. 7(2) provides for some exceptions 'subject to appropriate measures being provided, taking into account the way the test will be carried out, to give effect to the other provisions of this Protocol'. Although exceptions are not permitted 'with regard to genetic tests with important implications for the health of the persons concerned or members of their family or with important implications concerning procreation choices'. The Protocol would therefore restrict many tests currently offered by DTCGT companies, including carrier testing and predisposition testing.

Article 8 requires that sets out information requirements for people undergoing genetic testing. According to 8(1) individuals undergoing tests 'shall be provided with prior appropriate information in particular on the purpose and the nature of the test, as well as the implications of its results'. Article 8(2) then specifies that individuals undergoing 'predictive genetic tests' should receive genetic counselling. If applied to the DTCGT industry this would require companies to provide genetic counselling to consumers. Article 9(1) then sets out requirements for consent, specifying that a genetic test can only be carried out 'after the person concerned has given free and informed consent to it'.

Finally, article 16 affords protection for privacy and the right to information while also acknowledging a person's right to choose not to be informed of test results. It specifies in 16(2) that:

> Everyone undergoing a genetic test is entitled to know any information collected about his or her health derived from this test. The conclusions drawn from the test shall be accessible to the person concerned in a comprehensible form.

Relying on the Protocol could lend support to banning DTCGT tests for health purposes without clinical utility in the UK. It could also serve to improve governance mechanisms for tests that are permitted to be sold and help to improve standards and supervision of such tests.

(iii.) Universal Declaration on the Human Genome and Human Rights

The Universal Declaration on the Human Genome is an important document in this context. It affords special protection to the human genome and human dignity. Article 1 states that:

> The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity.

Article 2 of the Declaration highlights the importance of freedom from discrimination on the basis of genetic characteristics, stating that 'dignity makes it imperative not to reduce individuals to their genetic characteristics and to respect their uniqueness and diversity'. Articles 5 to 7 set out certain rights, including the requirements for research and the right not to be discriminated against (article 6). These also stress the importance of informed consent and protection of the confidentiality of genetic information the right to choose whether or not to be informed of test results. Article 5 (b) requires that:

> In all cases, the prior, free and informed consent of the person concerned shall be obtained. If the latter is not in a position to consent, consent or authorization shall be obtained in the manner prescribed by law, guided by the person's best interest.

While article 5 (d) requires that, where research is performed, 'protocols shall, in addition, be submitted for prior review in accordance with relevant national and international research standards or guidelines'. If applicable to DTCGT this should mean that DTCGT research projects should also follow this requirement. Article 7 then specifies that, 'Genetic data associated with an identifiable person and stored or

processed for the purposes of research or any other purpose must be held confidential in the conditions set by law'.

These provisions clearly have direct applicability to genetic tests offered by DTCGT companies and could be used to support suggestions for improving the protection of consumers' privacy and confidentiality in this context.

(iv.) European Convention on Human Rights (ECHR)

The ECHR is a very important source for human rights protection in the EU. The Human Rights Act 1998 implements the Convention in the UK. Schedule 1 of the Act sets out the rights and freedoms provided for in the Convention. In the context of the current discussion the most relevant rights protected under the ECHR and the HRA are the right to privacy and the prohibition against discrimination. Article 8 of the ECHR as set out in Schedule 1 of the HRA provides that, 'Everyone has the right to respect for his private and family life, his home and his correspondence'. Meanwhile, article 14 provides that:

> The enjoyment of the rights and freedoms set forth in this Convention shall be secured without discrimination on any ground such as sex, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status.

This area of law has direct applicability to the DTCGT industry in relation to protecting consumers' rights in this context. Regardless of the suggestions herein relating to challenging terms on the grounds of unfairness, DTCGT companies should also be complying with these laws and should be affording sufficient protection to consumers' privacy rights. Current business practice does not seem to be doing this and there is a real need for improvement.[667]

---

[667] Hsiao-Ying Huang, and Masooda Bashir, 'Direct-to-consumer genetic testing: contextual privacy predicament' Proceedings of the 78th ASIS&T Annual Meeting: Information Science with Impact: Research in and for the Community (2015) American Society for Information Science 50.

(f) Privacy, Confidentiality, and Data Protection legislation

The main focus herein is on the rights of individuals in their sequenced genetic data. Generally, these rights are protected in three legal areas: confidentiality; privacy; and data protection, and such rights and their legal regulation are very much context dependent. This section will briefly discuss these three topics.

(i.) Confidentiality

In a medical setting a doctor owes a duty to patients to keep information confidential. In UK law, there is a distinction between confidentiality, privacy protection, and data protection.[668] The Nuffield Council in its recent report on *The Collection, Linking And Use Of Data In Biomedical Research And Health Care*[669] provides a helpful definition of confidentiality:

> Confidentiality concerns the assurance that information provided by a person (or by another body) will not be further disclosed without their permission (except in accordance with certain established laws, norms or expectations about when confidentiality obligations may be set aside). Duties of confidence are created by well-established expectations that attach to certain relationships (for example, between a doctor and a patient or between a lawyer and a client) or may be agreed between parties in a specific context (for example, parties to a commercial contract or contract of employment). They allow information to be made available for the purposes of that relationship (and perhaps also to others whose involvement is necessary to achieve those purposes), but for no other purpose. In short, confidentiality is one – but only one – of the tools used to achieve and maintain privacy.[670]

Due to the commercial context of DTCGT ordinarily it might not be expected that a DTCGT company would owe an obligation of confidentiality, especially where companies provide so-called recreational testing, unless they include such a clause in their contracts. However, due to the nature of the services DTCGT companies are

668 Herring (n 282) 220-6

669 Nuffield Council on Bioethics, *The collection, linking and use of data in biomedical research and health care: ethical issues* (Nuffield Council on Bioethics, February 2015)

670 ibid 50

providing and in accordance with the work of several policymakers, such as the ESHG, it is possible that improved regulation of the industry might involve imposing a duty of confidentiality on companies. It is also possible that where DTCGT companies allow for ordering via physicians that such a duty might already arise.

(ii.) Privacy

Privacy as an interest differs from confidentiality. There is continuing debate over how to define privacy, but a useful definition is that of Clarke, which suggests that 'Privacy is the interest that individuals have in sustaining a 'personal space', free from interference by other people and organisations'.[671] Privacy interests can depend on context and privacy can be viewed as multi-dimensional. The main dimensions can be described as: 'privacy of the person'; 'privacy of personal behaviour'; 'privacy of personal communications'; and 'privacy of personal data'.[672] With the advances in information technology and the growth in use of the Internet for a variety of purposes the last two dimensions are often linked and can be viewed together under 'the term 'informational privacy''.[673] The Nuffield Council's description is also useful. They note that privacy:

> concerns the interest people have in others' access to themselves, their homes and property, or to information about them. What counts as 'private' can change depending on social norms, the specific context, and the relationship between the person concerned and those who might enjoy access. Informational privacy is maintained by selectively withholding or allowing access or through establishing limits on acceptable behaviour by others (e.g. proscribing voyeurism).[674]

In the DTCGT context, the area of law, which appears to have most direct application regarding consumer rights in their sequenced genetic information is that

---

671 Roger Clarke, 'Introduction to Dataveillance and Information Privacy, and Definitions of Terms' <rogerclarke.com/DV/Intro.html#Intro> accessed 31 August 2015

672 ibid

673 ibid; also see generally Laurie, *Genetic Privacy* (n 342)

674 Nuffield Council on Bioethics 4

of data protection, as in this context it is informational privacy that is most relevant. Informational privacy can be described, as 'the interest of individuals in exercising control over access to information about themselves'.[675] Clarke suggests that 'information privacy is the interest an individual has in controlling, or at least significantly influencing, the handling of data about themselves'.[676] A consumer's privacy rights over their sequenced genetic information are best protected under Data Protection law, which will be discussed in the next section.

Because of certain aspects of the nature of genetic information, privacy is an important issue in the context of DTCGT and this has been stressed in the ESHG's Statement and the HGC's Principles. Genetic information can serve as a unique identifier for an individual. It can also be used both in genealogical research and criminal investigations to identify related individuals.[677] As DNA does not change in a way that would make the information non-identifiable over time, stored sequenced data does pose some level of risk to an individual's privacy. While previously researchers have often relied on de-identification or pseudonymisation techniques it has become apparent that it may not be possible to truly de-identify genetic data.[678] This has consequences not only for the individual to whom the genetic data pertains, but also to their family, which also means that where one family member undergoes genetic testing it will necessarily reveal information about others.[679]

Other types of personal information do not automatically have this implication and thus some scholars such as Woodage have advocated for a change of

675 Jeroen van den Hoven et al, 'Privacy and Information Technology' in Edward N Zalta (ed), *The Stanford Encyclopedia of Philosophy* (Winter edn, 2014) <plato.stanford.edu/archives/win2014/entries/it-privacy/> accessed 10 June 2015

676 Clarke (n 671)

677 Tania Simoncelli, 'Dangerous excursions: the case against expanding forensic DNA databases to innocent persons' (2006) 34 The Journal of Law, Medicine & Ethics 390

678 Nuffield Council on Bioethics 69-71

679 ibid 123

approach in this context. For Woodage the nature of genetic information means that it cannot in fact be kept private and so he argues that there is a need to educate people 'about the ways genetic information can be used and misused', to strengthen protections against the misuse of such information and to create legislation, which allows individuals 'access to their own genetic records and to know who else has access to the information'.[680] Others have suggested the need for improved cryptographic techniques [681]

In preliminary analysis of company privacy policies, which was conducted as part of current research, it was found that 25% of companies do state that they will share genetic information with law enforcement agencies.[682] There has also been concern expressed regarding the retention of DNA profiles of innocent persons in criminal databases, most notably the UK's National DNA Database (NDNAD) and the USA's Combined DNA Index System (CODIS).[683] Given that the age of criminal responsibility can actually be very low in some states. For example, the age of criminal responsibility in the UK is ten, it does seem advisable to restrict such retention of DNA profiles of minors or at least to place time limits on such retention. In the DTCGT context, where companies perform tests on minors, the retention of genetic information needs to be monitored. It is possible that time limits should be implemented generally as well, so that companies do not retain genetic information indefinitely.

680 Woodage (n 396) 684

681 Naveed et al (n 312)

682 Phillips, 'Genomic Privacy and Direct-to-Consumer Genetics Big Consumer Genetic Data – What's in that Contract?'

683 Frederick R Bieber, Charles H Brenner and David Lazer, 'Finding criminals through DNA of their relatives' (2006) 5778 SCIENCE-NEW YORK THEN WASHINGTON- 1315; Helen Wallace, 'The UK national DNA database' (2006) 7 EMBO Reports S26; Lila Kazemian, Ken Pease and David P Farrington, 'DNA retention policies: The potential contribution of criminal career research' (2011) 8 European Journal of Criminology 48

(iii.) Data Protection in the UK

In the UK, the Data Protection Act 1998 (DPA) governs the use and processing of personal data and sensitive personal data. The Information Commissioner's Office (ICO) is responsible for enforcing the Act. At present, in the UK and EU, 'the central tenet of data protection law is that personal data should be processed fairly and lawfully'.[684] The DPA was enacted in order to make English law consistent with the Data Protection Directive.[685] The Data Protection Directive itself was heavily influenced by the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (ETS No. 108). Data Protection law in the UK will undergo significant reform in the very near future, as the European Council has now approved the new Data Protection Regulation ((EU) 2016/679) as of April 2016,[686] which will reform data protection law throughout the EU. The new Data Protection Regulation will impose greater restrictions on data processers and controllers generally, which might have an impact on regulating DTCGT companies and future research will examine the content of the Data Protection Regulation and its potential impact on regulation of DTCGT. While herein I have mainly focussed on how specific terms in DTCGT contracts may be challenged on the grounds of unfairness and I do argue for the Competition and Markets Authority to take on a more active role in regulating DTCGT, I also recommend that the ICO may need to take on a greater role in regulating DTCGT in the future.

It is likely that genetic test results provided by DTCGT companies will constitute 'sensitive personal data' as in accordance with the DPA such results may

684 Nuffield Council on Bioethics (n 670) 63

685 Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data

686 European Commission, 'Reform of EU data protection rules', last updated 10th of May 2016, <http://ec.europa.eu/justice/data-protection/reform/index_en.htm> accessed 12 May 2016.

reveal information about a person's racial or ethnic origin (s 2(a)) and also, information relating to a persons' 'physical or mental health of condition' (s 2(e)). (In principle 7 of its Framework of Principles, the HGC classed genetic information as sensitive personal information). The DPA sets out principles governing data processing of personal data in Schedule 1. The principles provide that:

1 Personal data shall be processed fairly and lawfully and, in particular, shall not be processed unless –

(a) at least one of the conditions in Schedule 2 is met, and

(b) in the case of sensitive personal data, at least one of the conditions in Schedule 3 is also met.

2 Personal data shall be obtained only for one or more specified and lawful purposes, and shall not be further processed in any manner incompatible with that purpose or those purposes.

3 Personal data shall be adequate, relevant and not excessive in relation to the purpose or purposes for which they are processed.

4 Personal data shall be accurate and, where necessary, kept up to date.

5 Personal data processed for any purpose or purposes shall not be kept for longer than is necessary for that purpose or those purposes.

6 Personal data shall be processed in accordance with the rights of data subjects under this Act.

7 Appropriate technical and organisational measures shall be taken against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data.

8 Personal data shall not be transferred to a country or territory outside the European Economic Area unless that country or territory ensures an adequate level of protection for the rights and freedoms of data subjects in relation to the processing of personal data.

As genetic tests results can be viewed as personal data or sensitive personal data then DTCGT companies should be following the principles set out in the DPA. At present, it is questionable whether many DTCGT companies are actually complying with such principles when providing services to UK consumers. Although the DPA does not define consent, the Data Protection Directive which it implements defines consent as '…any freely given specific and informed indication of his wishes by which the data subject signifies his agreement to personal data relating to him

being processed.'687 On this basis, consent needs to be active and it is likely that the consent mechanisms used by DTCGT companies will not be in compliance with data protection standards and consequently that they may be open to challenge under data protection law. In the future, DTCGT companies will need to reform their consent mechanisms in order to comply with this.

In its Opinion 03/2012 on developments in biometric technologies Article 29 Data Protection Working Party (Working Party) raised a number of concerns in the context of the use of DNA. Regarding linkability, it stated that 'Given the amount and variety of information that can be derived from DNA sequencing, DNA provides high potential for misuse as the extracted data can be easily linked with other databases allowing profiling of the individual. A familial search also allows creating links with relatives.'[688] It also highlighted the need for appropriate consent and transparency, the potential for repurposing data, and suggested that DNA counted as sensitive data.[689] The Opinion recommends undertaking Privacy Impact Assessments for a variety of biometric technologies, including DNA tests and its guidance could be drawn upon for Privacy Impact Assessments involving DTCGT companies.[690]

It is also possible to make a comparison here between DTCGT companies and cloud computing service providers, as the DTCGT industry's use of wrap contracts raises similar issues to cloud computing.[691] The European Data Protection Supervisor and the Working Party have both released opinions on cloud computing.[692] The

687 ICO, *The Guide To Data Protection* (ICO, 11th May 2016 -2.4.22) <https://ico.org.uk/media/for-organisations/guide-to-data-protection-2-4.pdf> accessed 12 May 2016.

688 Article 29 Data Protection Working Party, Opinion 03/2012 on developments in biometric technologies (n 579) para 4.4.5, 26-27

689 ibid para 4.4.5, 26-27

690 ibid para 5.3

691 McGillivray (n 314) 217

692 ibid – citing Article 29 Data Protection Working Party, Opinion 05/2012 on Cloud Computing, European Commission 27 (1st July 2012) <http://ec.europa.eu/justice/data-

Working Party's report highlighted the lack of transparency and chain of accountability in cloud computing contracts.[693] In 2015, the Working Party released a further opinion on 'the Data Protection Code of Conduct for Cloud Service Providers … drafted by the Cloud Select Industry Group (C-SIG), a working group composed of representatives of the industry'.[694] Significantly for present purposes the 2015 Opinion sought to assess whether the Code addressed the following matters:

> liability: the Code must prevent the adoption of terms of service that unduly limit obligations and responsibilities. The Code must specify (in an Annex) when the CSP is a co-controller, a controller or a processor, and allocate liabilities;
> — transparency on the location(s) of the data processing; processing of special categories and sensitive data (such as financial or health data);
> — applicability of the European definition of personal data; requirements for international transfers and law enforcement access requests;
> — security measures and the level of detail on those measures;…[695]

It would seem that were a code of conduct to be developed for the DTCGT industry, that it would need to take into account these matters as well. At present, DTCGT companies generally are not addressing these matters adequately.

The Human Genetics Commission and the European Society of Human Genetics, whose work will be considered later in this chapter have both stressed the importance of protection for privacy in this context. The ESHG stated that:

---

protection/article-29/documentation/opinion-recommendation/files/2012/wp196_en.pdf> accessed 12 May 2016; and Peter Hustinx, Opinion of the European Data Protection Supervisor on the Commission's Communication on 'Unleashing the Potential of Cloud Computing in Europe' Eur. Data Protection Supervisor 4 (16th November 2012) <https://secure.edps.europa.eu/EDPSWEB/webdav/shared/Documents/Consultation/Opinions/2012/12-11-16_Cloud_Computing_EN.pdf> accessed 28 May 2016.

693 ibid – citing Article 29 Data Protection Working Party, Opinion 05/2012 on Cloud Computing, European Commission 27 (1st July 2012) 6, 8.

694 Article 29 Data Protection Working Party, Opinion 02/2015 on C-SIG Code of Conduct on Cloud Computing (22nd September 2015) <http://ec.europa.eu/justice/data-protection/article-29/documentation/opinion-recommendation/files/2015/wp232_en.pdf> accessed 29 May 2016.

695 Article 29 Data Protection Working Party, Opinion 02/2015 on C-SIG Code of Conduct on Cloud Computing, 'Summary' 2.

> In particular, companies offering DTC genetic tests should preserve the customer's privacy, keep their data confidential, inform them about their security procedures, explain what will happen to the sample and the data when the testing process is concluded, and have a clearly laid-out plan as to what will happen to the samples and data should the company be sold or go bankrupt. Companies inviting their customers to share their genetic information via a web community or forum should inform people about the potential risks for disclosure of this type of sensitive information.[696]

In the context of wrap contracts more generally, Kim has advocated for a introducing a new model of specific assent[697] and such a model either with multiple clicking or emailed consent could be utilised in the DTCGT context and might allow consumers to decide how they would like their genetic information and other personal information to be used, stored, and shared.

(iv.) Genetic privacy

Genetic privacy is an important issue in this context and it is likely that existing data protection law could be utilised to regulate DTCGT companies' use, sharing, storage, and processing of genetic data. Several policymakers have stressed the importance of adequate privacy protection in this context and at present, it does seem that there is a need for companies to improve both their policies and practices regarding protection of the privacy rights of consumers in their genetic data.

As previously noted, protection of genetic privacy in the UK largely derives from data protection legislation and a person's interest generally can be seen as a right concerned with informational privacy. In relation to possible issues arising in the context of informational privacy more generally, Taylor notes that the areas of concern can be divided 'into two categories: those associated with unwanted access and those associated with unwanted uses of data'.[698] Given the diverse uses to which genetic information can be put and the trend of DTCGT companies to in fact make broad use of the information

696 ESHG, 'Statement' (n 357) 1272-3.
697 Kim (n 227) 192-200
698 Taylor, *Genetic data and the law: a critical perspective on privacy protection* 2

collected from their consumers, it is desirable that Data Protection law is applied to regulate the industry in a similar way to its use in regulating health research.

It is also useful to note here the work of the Health Law Institute at the University of Alberta, which conducted a study on the privacy policies and practices of DTCGT companies.[699] Its report analysed the privacy policies of 32 companies 'against the fair information principles developed by the Canadian Standards Association'.[700] The report concluded that there was much variation in these policies and that regarding privacy protection practices many companies made claims on their websites, which were 'no more than advertising claims'. It also found that many policies were internally inconsistent and it ended with a list of questions it 'recommended consumers should consider before purchasing genetic tests'.[701]

3 Possibilities for legal regulation in the USA

A large number of DTCGT companies are based in the US. Of the 102 identified that offer or have offered some form of health related testing, 55 (54%) are based in the USA and the largest number 17 are based in California. Of the total 229 companies identified 51% are located in the USA. In the USA, the majority of DTCGT tests have also not been subject to premarket review, but since 2010 the FDA has altered its stance on the regulation of DTCGT testing.[702]

The most recent developments here are the FDA's action against 23AndMe in November 2013 requiring it to cease selling its health related testing service and classing

699 Health Law Institute (n 244)
700 ibid 3
701 ibid 33-4
702 Patsner 237-77; Vorhaus and Contributor, 'DTC Genetic Testing and the FDA: is there an end in sight to the regulatory uncertainty?' (n) accessed 19 May 2014; Frueh et al; Zettler, Sherkow and Greely

its test kit as a medical device[703], the class actions lodged against 23andMe, and the FDA's new *Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories*.

(a) FDA and Medical Devices

In the US, there has been a division in regulation between diagnostic tests developed by manufacturers and sold on to other companies, which must undergo pre-market review and Laboratory Developed Tests ('LDTs' or 'home brews').[704] Many DTCGT tests have escaped premarket review due to their classification as LDTs.[705] In July 2014, US senators wrote to the FDA requesting that they release Draft Guidance on the Regulation of LDTs, which they had had on file for some time. This Guidance has since been released, but in relation to the regulation of DTCGT it has not been as helpful as anticipated. Specifically, according to footnote 4 of the *Anticipated Details of the Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories,* the FDA is not going to regulate DTCGT tests. This is unfortunate in terms of improving regulation of DTCGT tests provided for health related purposes, and sits uncomfortably with the FDA's previous actions, as it has not previously produced specific regulation for DTCGT. According to footnote 4:

> FDA generally does not exercise enforcement discretion for direct-to-consumer (DTC) tests regardless of whether they meet the definition of an LDT provided in this guidance. Therefore, the enforcement policies in this

703 US Food and Drug Administration, 'Warning letter of November 22, 2013' <http://www.fda.gov/iceci/enforcementactions/warningletters/2013/ucm376296.htm> 23 May 2014

704 This section is very similar to my presentation at the Society for Computers & Law's (SCL) Technology Law Futures Forum in 2014. I also had a short article published in SCL's magazine and on their website based on my presentation entitled 'Direct-to-Consumer Genetic Testing – A Brief Introduction', this is available at <scl.org/site.aspx?i=ed38110> accessed 6 August 2015.

705 Patsner

> guidance do not apply to DTC tests, and FDA's usual enforcement policies apply to DTC tests.[706]

Several US states have since introduced their own regulations, most notably California and New York.[707] However, there continues to be a lack of federal regulation. The FDA's warning letter has been interpreted by some, as constituting an outright ban on health related DTC services, although it is possible that this is not the case. The letter stated that the 23andMe Saliva Collection Kit had not received appropriate 'marketing clearance or approval in violation of the Federal Food, Drug and Cosmetic Act (the FD&C Act)'. It went on to classify the kit as a:

> device within the meaning of section 201(h) of the FD&C Act, 21 U.S.C. 321(h), because it is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or function of the body.[708]

Central to the discussion on regulation of DTCGT test kits as medical devices is the FDA's definition of a medical device, which is as follows:

> An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease.[709]

It seems likely that many DTCGT test kits used by companies performing health related testing would fit this definition.

Prior to the FDA's action in November 2013, the majority of DTCGT tests had not been subject to premarket review, although since 2010 the FDA had begun to alter its

---

706 Food and Drug Administration, 'Anticipated details of the draft guidance for industry' (2014) Food and Drug Administration staff, and clinical laboratories: framework for regulatory oversight of laboratory developed tests (LDTs)

707 Genetics & Public Policy Center, 'Survey of Direct-to-Consumer Testing Statutes and Regulations' (2007) <dnapolicy.org/news.release.php?action=detail&pressrelease_id=81> accessed 10 October 2012 - checked again 15 June 2014

708 FDA, 'Warning Letter' (n 523)

709 Federal Food Drug & Cosmetic (FD&C) Act, section 201(h)

stance it still has not developed specific regulation for the industry.[710] States which restrict DTCGT include: Arizona; California; New York; Connecticut; Vermont; Colorado; Maine; Maryland; Massachusetts; Nevada; New Jersey; and Oregon.[711] The states of California and New York have been prominent in restricting DTCGT testing to protect their citizens[712]. In 2008, the California Department of Public Health sent warning letters to 13 DTCGT companies 'informing them that under California law, offering a clinical laboratory test directly to the consumer, without a physician order, is prohibited'.[713] The New York State Department of Public Health took similar action. Companies that wanted to continue to offer their services to Californian and New York residents were required to obtain appropriate licensing for their laboratories, including CLIA certification.[714] Requiring all DTCGT companies to acquire appropriate licensing and certification seems to be a particularly appropriate means of improving regulation of the industry and in line with the ASHG's Statement.

Thus, there continues to be a lack of federal regulation. It is desirable that the FDA does take further action to regulate the industry in its entirety and this could take the form of issuing a statement that all health-related DTCGT services using test kits similar to that of 23andMe are selling medical devices and consequently, are subject to the FDA's regulatory oversight. Although, several US states have since introduced their

---

710 Patsner237-77;Vorhaus and Contributor, 'DTC Genetic Testing and the FDA: is there an end in sight to the regulatory uncertainty?'; Frueh et al; Zettler, Sherkow and Greely; Sarah F Sunderman, 'The Need For Regulation Of Direct-To-Consumer genetic Testing In The United States: Assessing And Applying The German Policy Model' (2013) 12 Wash U Global Stud L Rev 357

711 T Ray, 'Will Other States Follow NY, Calif., in Taking On DTC Genetic-Testing Firms' *GenomeWeb* (25 June) Pharmacogenomics Reporter <http://www.genomeweb.com/dxpgx/will-other-states-follow-ny-calif-taking-dtc-genetic-testing-firms-0> accessed 9 July 2012; Genetics & Public Policy Center, 'Survey of Direct-to-Consumer Testing Statutes and Regulations'

712 Ray, 'Will Other States Follow NY, Calif., in Taking On DTC Genetic-Testing Firms'

713 S Tamir, 'Direct-to-consumer genetic testing: ethical-legal perspectives and practical considerations' (2010) 18 Med Law Rev 213, 224

714 ibid 224; D Vorhaus, 'The Past, Present and Future of DTC Genetic Testing Regulation' <genomicslawreport.com/index.php/2010/08/05/the-past-present-and-future-of-dtc-genetic-testing-regulation/>

own regulations either restricting or banning DTCGT, comprehensive federal regulation is needed.

(b) Genetic Information Non-Discrimination Act

Meanwhile, in the USA, the Genetic Information Non-Discrimination Act (GINA) was enacted in 2007. It is aimed chiefly at preventing discrimination in health insurance and employment[715] and it prohibits genetic discrimination in the context of employment and insurance, but the Act leaves many gaps. For instance, it does not apply to life insurance, long term care, disability insurance or the military.[716] Michelle Irick has recently suggested it might be possible and desirable to amend GINA so that its remit is extended to cover the DTCGT industry.[717] This idea has appeal, especially given the possibility that DTCGT companies might share data with insurance companies. As previously noted, several prominent companies have already entered partnerships with the pharmaceutical industry, so this possibility may be quite likely.

(c) Health Insurance Portability and Accountability Act (HIPAA)

This Act ordinarily applies to genetic tests carried out in a clinical setting and affords the protection of confidentiality to test results. The American Society of Human Genetics in its Statement on DTCGT, which will be mentioned later in this chapter has recommended that DTCGT companies should comply with HIPAA requirements. If HIPAA were to apply to DTCGT companies that provide tests for health purposes it should improve protection for consumers' privacy in this context by requiring companies to keep test results confidential.

---

715 Woodage (n 396) 690

716 A Foster, 'Critical Dilemmas in Genetic Testing: Why Regulations to Protect the Confidentiality of Genetic Information Should Be Expanded' (2010) Baylor L Rev; Naveed et al (n 312) 10.

717 MD Irick, 'Age of an Information Revolution: The Direct-to-Consumer Genetic Testing Industry and the Need for a Holistic Regulatory Approach' (2012) 49 San Diego L Rev 279, 328-9.

(d) 23andMe Litigation – *Tompkins v 23andMe*

In the past eighteen months 23andMe has been sued in multiple class actions. These allege a variety of claims related to 'false advertising, unfair competition, and consumer protection'.[718] Nine cases have been filed and eight of these cases were consolidated for pretrial purposes (there are also three pending arbitrations) and on the 28th of April 2014 23andMe filed an omnibus motion to compel arbitration. This was followed on the 28th of May 2014 by the plaintiffs filing a motion in opposition with 23andMe filing a reply on 4th June. On the 14th of May 2014 the Court appointed interim class counsel. Briefly, the claimants' case:

> alleges that 23andMe, Inc. ("Defendant") falsely and misleadingly advertises their Saliva Collection Kit/Personal Genome Service ("PGS") as providing "health reports on 240+ conditions and traits", "drug response", "carrier status", among other things, when there is no analytical or clinical validation for the PGS. [719]

As of 14 May 2014, lead counsel have been appointed by the Court and the Casey Gerry Ankcorn group will lead the case.[720] This was followed on the 28th of May 2014 by the plaintiffs filing a motion in opposition with 23andMe filing a reply on 4th June. On the 14th of May the Court appointed interim class counsel.

In June 2014, Koh J ruled to compel arbitration granting the motion, thus upholding the arbitration clause in the 23andMe agreement. The Plaintiffs' claims were dismissed without prejudice, but the Plaintiffs have since filed a Notice of Appeal on the 23rd of July 2014 and the appeal is scheduled for a hearing before the Court of Appeal of

718 *Tompkins v 23andMe, INC* (Dist Court, ND California 2014)

719 *Casey v 23andMe Inc* (Case 3:13-cv-02847-H-JMA)

720 Marisa Kendall, 'Koh Appoints Lead Counsel in Scrum Over 23andMe Suits' (*The American Lawyer*, 2014) <americanlawyer.com/id=1202655508972/Koh-Appoints-Lead-Counsel-in-Scrum-Over-23andMe-Suits?slreturn=20140516142508> accessed 15 May 2014;Benjamin Cohn and Dalga Surofchy, 'Fighting for the Right to Know: OBR-Bay Debates FDA regulation of DTC Genetic Testing' (*Oxbridge Biotech Roundtable*, 2014) <http://www.oxbridgebiotech.com/review/featured/23andme-debate/> accessed 27 May 2014

the Ninth Circuit on 31st October 2014. (The Case number is No. 14-16405).[721] Consequently, at the time of writing these cases are yet to be resolved and their progress will continue to be monitored. It seems the actions have now been divided into two groups and 23andMe has argued that its Terms of Service bar class arbitration. According to a recent article by Kendall, a hearing held in San Francisco in June 2015 was decided in favour of 23andMe. Judge Earnest Goldsmith said that he was:

> unlikely to overturn an arbitrator's decision that claims against the company for its marketing of the kits cannot be arbitrated on a class basis.
> Though the user agreement governing the dispute does not explicitly ban class arbitration, Goldsmith noted that it was written using singular phrases such as "you," "your" and "either party."
> Goldsmith sided with 23andMe in a tentative order. He did not rule from the bench but told lawyers he remained "fairly comfortable" with his decision.
> (…)Two teams of lawyers filed class arbitration complaints but came up with different results. Cotchett lost its bid before an arbitrator in September, prompting the appeal to Goldsmith That matter is scheduled for a hearing next month before U.S. Magistrate Judge Paul Grewal of the Northern District of California.[722]

However, as of August 2015, no further developments seem to have occurred, although this is still being monitored.

The reasoning in the *Tompkins* order has been criticised and the criticism may be justified. Central to understanding the criticism is an understanding of the process, which a consumer follows in purchasing a DTCGT test from 23andMe. When a consumer purchases a test, he/she is essentially ordering a service, and this does involve several steps. The consumer will purchase the test online and this involves paying the purchase price and only then will they receive a test kit in the mail. The consumer will then use the

---

721 Ankcorn Law Firm, '23andMe: Going Up On Appeal' <http://www.markankcorn.com/blog/2014/8/3/23andme-going-up-on-appeal> accessed 23 September 2014.

722 Marisa Kendall, 'SF Judge Sides With 23andMe on Class Claims' *The Recorder* (10 June 2015) <therecorder.com/id=1202729012905?keywords=Marisa+Kendall>

kit to collect a sample of their DNA and send it back to the company for sequencing. After the company receives the sample they will sequence it and communicate the results to the consumer. For many companies once the consumer receives the kit the consumer is required to register the kit online and create an online account, which is sometimes used for communication of results, other communication and social networking functions if these are offered by the company. In the 23andMe case terms were allegedly only viewable when consumers registered their kits and not when they made their initial orders. Koh J interpreted this registration process as constituting a new contract. This interpretation has been criticised and it seems that the better view is that this should be viewed as an amendment to the original contract, because a consumer may be using the test kit to access a service, but the object of their contract with the company is the provision of genetic sequencing, not the provision of a test kit. Specifically the judgement has been criticised on the grounds that:

> it treats the registration process as a completely new contract, when I see it as an amendment of the existing contract formed when the buyer made the purchase. If it's an amendment, then the delivery of services can't provide new consideration because that's why the buyer bought the services in the first place. As a result, the resolution ignores the buyer's economic realities.[723]

Furthermore, if the test was purchased as a gift, the purchaser would have had no opportunity to read the arbitration clause and thus to agree to it, as they are not obliged to create an account, which is problematic and means that the purchaser of a gift has not given assent to the terms of the contract and consequently enforcement of contractual terms against purchasers of gifts is open to challenge.

---

723 E Goldman, '23andMe's Browsewrap Fails, But Its Post-Purchase Clickthrough Works Anyway– Tompkins v. 23andMe' (2014) <http://blog.ericgoldman.org/archives/2014/07/23andmes-browsewrap-fails-but-its-post-purchase-clickthrough-works-anyway-tompkins-v-23andme> accessed 3 July 2014

More recently, Moringiello mentioned Koh's order in *Tompkins* in her article that was part of the Symposium based around Kim's book, *Wrap Contracts*. She wrote that:

> The recent opinion in Tompkins v. 23andMe, Inc. n32 illustrates both the doctrinal confusion that can result from adherence to an electronic contracting lexicon that is limited to the terms "clickwrap" and "browsewrap" and the tendency of courts to hold that so long as there is notice of the notice of contract terms, a contract will be formed when the web site user takes the requested acceptance action.[724]

Given that this is the only case to date involving DTCGT it is helpful to discuss Moringiello's work here. She notes that:

> One unique aspect of 23andMe is that the company presented its terms of service in two different ways at two different times to its customers. Each customer who bought a DNA kit online could proceed through the purchase process without ever seeing the terms of service. In order to see the terms, the purchaser would have had to scroll through a "significant amount of information" to find a hyperlink labeled "Legal" at the bottom of the web page.[725]

When a consumer then wishes to send their DNA sample to the company for sequencing she is obliged to register on the website. During registriation she would then encounter:

> the statement "When you sign up for 23andMe's service, you agree to our Terms of Service. Click here [hyperlinked] to read our full Terms of Service." Below that statement was a button that displayed the statement "I accept the Terms of Service;" the customer could not proceed with the registration process without clicking that button.[726]

The court 'applied a traditional browsewrap analysis in holding that the first set of terms was unenforceable' finding that it was not necessary 'for a website user to scroll down to see the link to the terms and the terms used the classic browsewrap language that purported to bind an individual who merely visited the website'.[727] However, the second set of terms were presented as multiwrap and unfortunately, the court did not view the

---

724 Juliet M Moringiello, 'Notice, Assent, and Form in a 140 Character World' (2014) 44 Southwestern Law Review, Forthcoming 275-284

725 ibid 281

726 ibid 281

727 ibid 282

presentation through multiwrap as raising 'unique notice issues' and similarly to previous cases, it 'found that the terms looked like clickwrap terms, and thus, was not troubled by the fact that the only notice given by the click button was a notice that terms could be found elsewhere'.[728] However, the use of multiwrap raises similar issues to the use of rolling contracts in the sense that it does not send a consumer any 'signal regarding the length and scope of the terms, and thus poses similar timing and effort challenges'.[729] The court found that 'the purchasers had accepted the 23andMe terms of service because they had received notice (or, as Professor Kim says "notice of notice") of the terms'.[730] The court then examined whether the arbitration clause was unconscionable. Under Californian law for a court to find a term unconscionable there must be both procedural and substantive unconscionability. The court held that the 'clause was procedurally unconscionable', stressing that the term 'was buried at the end of the terms of service'.[731] However, it held that the term was enforceable:

> because it failed the substantive unconscionability test, in part because the court observed that forum selection clauses are "ubiquitous in online contracts and have the economic benefits of favoring both merchants and consumers".[732]

Moringiello argues that this case and other recent wrap cases in the US show that courts are currently 'ignoring some of the factual differences between paper and electronic standard forms'.[733]

728 ibid 282
729 ibid 282 citing *Tompkins v 23andMe* Case No. 5:13-CV-05682-LHK, 2014 WL 2903752 (ND Cal June 25, 2014) [14]
730 ibid 282 citing *Tompkins* [14]
731 ibid 283 citing *Tompkins* [14]-[15]
732 ibid 283 282 citing *Tompkins* [16]
733 ibid 283

4 Policy Response in the UK and EU

This section will now discuss the policy responses to DTCGT to date. It should be noted that the regulatory response to DTCGT so far has primarily been at this level, rather than through legislation. Several organisations in the EU, UK, USA, Canada, and Australia have released statements or reports making recommendations regarding the manner in which DTCGT services ought to be governed and provided.

(a) Human Genetics Commission (HGC)

The HGC was established in 1999 as an independent advisory body dealing with genetic issues.[734] The HGC took over from the Advisory Committee on Genetic Testing (ACGT), which had been established in 1996.[735] The ACGT developed a 'Code of Practice for' DTCGT. It also established a voluntary system to encourage and monitor compliance, which did have some degree of success, but has since ceased to be utilised.[736]

The HGC was disbanded in 2012, although its work was to be continued by the Emerging Science and Bioethics Advisory Committee (ESBAC).[737] However, ESBAC was in turn disbanded on 31st May 2014.[738] During its lifetime, the HGC released two important reports on DTCGT: *Genes Direct*[739]; and *More Genes Direct*,[740] as well as a set of principles – *A Common Framework of Principles for direct-to-consumer genetic*

734 Deirdre Janson-Smith, 'The Human Genetics Commission' <genome.wellcome.ac.uk/doc_WTD021009.html> accessed 24 July 2015; Rebecca Hill, 'Human Genetics Commission publish final report' (BioNews 7 July 2012) <http://www.bionews.org.uk/page_149450.asp> accessed 24 July 2015

735 Human Genetics Commission paras 1.3-5.

736 Hogarth, Javitt, and Melzer (n 236) 169; Hogarth, Melzer and Zimmern, 'The regulation of commercial genetic testing services in the UK'.

737 Unfortunately, since its amalgamation, it has not done any more significant work in this area.

738 Emerging Science and Bioethics Advisory Committee, 'Emerging Science and Bioethics Advisory Committee (closed)' <gov.uk/government/groups/emerging-science-and-bioethics-advisory-committee> accessed 5 August 2015

739 HGC, *Genes Direct* (n 258)

740 Human Genetics Commission, *More Genes Direct* (n 258)

testing services intended to provide guidance on the regulation of DTCGT. After its initial report in 2003, *More Genes Direct* was the result of a meeting held in 2007 and prompted by rapid growth of the DTCGT industry. This meeting considered the developments that had occurred since the original report and 'focussed on three key areas: pre-market review of tests; quality assurance of testing services; advertising and promotion, and the provision of independent, impartial advice'.[741]

The HGC recommended stricter regulation of DTCGT and that 'most genetic tests that provide health information should not be offered as direct genetic tests' and that the Medicines and Healthcare Products Regulatory Agency (MHRA) should have an important role in 'developing an appropriate regulatory framework' for DTCGT.[742] However, this role was rejected by the UK Government in its response to the *Genes Direct* report.[743] The then Minister of State, Andy Burnham in a letter to Baroness Helena Kennedy QC wrote that:

> MHRA is not able – under UK and EU law – to operate in the areas that you advocated. I warmly support your proposal that HGC should host a pan-European meeting on the regulation of direct-to-public genetic tests. HGC should fund this event out of its existing budget.[744]

(i.) Common Framework of Principles

The *Common Framework Of Principles For Direct-To-Consumer Genetic Testing Services* (*Principles*) were released in 2010. They were intended to apply to:

- tests that are provided directly to the public without an intermediary between the consumer and the test provider
- tests that are provided via a non-medical intermediary, such as a pharmacist or alternative health practitioner

741 ibid 3.3
742 ibid part 5, 23; HGC, *Genes Direct* (n 258)
743 HGC, *Genes Direct* (n 258) 39-40
744 Letter from Andy Burnham MP to Baroness Helena Kennedy QC (10 July 2006) – included in the HGC's More Genes Direct appendix 3,

- tests that are commissioned by the consumer but where a medical practitioner or a health professional is involved in the provision of the service.[745]

Consequently, if relied upon these are applicable to all types of DTCGT. Also, the principles were framed so as to be flexible and user-friendly and to be capable of being applied in different jurisdictions.[746] Their overriding purpose is 'to ensure good practice in the provision of genetic testing services directly to the consumer'.[747]

The HGC's *Principles* are useful and could be drawn upon to provide the basis for development of a code of conduct for the industry. They divide genetic tests into 11 categories.[748] These categories are:

1 diagnostic;
2 pre-symptomatic;
3 carrier screening;
4 prenatal diagnostics;
5 susceptibility/pre-dispositional health tests;
6 pharmacogenetic tests;
7 nutirigenetic tests;
8 lifestyle/behavioural tests;
9 phenotype tests;
10 genetic relatedness tests;
11 and ancestry tests.[749]

The *Principles* stress the importance of: responsible marketing practices; the provision of appropriate information to consumers; adequate consent mechanisms; data protection mechanisms; sample handling; appropriate laboratory processes; responsible interpretation of test results; the provision of results; continuing support; and the provision of mechanisms for consumer complaints. These principles, if complied with by DTCGT companies do provide a useful starting point for improving standards. In the context of the provision of information principle 4.1 requires that 'the test provider

745 HGC, *A Common Framework of Principles* (n 232) 2
746 HGC, *Human Genetics Commission Final Report* (Department of Health, 2012)17
747 ibid at para 1.1
748 ibid 3
749 HGC, *A Common Framework of Principles* (n 232) 2-3

should supply easily understood, accurate, appropriate and adequate information'.[750] This includes educational material about genetics, which will 'enable a consumer to understand the scientific basis of genetic testing'.[751] Information about the availability of genetic counselling is also supposed to be offered. Principle 4.1 also requires companies to provide 'a statement that the results of the test might be able to reveal information about genetic relationships' and that 'that the results of the genetic test might have implications when purchasing life insurance'. These requirements would be particularly helpful, because if DTCGT testing is to fully live up to some of its marketing claims a consumer needs to be able to fully comprehend the information they receive regarding their DNA analysis.

Principle 6 deals with the mechanisms for consent which DTCGT companies should establish. It is very detailed and provides as follows:

> **6.1** In designing a direct-to-consumer genetic testing service, the test provider should give consideration, not only to the nature of the test and the information that it generates, but also to the personal and familial circumstances that may be relevant to consumers.
>
> **6.2** A genetic test should be carried out only after the person concerned has given free and informed consent. Informed consent can only be provided when a consumer has received sufficient relevant information about the genetic test to enable them to understand the risks, benefits, limitations and implications (including the implications for purchasing insurance) of the genetic test.
>
> **6.3** The test provider should take reasonable steps to assure themselves that a biological specimen provided for testing was obtained from the person identified as the sample provider.
>
> **6.4** The test provider should require consumers to sign a statement confirming that they give their informed consent to the specific genetic tests to be undertaken on their biological material. The document should record the sample provider's age and that they have read and understood the information with which they have been provided. The statement should include an explanation of what will happen to the consumer's biological samples and personal data if the controlling share of the company is taken over by a third party.

---

750 HGC, *A Common Framework of Principles* (n 232) 4(1)

751 ibid 4(1)

6.5 The test provider should retain documentary evidence of the provision of informed consent by the consumer for the duration of storage of the consumers' biological samples and personal records.

6.6 Separate, specific, informed consent should be requested by the test provider if the test provider wishes to perform further tests that are not covered by the original consent or if biological samples are to be stored by the test provider after the consumer has been provided with the genetic test results. Likewise, separate informed consent should be requested by the test provider before biological samples are used for any secondary purposes, e.g. research, or before any third party is permitted access to biological samples. Consumers' biological samples and personal genetic data should only be used for research that has been approved by a research ethics committee (REC) or other relevant competent authority.

6.7 Except in exceptional circumstances provided for by law and appropriate guidance, companies offering direct-to-consumer genetic tests should not provide tests to adults unable to provide informed consent.

6.8 Companies offering direct-to-consumer genetic tests should be aware of the laws that exist in some countries prohibiting DNA theft, which make it illegal to obtain or test DNA without the consent of the person from whom it originated. In line with these laws a test provider should make consumers aware of the law and should not perform a test if they have reason to believe that a biological sample they have been provided with for genetic testing purposes has been taken from a third party who has not given their consent for the tests to be performed. Requests to recover DNA for genetic testing purposes from secondary objects or materials, when there is reason to believe that the person from whom the DNA originates is still alive, should raise suspicion and should be declined.

6.9 The following principle applies to tests in categories 1-3, 5 and 6 (and categories 7 and 8 where these have been evaluated as 'high impact' – see 'How to use the Principles'). Genetic tests in respect of children when, according to applicable law, that child does not have capacity to consent should normally be deferred until the attainment of such capacity, unless other factors indicate that testing during childhood is clinically indicated. If postponement would be detrimental to the child's health, or the management of the child's health may be altered significantly depending on the test result, then testing should be organised by a health professional who has responsibility for ensuring that any medical intervention or screening indicated will be arranged and proper arrangements made for any subsequent care.

Principle 7 is focussed on data protection and states that 'genetic information is sensitive personal data and requires the highest level of security and confidentiality'.[752]

[752] HGC, *A Common Framework of Principles* (n 232) 7(1)

Principle 7.2 suggests that companies 'should not release biological samples or records containing personal data and genetic information that can be linked to an identifiable person to any third party without the prior consent of the person to whom they relate', unless they are required to do so by law. Principle 7.3 specifies that where a company intends to store a consumer's data on a database it must first receive appropriate consent from the consumer for this purpose. If adhered to these principles would provide guidance for the industry. At present, as will be seen in chapters four and five it is likely that many companies are not obtaining adequate consent from consumers in relation to data sharing or participation in research.

In addressing the issue of uncertain standards, principle 9 is particularly helpful, as it deals with laboratory processes. Principle 9.1 requires that 'genetic testing services should be provided by competent laboratories'.[753] Laboratories can establish competence through accreditation 'to the International Organisation for Standardisation 9ISO) standards 15189 or 17025 or other equivalent recognition consistent with the OECD guidelines for quality assurance in molecular genetic testing'.[754] If principle 9 was adhered to by the DTCGT industry, this could greatly improve the standard of service offered by DTCGT companies.

Regarding the interpretation of test results, principle 10.1 states that:

> For tests in categories 1–6, interpretation of genetic test results should be carried out under the responsibility of an appropriately qualified professional, with recognised training and qualifications, working within the standards determined by an appropriate professional body and regulated by this professional body, employed by or working on behalf of the test provider. Similar standards should apply to tests in other categories where similar professional structures exist. There should be no remuneration structure in place that would allow this individual to benefit directly from any particular interpretation of the test results or the sale of any services or products related to those results.

---

753 HGC, *A Common Framework of Principles* (n 232) 9(1)
754 HGC, *A Common Framework of Principles* (n 232) 9(1)

This means principle 10.1 would cover all health related DTCGT testing except some types of nutrigenetic testing.

(b) Concordat and Moratorium on Genetics and Insurance

In the UK, there has been a Moratorium by the UK insurance industry and this been extended until 1 November 2017.[755] While this is useful, insurance companies arguably already make discriminatory decisions. A good example being where an insurance company declines cover for a preexisting condition and defines certain treatment as cosmetic in order to avoid cover, when it is not. Under clause 23 of the Concordat and Moratorium on Genetics and Insurance UK insurers agree:

> 1. they will not use information from predictive genetic test results to underwrite travel insurance, private medical insurance, or any other one-off or annual policy, or long term care insurance policies;
> 2. the broad classes of insurance for which genetic test results may be relevant are confined to the following products:
>   i. life;
>   ii. critical illness; and
>   iii. income protection.
> 3. where they make use of the results of approved tests to impose special terms or conditions, they will not impose unjustified exclusions from cover, or other special terms or conditions, which have the effect of preventing a policyholder from making a claim for a condition that is not related to the genetic condition identified by an approved test; and
> 4. unless it is to the applicant's advantage, if a predictive genetic test result is disclosed where it was not required to have been, insurers will not take it into account either:
>   i. in deciding whether or not to offer cover; or
>   ii. as a risk factor in setting terms. [756]

This can be compared with the work of the Canadian Life and Health Insurance Association (CLHIA), which has followed a similar line with its Position Statement On Genetic Tests.[757] In this Statement it provides that:

---

755 Association of British Insurers, *Concordat and Moratorium on Genetics and Insurance* (Department of Health, 2011) para 2

756 ibid para 2

> The industry's policy is that insurers would not require an applicant for insurance to undergo genetic testing. However, if genetic testing has been done and the information is available to the applicant for insurance and/or the applicant's physician, the insurer would request access to that information just as it would for other aspects of the applicant's health history.
>
> This policy is based on the general principle that the insurance contract is a "good faith" agreement and that both parties have an obligation to disclose any information that may be relevant to the contract so that the contract can be entered into on an "equal information" footing. That principle is included in the insurance legislation in each province, and the contract is voidable if any relevant information is withheld or misrepresented. This policy is also based on the general principle that the insurer needs to have all available material information about the applicant's risk, in order to properly assess that risk.

As will be mentioned later in this chapter, the Office of the Canadian Privacy Commissioner has recommended extending this moratorium. However, it is desirable that in the long term new legislation is enacted which affords consumers stronger protection, than an industry's voluntary commitment offers.

(c) European Society of Human Genetics

Another important organisation, which has also released policy guidance on DTCGT, is the European Society of Human Genetics (ESHG). The ESHG's Statement on DTCGT for Health-Related Purposes[758] emphasised the importance of the right to genetic information, but noted that such a right could only be fully embraced by an individual where she is 'offered adequate pre-test information, including counselling and psychosocial support when appropriate, and when the tests offered are of good quality and medically relevant.'[759] They also expressed concern regarding: the quality of testing; labelling information; and the provision of pre-test information and genetic conselling. They stressed that: DTCGT companies should offer 'high quality testing services';

---

757 CLHIA, 'Position Statement on Genetic Testing' (CLHIA 2010)
758 ESHG, 'Statement' (n 357) 1271-1273
759 ESHG, 'Statement' (n 357) 1271–1273

should obtain adequate informed consent; should restrict the availability of DTCGT services to minors; should implement comprehensive privacy policies dealing with the storage and use of consumers' data; and should have unbiased and fair marketing practices.[760]

Overall, the *Statement* highlights the importance of the following factors in the provision of DTCGT testing services: informed consent; individualized medical supervision; quality of genetic testing services; respect for privacy; the right to genetic information; the oversight of genetic testing; and the impact on the healthcare system.

(d) European Academies of Science Advisory Council (EASAC) and Federation of European Academies of Medicine, (FEAM) Report

EASAC and FEAM established in 2001 and 1993 respectively are advisory bodies representing the interests of the European scientific community. In response to the general concerns raised by DTCGT they conducted a joint project investigating DTCGT, which culminated in their 2012 report, *Direct-to-consumer genetic testing for health-related purposes in the European Union.*[761] The *Report* set out a set of principles, which they suggested should be utilised in considering appropriate governance for DTCGT. Their principles resemble the HGC's and the ESHG's *Statement* previously mentioned. They suggest that certain types of tests 'for high-penetrance genotypes, including monogenic disorders, should generally be provided within the clinical genetic service'. This would mean that many health tests currently offered by DTCGT companies ought not to be available. They also suggest that DTCGT tests should come within the remit of the IVD Directive, although in order for the Directive to effectively regulate DTCGT

760 ibid 1271–1273

761 EASAC and FEAM, *Report* (n 439);Volker ter Meulen et al, *Direct-to-consumer genetic testing for health-related purposes in the European Union* (EASAC Policy Report, 2012)

services it needs revision. They further suggest that, susceptibility tests 'for complex disorders should be regulated on the basis that the claims about the link between the genetic markers and the disease are scientifically valid, and based on evidence that meets the standards of STARD (Standards for the Reporting of Diagnostic Accuracy Studies)' (principle 3). They also stress the importance of test quality (principle 5). Regarding transparency they suggest in principle 4 that:

> Transparency in information provision to consumers (truth in labelling) is of fundamental importance because it enables easier distinction between claims that are justified and those that are not. The information should also emphasise who is advised not to use DTC GT services. Information supplied should be governed by enforcement of advertising standards for evidence-based claims and accurate information in consumer law protection.

They also stress the importance of adequate consent and international collaboration 'to ensure that global Internet provision can be regulated consistently and supported by cross border co-operation' (principle 9). They also support prohibiting the testing of minors, pregnant women or third parties who have not provided adequate consent (principle 7).[762] These principles together with the other policy guidance discussed above could be drawn upon to develop industry specific guidance at the EU level.

5 Policy Response in the USA and Canada

(a) US Response

In the USA, the Government Accountability Office (GAO), the Secretary's Advisory Committee on Genetics, Health, & Society (SACGHS), the American Society of Human Genetics (ASHG) and Association for Molecular Pathology (AMP) have all done work in this area.

---

762 EASAC and FEAM, *Report* (n 439)

(i.) GAO

The GAO issued a report on DTCGT in 2010, which found that different testing companies could provide contradictory results when testing DNA from the same individual.[763] Briefly, in order to investigate DTCGT products, the GAO purchased tests from four DTCGT companies. They then used:

> online search terms likely to be used by actual consumers, we identified and selected these companies because they were frequently cited as being credible by the media and in scientific publications and because they all provided consumers with risk predictions, accessible through secure Web sites, for a range of diseases and conditions.[764]

They 'purchased 10 tests from each company (…) to compare risk predictions for a variety of serious illnesses and determine whether the companies were consistent in their predictions'.[765] They 'then selected five DNA donors and created two profiles for each donor, one using factual information about the donor and one using fictitious information, including age, race or ethnicity, and medical history' and then 'sent two DNA samples (saliva or a cheek swab) to each company—one sample using the factual profile and one using the fictitious—to determine whether altering the donors' backgrounds had any effect on the companies' DNA analysis'.[766] They also made 'calls to the companies seeking additional medical advice for both our factual and fictitious donors'.[767] In summary they found the results provided by the companies to be:

> misleading and of little or no practical use to consumers. Comparing results for 15 diseases, we made the following observations:
>
> (1) each donor's factual profile received disease risk predictions that varied across all four companies, indicating that identical DNA can yield contradictory results depending solely on the company it was sent to for analysis;
>
> (2) these risk predictions often conflicted with the donors' factual illnesses

763 US Government Accountability Office
764 ibid 2
765 ibid 2
766 ibid 3
767 ibid 3

and family medical histories;

(3) none of the companies could provide the donors who submitted fictitious African American and Asian profiles with complete test results for their ethnicity but did not explicitly disclose this limitation prior to purchase;

(4) one company provided donors with reports that showed conflicting predictions for the same DNA and profile, but did not explain how to interpret these different results; and

(5) follow-up consultations offered by three of the companies provided only general information and not the expert advice the companies promised to provide.[768]

While the report has been criticised it does highlight problems in this area.[769] Especially for disease risk predisposition testing where tests are not standardised and the interpretation of specific gene variants regarding their effect on disease risk is disputed even in the research community, it is questionable whether the services of many DTCGT companies offer any real benefit to consumers.[770]

(ii.) American Society of Human Genetics (ASHG)

The ASHG released a *Statement on Direct-to-Consumer Genetic Testing in the United States*[771] in 2007. This Statement recommended that the Centers for Medicare and Medicaid Services (CMS) 'create a genetic-testing specialty under CLIA, to ensure the analytic validity of tests and the quality of genetic testing laboratories' and also that 'CMS should ensure that all DTC genetic-testing laboratories are certified under CLIA and should maintain a publicly accessible list containing the certification status of laboratories'.[772] It went on to recommend that, 'FDA and the FTC should work together to develop guidelines for DTC testing companies to follow, to ensure that their claims are truthful and not misleading and that they adequately convey the scientific limitations for

768 ibid 4-5

769 Turna Ray, 'GAO Stands By Its 2010 Report on DTC Genomics Firms; Lead Investigator Assigned to New Position' *GenomeWeb* (16th March 2011)

770 Dreyfuss; Nicholas J Roberts et al, 'The predictive capacity of personal genome sequencing' (2012) 4 Science translational medicine 133ra58

771 K Hudson et al, 'ASHG Statement* on direct-to-consumer genetic testing in the United States' (2007) 81 American Journal of Human Genetics 635

772 ibid 637

particular tests'.[773]

It also stressed the importance of the following: transparency in companies' practices; that they should provide appropriate information regarding the risks and benefits of DTCGT; and also that professional medical organisations should provide further education to their members, so that physicians can adequately interpret and understand DTCGT services and results.[774]

Regarding transparency, it stated that 'companies must provide all relevant information about offered tests in a readily accessible and understandable manner'[775] and specifically:

> a. Companies offering DTC genetic testing should disclose the sensitivity, specificity, and predictive value of the test, and the populations for which this information is known, in a readily understandable and accessible fashion.
>
> b. Companies offering DTC testing should disclose the strength of scientific evidence on which any claims of benefit are based, as well as any limitations to the claimed benefits. For example, if a disease or condition may be caused by many factors, including the presence of a particular genetic variant, the company should disclose that other factors may cause the condition and that absence of the variant does not mean the patient is not at risk for the disease.
>
> c. Companies offering DTC testing should clearly disclose all risks associated with testing, including psychological risks and risks to family members.
>
> d. Companies offering DTC testing should disclose the CLIA certification status of the laboratory performing the genetic testing.
>
> e. Companies offering DTC testing should maintain the privacy of all genetic information and disclose their privacy policies, including whether they comply with HIPAA.
>
> f. Companies offering DTC testing and making lifestyle, nutritional, pharmacologic, or other treatment recommendations on the basis of the results of those tests should disclose the clinical evidence for and against the efficacy of such interventions, with respect to those specific recommendations and indications.[776]

---

773 ibid 63
774 ibid 636-7
775 ibid 636
776 ibid

Significantly, if these provisions were followed American DTCGT companies would be subject to the Health Insurance Portability and Accountability Act (HIPAA), which should improve privacy protection in this context. Also, they advocate for possible oversight of CLIA, CMS, FTC and FDA and this was followed it should lead to enhanced regulation of the industry.

(iii.) Genetic Testing Register

In 2012, the National Institutes of Health (NIH) created the Genetic Testing Registry (GTR),[777] which is 'a public database of test information submitted voluntarily by genetic test providers'.[778] While the GTR is a voluntary register and it is primarily intended for use by medical practitioners and researchers, it may prove to be useful tool in improving standards across the industry.[779]

(iv.) Association for Molecular Pathology

The Association for Molecular Pathology (AMP) released a *Position Statement on Direct Access Genetic Testing* in 2007. In accordance with the concerns raised by the work of the GAO, AMP recommended that 'genetic tests should be provided to the public only through the services of an appropriate health care professional and a properly certified laboratory'.[780] However, in February of 2015 it released a revised *Position Statement on Direct Access Genetic Testing*[781]. In the updated *Position Statement* it identified four

---

779 WS Rubinstein et al, 'The NIH genetic testing registry: a new, centralized database of genetic tests to enable access to comprehensive information and improve transparency' (2013) 41 Nucleic acids research D925

779 WS Rubinstein et al, 'The NIH genetic testing registry: a new, centralized database of genetic tests to enable access to comprehensive information and improve transparency' (2013) 41 Nucleic acids research D925

779 WS Rubinstein et al, 'The NIH genetic testing registry: a new, centralized database of genetic tests to enable access to comprehensive information and improve transparency' (2013) 41 Nucleic acids research D925

780 Association for Molecular Pathology, *Association for Molecular Pathology Position Statement: on Direct Access Genetic Testing (Direct to Consumer Genetic Testing)* (Association for Molecular Pathology, 2007)

781 AMP

categories of DTCGT tests. These were: (1) clinically meaningful; (2) business interest; (3) ancestry; and (4) recreational/novelty. The only category of testing which AMP supported the provision of 'under certain conditions' were those that were clinically meaningful, which it defined as those that 'provide information that can diagnose, predict, prognosticate, and/or otherwise reveal information relevant to a patient's health'.[782] Regarding the other categories, it opposed business interests tests, which it defined as those where the 'information garnered from the testing does not meet criteria for 'clinically meaningful' and companies attempt to sell products or services owned and/or endorsed by the laboratory'.[783] Finally, it opted for a neutral stance for both ancestry and recreational testing. Many tests currently offered by DTCGT companies may not meet the 'clinically meaningful' criteria.

AMP's conditions for the provision of tests, which are clinically meaningful are as follows:

> The association between the genetic marker for which testing is performed and the relevant disease must be robust and supported by strong scientific evidence in the peer reviewed literature, and/or be based on evidence referenced or annotated in current genetic/genomic databases.
> Testing should comply with the CLIA statute and regulations, and all applicable state and federal laws and regulations.
> Transparency regarding the analytical and clinical validity of the tests should be present in all marketing materials and included in the report. Specifications include but are not limited to, analytical and clinical sensitivity/ specificity, and the limitations of assay. These should be described in terms understandable to an educated lay reader (see next bullet point). In addition, the underlying data and analytical methodology, including computational and/or statistical methods employed, power analyses, confidence analyses, etc. upon request should be readily available to health professionals.
> Reporting of test results and the limitations of the test should be in lay language. Additionally, the report should include an interpretation of the finding and describe its significance for the consumer's health status.
> Test validation and interpretation should be performed by certified molecular laboratory professionals.

---

782 AMP, 'Association for Molecular Pathology Position Statement: Direct Access Genetic Testing (Direct to Consumer Genetic Testing)' (AMP 2015)

783 ibid

> AMP strongly supports referral for genetic counseling services and the provision of educational materials. Test providers should encourage genetic counseling as an additional step for consumer education. Resources such as referrals to the National Society of Genetic Counselors' directory or through genetic counseling contracting services are considered appropriate.
> Direct access laboratories should recommend that consumers discuss their test results with their physicians.

Thus, AMP overall are highlighting the need for transparency, the importance of scientific evidence to support the validity and utility of tests and the provision of genetic counselling. As will be shown in the next two chapters, current business practice is often failing to be meet these requirements.

(b) Canadian Response

This section will briefly consider some of the most significant developments regarding DTCGT regulation in Canada to date. In Canada, while there is a lack of specific regulation of DTCGT at present and 23andMe and other companies are currently permitted to offer services to Canadian consumers several bodies are interested in DTCGT and have released guidance. Most significant in this context to date is the work of: the Canadian College of Medical Geneticists (CCMG) which released its *CCMG Statement on direct-to-consumer genetic testing*[784] (*Statement*) in 2012; and more recently the Office of the Canadian Privacy Commissioner's (OPC) *Statement on the use of genetic test results by life and health insurance companies* (*Statement on Use*) released in 2014.[785]

784 CCMG (n 294)

785 Office of the Privacy Commissioner (OPC), *Statement on the use of genetic test results by life and health insurance companies* (OPC, 2014)

(i.) CCMG's Statement

The CCMG's 2012 *Statement* emphasised similar points to EASAC and FEAM, ESHG, and the ASHG including that:

> Only scientifically valid tests should be offered (…) Technical and clinical limitations of the testing, including sensitivity, specificity, and utility in assessing health, must be clearly stated in a manner understandable to the target market.[786]

In relation to marketing of DTCGT they also stated that:

> Genetic testing should be marketed appropriately irrespective of whether the results of testing are medically significant. Marketing should not include disclaimers that imply or state that testing is non-medical when the results are medically relevant.[787]

Finally, they also highlighted the possibility of DTCGT causing strain on a public health system through the provision of unnecessary treatment.[788]

(ii.) OPC's Statement on the use of genetic test results by life and health insurance companies

The OPC's Statement on Use[789] was based on their ongoing work 'examining the privacy implications arising from the collection and use of genetic information'. As part of this they commissioned several studies in order to address the question of:

> whether requesting access to existing genetic test results goes beyond that which is necessary for legitimate business purposes or beyond that which a reasonable person applying for life or health insurance would consider appropriate in the circumstances.
>
> In order to address this question, the OPC has adopted the following well-established four-point test as an analytical framework:
>
> 1. Are the collection and the use of this personal information necessary to achieve a legitimate business purpose?
> 2. Is the personal information likely to be effective in achieving that purpose?
> 3. Are the collection and the use proportionate to the benefits gained?

---

786 CCMG (n 294) 2-3
787 Office of the Privacy Commissioner (OPC) (n 785) 2
788 ibid (n 785) 2-3
789 ibid (n 785)

4. Are there less privacy-invasive alternatives?

As part of this two papers were commissioned addressing the impact on the Canadian insurance industry if they did not have access to genetic test results. Both papers found that, 'at the present time and in the near future, the impact of a ban on the use of genetic test results by the life and health insurance industry would not have a significant impact on insurers or the efficient operation of insurance markets'.[790] In preparing their Statement, they consider that 'where the personal information collected is perceived to be of particularly sensitive nature (such as a genetic test result) the need to consider less privacy invasive alternatives is particularly strong'.[791] They concluded that, 'it is not clear that the collection and use of genetic test results by insurance companies is demonstrably necessary, effective, proportionate or the least intrusive means of achieving the industry's objectives at this time'.[792] In deciding this they had regard to the following factors:

- the highly sensitive nature of genetic test results;
- the low predictive value of many genetic test results;
- that, at the present time, few people hold actuarially significant test results;
- the rare occurrence of monogenic disorders;
- the unregulated nature of the DTC industry and questions about the accuracy, validity and utility of DTC results;
- the public interest in encouraging individuals to voluntarily participate in health research without fear that their test results will be used for unrelated purposes;
- the importance of creating an environment in which individuals feel free to undergo medically valuable genetic tests without worrying about the impact on their ability to obtain insurance;
- and evidence that restricting insurers' access to genetic test results would not have a significant adverse impact on the viability of the life and health insurance industry[793]

790 (n 785) 3
791 (n 785) 4
792 (n 785) 5
793 (n 785) 5

Their ultimate recommendation was that the Canadian health and life insurance industry extend its moratorium until such time as it can be shown to be necessary to consider genetic test results. The moratorium 'currently calls on its members to refrain from asking applicants to undergo genetic testing, to also refrain from requesting access to existing genetic test results'.[794] The Canadian response thus resembles the UK approach with an industry moratorium.

6 OECD Guidelines for Quality Assurance in Molecular Genetic Testing

The OECD *Guidelines* are another useful resource in improving regulation. They resulted from the 2002 Working Party on Biotechnology's survey on 'the availability and extent of molecular genetic testing throughout the OECD Member countries'.[795] The Working Group examined the practices in place in 18 OECD Member states and its 2005 report emphasised the need to develop guidelines in order to harmonise practices globally. OECD Members 'agreed to develop guidelines setting out principles and best practices for quality assurance in molecular genetic testing for clinical purposes'[796] and these principles were released in 2007. Although these principles are only intended to apply to genetic testing for clinical purposes, it may be possible to broaden their scope and apply them to DTCGT companies offering health-related tests. The general principles for molecular genetic testing as set out in section 2 provide that:

> A.1 Applicable legal, ethical, and professional standards should be respected in the practice of molecular genetic testing.
>
> A.2. Molecular genetic testing should be delivered within the framework of health care.

---

794 (n 785) 5

795 OECD Guidelines for Quality Assurance in Molecular Genetic Testing, Organisation For Economic Co-Operation 5

796 ibid 6

A.3 All molecular genetic testing services should be provided and practised under a quality assurance framework.

A.4 Informed consent to test should be the norm and should be obtained in compliance with applicable legal, ethical, and professional standards.

A.5 Pre and post test counselling should be available. It should be proportionate and appropriate to the characteristics of the test, the test limitations, the potential for harm, and the relevance of test results to individuals and their relatives.

A.6 Personal genetic information should be subject to privacy protection and security in accordance with applicable law.

A.7 The benefits of cross border exchange of patient samples and personal information for molecular genetic testing should be recognised.

A.8 The use, storage, transfer and disposal of patient samples collected for molecular genetic testing should be subject to applicable legal, ethical and professional standards.

A.9 Advertising, promotional and technical claims for molecular genetic tests and devices should accurately describe the characteristics and limitations of the tests offered.

The general best practices recommended are:

A.i Regulatory and professional bodies should, as appropriate, review whether the instruments available to manage a quality assurance framework require adaptation and interpretation for laboratories providing molecular genetic testing.

A.ii Laboratories should make available information on the analytical and clinical validity of tests.

A.iii Molecular genetic test results should be reported back to the referring health care professional to enable counselling and healthcare decision-making.

In relation to the reporting of results, the Guidelines recommend that:

D.2 Within jurisdictions where reports may be issued directly to patients, governments, regulatory and professional bodies should encourage all laboratories performing clinical molecular genetic tests to recommend that patients consult an appropriate clinician or health care professional to help them understand the implications of the test result.

D.3 Governments and regulators should require that in issuing and archiving reports, all laboratories comply with applicable law and regulations, including those concerning the confidentiality of information.
D.4 The interpretation of molecular genetic test results should be appropriate to the individual patient and clinical situation and should be based on objective evidence.

The Guidelines provide further detailed principles and best practices that specify the types of information which should be provided to patients and clinicians and also make recommendations regarding how this information should be communicated. While the Guidelines were developed for tests conducted in a clinical setting, if DTCGT companies were to follow the Guidelines this would help to improve standards across the industry and enhance consumer protection.

7 Common themes of policy responses

Overall, there is much commonality amongst the different policy documents to date. It is possible to identify key points that might in turn provide the basis for either new legislation or an industry code of conduct. Many organisations emphasize the importance of test quality, which should entail consideration of both analytical validity and also the quality of interpretation of test results. Tests should be medically relevant. Generally, tests should not be offered to minors, pregnant women or third parties who have not consented to testing. Certain types of test such as what AMP dubs 'business interest' tests should actually be prohibited. Also, many tests that lack clinical validity and utility should also be prohibited.

Furthermore, tests should only be provided when companies have received a person's informed consent, which should be free and voluntary. Further specific consent should also be obtained where companies intend to perform secondary tests or engage in research involving consumers' genetic information. Companies ought to provide genetic counselling services or make information about genetic counselling available. Companies should provide consumers with adequate information regarding the respective risks, benefits, and limitations of testing and also implications or consequences of undergoing testing, such as how this might relate to obtaining insurance. Companies should also

consider the potential impact, which tests can have on families and give consideration to the personal circumstances of consumers.

Policy guidance also often stresses the importance of protection of an individual's privacy rights and often stress the importance of secure storage of biological samples and genomic data.[797] They also stress the need for maintaining the confidentiality and privacy of consumers. More mechanisms for enforcing compliance may be required. There are lots of potential problems here. These include: possible secondary uses which the information may be put to by the testing entities; circumstances in which these uses may be justified, for example in cases of medical emergency where stored data may be useful in the treatment of the person tested; the effect of consent including a waiver of any rights to the benefit of research derived from these uses; the possibility of data mining and using stored data to make money from research interests; should the money derived from such a use be held for the benefit of the individual contributors or their heirs? It is hoped that the current research will serve to stimulate discussion.

Overall, many of these documents stress the importance of unbiased marketing of tests and promote the need for greater transparency in both marketing and the provision of information regarding testing and the use, storage and processing of genetic information. At present, as will be shown in chapters four and five many companies are not being sufficiently transparent in their marketing and may also not be providing sufficient information to consumers about the respective risks and benefits of testing.

As will be shown in chapter five companies are often seeking to avoid liability and using wrap contracts to avoid obligations imposed by statute, such as the requirements to supply services with reasonable care and skill and also, that services and digital information be fit for purpose, as set out in the Supply of Goods and Services Act

797 HGC, (n 3); Genetics1271–1273

and the Consumer Rights Act. While policy guidance stresses the importance of clinical validity companies often state that their services are provided on an 'as is' basis and also attempt to avoid liability for tests being fit for purpose.

8 Way Forward for Regulation

As discussed in chapters three and five, current company practice overall is at odds with the views of policymakers. There is a clear need for companies to improve their practices and if regulation does not come in the form of legislation, then documents such as the HGC's Framework of Principles and the work of EASCA and FEAM, the Additional Protocol, and the OECD Guidelines could provide guidance for the creation of an industry code of conduct. At present, as will be shown in chapter five the industry is largely engaged in self-regulation through the use of wrap contracts. However, this form of self-regulation is not balanced and does not provide sufficient protection for the individuals tested. If the industry is to be self-regulated then general business practice needs to change and if no code of conduct is forthcoming, it is desirable that companies begin to improve their contracts and the content of their websites.

9 Conclusion

This chapter has shown that there are several areas of existing law, which might be drawn upon to improve regulation of the DTCGT industry. As these services are currently framed as consumer services in the UK, then consumer protection legislation should have direct applicability. However, legislation on governance of medical devices together with data protection and human rights legislation may also be drawn upon to enhance protection for consumers' rights in this context. DTCGT companies should be complying with data protection law and the requirements of the HTA. If the IVD Regulation is enacted this should contribute to improved regulation of DTCGT that is

provided for health purposes, although as previously noted, it would still leave many lifestyle tests and some health tests largely unregulated. Ultimately it is desirable that specific legislation is enacted to govern the industry.

As can be seen from the preceding discussion, there are a large number of policy documents that could provide guidance for the industry and might provide a basis for developing new legislation. However, there is as yet a lack of specific legal regulation. It does seem that if the new IVD Regulation is enacted this might contribute to enhancing regulation of the industry. However, enforcement of the IVD Regulation may pose problems given that the resources of the MHRA are limited and many DTCGT companies operate internationally. Alternatively, there is potential for an increased role of the ICO in regulating the industry. While industry specific regulation might be the ideal solution, this raises the same issue of enforcement and consequently and it is vital that whether or not the new IVD Regulation is enacted the industry does need to be encouraged to improve its standards. The HGC's Framework of Principles could provide the basis for development of an industry code of conduct and the industry could look to examples of codes of conduct from other industries. It might also be possible for the companies to work with the ICO to develop their policies.

The next chapter will provide a review of DTCGT wrap contracts. It will use examples drawn from the contracts of DTCGT companies providing tests for health purposes as a representative case study of the industry as a whole. In so doing it will also identify specific terms which are likely to be deemed unfair under the CRA. Specifically, terms allowing for unilateral variation, terms covering consent and assent, terms limiting scope of purpose, terms limiting liability for fitness for purpose or personal injury are likely to be deemed to be unfair terms and it is hoped that the Competition and Markets Authority will take on an active role in policing these terms and improving DTCGT

contracts. It is argued that the use of wrap contracts in this context can be seen as a form of private legislation used by the industry as a means of industry self-regulation, which at present is skewed heavily in its favour and does not afford sufficient protection or consideration of the rights of consumers.

CHAPTER FIVE – THINK BEFORE YOU CLICK: UNFAIR TERMS IN DTCGT WRAP CONTRACTS

1 Introduction

Clickwrap and browsewrap contracts will often now provide the main means of regulation of interactions between consumers and companies on the Internet. There is growing concern over their use and their effects on consumers' rights and consumer protection more generally.[798] The present chapter sets out the findings of a review of the wrap contracts used by DTCGT companies that provide testing for health purposes. This takes the form of descriptive comparative document analysis of these contracts. It provides an outline of the typical terms likely to be included in a DTCGT contract and a discussion of terms, which are likely to be deemed unfair and unenforceable under UK law. In this chapter and in chapter six it will be argued that several terms commonly included in DTCGT contracts are likely to be deemed to be unfair terms under UK law and consequently unenforceable. Given the frequency of use of these terms I suggest that the best means of enhancing protection for consumers in this context in the short-term is for the Competition & Markets Authority to begin to take pre-emptive action and work with the industry to discontinue the use of such terms. Specifically the following terms are likely to be deemed to be unfair or fail to meet transparency requirements: clauses allowing for unilateral variation of the contract; clauses disclaiming liability for fitness for purpose or for personal injury caused by the company's negligence; clauses limiting scope of purpose; clauses purporting to bind the consumer to resolve any disputes in another jurisdiction; and consent clauses. The specific provisions of the applicable

[798] See generally, Kim (n 227) and Margaret Jane Radin, *Boilerplate* (Princeton Press 2013); Victoria C Plaut and Robert P Bartlett III, 'Blind consent? A social psychological investigation of non-readership of click-through agreements' (2012) 36 Law and human behavior 293

legislation, namely the Consumer Rights Act 2015, and other relevant legislation will be considered in chapter six.

This chapter provides a case study of the contracts of DTCGT companies that provide health testing. The choice was made to focus on health testing companies, as it was not possible to analyse the contracts of the entire industry herein and companies that are engaged in offering health testing can be viewed as a good example that is representative of the broader issues raised by the DTCGT industry. Namely, DTCGT companies that perform health testing offer a diverse range of tests, often may provide testing for other purposes and are often entering into the medical research space with their research ventures and partnerships and mergers with other companies. Thus, the health testing industry highlights the potential for data sharing in this context. It also is the most reflective of the shift from patient to consumer, as these companies are often offering tests, which were only previously offered in a clinical setting. These are normally to be found on websites as Terms of Use, Terms of Service, Terms and Conditions, Privacy Policy or Privacy Statement. All documents were downloaded between 2011 and 2014. However, most versions were accessed between January 2013 and November 2014. Some companies may have altered their policies since November 2014 and these changes cannot be considered herein. As noted in chapters three and four it is also likely that DTCGT companies' consent mechanisms will not be sufficient to meet the requirements of the Human Tissue Act or of data protection law.

Chapter six will provide an overview of contract law, as it is applicable to the DTCGT industry with a particular focus on the nature of wrap contracts and the legislation regulating unfair terms in business to consumer contracts, especially the newly enacted Consumer Rights Act 2015. However, because it is likely that many DTCGT contracts are prima facie valid contracts it is important to consider the content of

these contracts and whether there is anything problematic about that content. As it will always be difficult for an individual consumer to pursue litigation against a large company if certain terms currently included in these contracts seem likely to be deemed as unfair it is desirable that the Competition & Markets Authority (CMA) works with the industry to prevent the use of such terms.

In analysing these documents it appears that many contracts and privacy policies have not been specifically drafted to address the issues raised by the DTCGT industry. Although it is not possible to explore this issue in depth here it is concerning, given the nature of DTCGT services and more research is needed. Furthermore, while the privacy policies of DTCGT companies have also been analysed, as this research is primarily concerned with the contracts used by DTCGT companies the focus will be on contractual terms and how these might be challenged under contract law, rather than with discussion of whether the terms included in DTCGT privacy policies comply with data protection law, although preliminary analysis suggests that DTCGT companies are often not complying with data protection law and it may be necessary for the ICO to investigate this. The privacy and security issues raised by DTCGT have been considered in earlier chapters, but more detailed analysis of privacy policies will be conducted in future research. It should be noted though that sometimes privacy policies and terms and conditions are combined in one document and consequently some terms that are included in documents entitled 'Privacy Statement'(s) will be considered herein. Furthermore, given the tendency to combine privacy policies with contracts the impact of unilateral variation clauses is increased, as clauses of this type may permit a company to alter their policies on use, storage, sharing, and sale of stored genetic information in significant ways that may have serious consequences for consumers. As will be seen later in this chapter the fact that very few companies that allow for unilateral variation in their

contracts will also notify their customers of changes means that clauses of this type need to be monitored and it would be beneficial for consumers if the CMA could work to discontinue the inclusion of these terms.

It is important to again note the importance of the shift from providing genetic tests in a clinical setting to providing them directly to consumers in their homes. The significance of this shift is compounded by the other features of the DTCGT industry chiefly related to the fact that it is an Internet based industry. As Kim notes:

> The Internet seems uniquely suited to impulsivity and impatience. Robert Hilmann observes that the online environment may be less conducive to informed contracting than the offline one as users may not assign the "same significance to a mouse click as a signature on a paper form," may "expect speed and instant gratification," and may be "overeager, even 'click-happy'"(…) There is a feeling of unreality or "online disinhibition," which is a term sociologists and psychologists use to mean that users dissociate their online persons from their offline selves.[799]

In light of this, it is possible that the very nature of the online environment may actually be detrimental to consumers in the context of providing DTCGT services. Given the complex nature of test results and the uses to which genetic data may be put, the digital environment may not be conducive to enabling consumers to make informed decisions regarding the purchase of these tests. While more studies are needed, there is also evidence to suggest that many consumers may misunderstand the effect of online contracts and privacy policies. Recent studies by Haynes,[800] Kacen et al,[801] and Thompson[802] highlight the difficulties in this area, as it seems many consumers think that the mere existence of a privacy policy on a website means that the company will not

799 Kim (n 227) 61.

800 Allyson W Haynes, 'Online privacy policies: Contracting away control over personal information' (2006) 111 Penn St L Rev 587

801 Jacqueline J Kacen, James D Hess and Wei-Yu Kevin Chiang, 'Bricks or clicks? Consumer attitudes toward traditional stores and online stores' (2013) 18 Global Economics and Management Review 12

802 David Thompson, 'I Agreed to What-A Call for Enforcement of Clarity in the Presentation of Privacy Policies' (2012)

share or sell personal data, when in fact the opposite is often true, with many policies serving as notice that companies will share or sell data.

2 Summary of review

Of 102 companies identified that provide health related genetic testing, 31 companies did not have terms and conditions publically available. Of the 31 that did not have terms available, some of the websites did have sections on their websites entitled Terms and Conditions, but when the link was clicked upon no terms or text were available. Consequently, this chapter's focus is on the 71 companies, which did have terms and conditions available. It is possible that those companies, which did not have terms and conditions available, do in fact have terms and conditions and so it should not be assumed that they do not or that companies, which have their terms and conditions available are necessarily engaged in more responsible business practice than those that do not.

All the DTCGT contracts and privacy policies examined herein are wrap contracts, either clickwrap (click-through) or browsewrap. These are two contractual forms, which are common to all forms of online commerce. DTCGT companies and other Internet companies use wrap agreements because it allows them to set the terms of the bargain and to minimise their risk.[803] This can in fact be seen as a form of private legislation skewed in favour of the industry. As it is frequently the case that people do not read these contracts and they cost little for the company to create there is a growing trend for companies to make their contracts longer and more one sided. In e-commerce more generally it is common practice for companies to borrow and copy from the

[803] Kim (n 227)

contracts of their competition[804] and the examples in this chapter will be illustrative of this practice as sometimes the terms used by different companies use wording that is identical or extremely similar.

3 The Typical DTCGT Contract

A DTCGT contract will often include the following terms: a clause allowing the company to unilaterally alter its terms; clauses indicating that services are provided for informational purposes and do not constitute medical advice; a clause governing consent; a clause governing acceptance of the contract; exclusion clauses disclaiming liability; clauses requiring consumers to indemnify the company; clauses disclaiming warranties; clauses governing intellectual property; clauses governing disclosure of data; clauses making arbitration compulsory; clauses proscribing the choice of law or jurisdiction for setting disputes; and clauses limiting remedies and damages. As will be seen from the examples given the majority of these terms are open to challenge on the grounds of their unfairness.

DTCGT contracts generally resemble contracts used by Internet service providers. A recent study by Loos and Luzak comparing the terms included in the contracts of Google, Twitter, Facebook, and Dropbox[805] suggested that many of these terms would be likely to be deemed unfair under EU law. In this study they primarily relied upon the provisions of the Unfair Terms Directive and the case law of the CJEU in investigating potential unfairness. They examined the following types of terms: terms providing for unilateral alteration of terms or unilateral changes to the nature of the service offered; 'exclusions or limitations of liability'; 'international jurisdiction

804 ibid 61

805 Marco Loos and Joasia Luzak, 'Wanted: A Bigger Stick. On Unfair Terms in Consumer Contracts with Online Service Providers' (2015) On Unfair Terms in Consumer Contracts with Online Service Providers (January 8, 2015) Centre for the Study of European Contract Law Working Paper Series

clauses'; and 'choice-of-law clauses'.[806] They concluded their 'analysis by illustrating the overarching problem of many online contractual terms, namely, their lack of transparency',[807] which is add odds with the requirement of article 5 of the Unfair Terms Directive, which requires, that 'terms must always be drafted in plain, intelligible language'.[808] In line with their work, as will be demonstrated by the examples provided in this chapter, as many terms commonly included in DTCGT contracts resemble those included in those of internet service provider contracts using similar language, it seems likely that they would also be construed as unfair under EU law and that they may also fail to meet transparency requirements.

To date most clickwrap and browsewrap disputes have centred on forum selection and arbitration clauses[809] and the current 23andMe case (which was mentioned in chapter four) fits into this pattern by focussing on the arbitration clause in 23andMe's Terms of Service. However, overall arbitration clauses are not as common in the contracts of DTCGT companies providing health services, as they are in online contracts more generally and while they are significant this chapter will also consider several other clauses, which should be seen as important in relation to their impact on consumers' rights in the DTCGT context and which are frequently included in DTCGT contracts.

DTCGT contracts include many terms and are normally thousands of words in length. Here are some examples: 23andMe's Terms of Service is 9,081 words, and its Privacy Statement is 32 pages long and 15,807 words long; while Gene By Gene's DNA DTC Terms and Conditions is 3,645 words and its consent document is 4,718; and DNA

806 ibid (n 805) 3

807 ibid (n 805) 3, and 24-5

808 ibid (n 805) 24, citing Directive 93/13/EEC of 5 April 1993 On Unfair Terms In Consumer Contracts

809 Kayleen Manwaring, 'Enforceability of Clickwrap and Browsewrap Terms in Australia: Lessons from the US and the UK' (2011) 5 Studies in Ethics, Law, and Technology, 1-17, 13

Spectrum's Terms of Service is 5,165 words long.[810] It is common for online contracts generally to be at least 6,000 words in length. Examples from other industries are the iTunes agreement, which is 19, 972 words long and Amazon's Terms and Conditions which is 36,275 words long.[811] While all the terms included in DTCGT contracts are interesting, what follows is a discussion of the terms that are considered most important for consumers. The examples provided are from companies categorised as providers of health related testing, regardless of their location and including those offering their services through physicians. Central to this discussion is whether some of these terms qualify as unfair terms in accordance with the definition provided by the CRA, that is, whether they cause an imbalance in the parties' rights to the detriment of the consumer.[812]

4 Unfair Terms in DTCGT Contracts

The next sections will provide a discussion of terms likely to be included in DTCGT contracts with a focus on those that are likely to be open to challenge on the grounds of unfairness. In doing this it will use examples to illustrate the content and language likely to be used in such clauses.

(a) Unilateral Variation Clauses

(i.) Summary of review of unilateral variation clauses

Clauses allowing DTCGT companies to alter their terms are particularly common with 72% of the 71 companies with terms available including such a clause.[813] Of these companies 39% include a term which allows them to alter their terms 'at any time', while

810 Copies of all contracts and privacy policies are on file with the author.
811 Wigley + Company Solicitors (n 228)
812 Consumer Rights Act 2015 s 62.
813 Phillips, 'Genomic Privacy and Direct-to-Consumer Genetics Big Consumer Genetic Data – What's in that Contract?'

32% allow for alteration of terms 'from time to time'. Only a very small minority of companies with variation clauses, 6%, will notify consumers of changes by email. Furthermore, 30% of companies will deem acceptance to altered terms through continued use of the website. 28% recommend that the customer checks their website periodically to ascertain whether changes have been made to their terms or privacy policy. Clauses of this type are very likely to be construed as being unfair according to the CMA's *Draft Guidance*[814] and its *Unfair contract terms guidance* (*Final Guidance*).[815] These are also covered in the CRA's Grey List in sections 10 and 11 of Schedule 2, but the CMA in its *Unfair Terms Explained* also suggests that these may be blacklisted under Part 1 of the CRA.[816]

While such clauses may be understandable from a company's perspective if these are to be included, then companies should be making efforts to provide sufficient notice of such clauses to consumers in order to meet the requirements of transparency. Loos and Luzak[817] have argued that such terms are likely to be deemed unfair in accordance with the Unfair Terms Directive, which from 2015 will be implemented in the UK through the CRA. Such clauses are listed in paragraph 1(j) of Annex I of the Directive as of a type that might be deemed to be unfair. As Lord Denning in *J Spurling v Bradshaw*[818] suggested in obiter dicta:

> the more unreasonable a clause is the greater the notice which must be given of it. Some clauses would need to be printed in red ink on the face

814 Competition & Markets Authority (CMA), *Draft Guidance on unfair contract terms - Consultation document* (CMA, 2015)

815 Competition & Markets Authority, *Unfair contract terms guidance - Guidance on the unfair terms provisions in the Consumer Rights Act 2015* (Competition & Markets Authority, CMA37, 31 July 2015)

816 Competition & Markets Authority, *Unfair contract terms explained* (Competition & Markets Authority, CMA37(a), 31 July 2015) 13-4, paras 65-8

817 Loos and Luzak (n 805) 6-10

818 [1956] 2 All ER 121

> of the document with a red hand pointing to it before the notice could be held to be sufficient.[819]

The English case law following on from *Spurling* has taken this to mean that the more onerous the term is, the greater the level of notice required. As Hedley writes, 'some US cases have refused to apply terms which are considered unconscionably biased against consumers' interests' and although UK 'notions of 'unconscionability' do not stretch so far, nonetheless consumer protection legislation will in many cases lead to the same result'.[820] American courts have often held that 'an opportunity to read is enough', but it is possible that UK courts will require more, as they have previously 'held that rather minimal notice may mean that the consumer agrees to the terms only in so far as they are usual and reasonable'.[821]Thus, very broad variation clauses are likely also to be unfair where there is insufficient notice and in the context of many DTCGT companies' contracts it seems that there would be insufficient notice.

(ii.) Examples of unilateral change of terms clause specifying that company can change terms from time to time

The following examples highlight the similarity in language used by different companies. Also, significant here is that 23andMe and Gene By Gene, which owns DNA DTC are probably the two largest and most prominent companies, so it is interesting that their clauses often use identical or nearly identical language. 23andMe includes the following clauses in their Terms of Service:

> 26. Changes to the Terms of Service
>
> 23andMe may make changes to the TOS from time to time. When these changes are made, 23andMe will make a new copy of the TOS available on its website and any new additional terms will be made available to you

819 Richard Lawson, *Exclusion Clauses and Unfair Contract Terms* (11th edn, Thomson Reuters (Professional) UK Limited 2014) 18, citing *J Spurling v Bradshaw* [1956] 2 All ER 121, [125]

820 Steve Hedley, *The Law of Electronic Commerce and the Internet in the UK and Ireland* (2nd edn, Cavendish Publishing Limited 2006) 248

821 ibid 248, citing *Interfoto Picture Library Ltd v Stiletto Visual Programmes Ltd* [1989] QB 433

from within, or through, the affected Services.

You acknowledge and agree that if you use the Services after the date on which the TOS have changed, 23andMe will treat your use as acceptance of the updated TOS.[822]

Meanwhile, DNA DTC includes the following clause in its Terms of Service:

20. Changes to the Terms of Service DNA DTC may make changes to the Terms and Conditions from time to time. When these changes are made, DNA DTC will make a new copy of the Terms and Conditions available on its website and any new additional terms will be made available to you from within, or through, the affected services. You acknowledge and agree that if you use the services after the date on which the Terms and Conditions have changed, DNA DTC will treat your use as acceptance of the updated Terms and Conditions.[823]

(iii.) Examples of unilateral change of terms clause specifying that company can change terms at any time

Similarly to the previous examples, Asper Biotech and DNA Traits also use identical wording in their variation clauses, which allow them to change their terms at any time.

Asper Biotech includes the following clause in its Terms and Conditions:

Asper Biotech may revise these Terms and Conditions at any time and for any reason. Modifications may be posted on the website. By continuing use of the website and Asper Biotech services after such changes are made you will be accepting such changes.[824]

DNA Traits includes the following clause in its Terms and Conditions:

DNATraits may revise these Terms and Conditions at any time and for any reason. Modifications may be posted on the website. By continuing use of the website and DNATraits services after such changes are made you will be accepting such changes.[825]

While Cancer Genetic Inc's clause is included under the subtitle 'Updates':

Cancer Genetics, Inc. periodically makes updates and/or revisions to the content contained on the CancerGenetics.com website. All content contained on this website is subject to change at any time without notice.

822 23andMe, TOS
823 DNA DTC, TOS
824 Asper Biotech, T&C
825 DNA Traits, T&C

> Cancer Genetics, Inc. may revise or modify these Terms of Use at any time without notice.[826]

DNA Spectrum's clause is particularly broad and reads as follows:

> Whole Agreement and Amendment
>
> This Agreement and the Privacy Policy constitutes the entire agreement between you and DNA Spectrum with respect to the subject matter hereof and supersedes and replaces all prior or contemporaneous understandings or agreements, written or oral, regarding such subject matter. DNA Spectrum may amend or modify this Agreement at any time by posting the new terms on its website. This Agreement may not be otherwise amended except in a written document signed by you and DNA Spectrum.[827]

GenePlanet allows itself to alter both its Terms and Conditions and Privacy Statement 'at any time'. The relevant clause in its Terms is as follows:

> 1. (2). We may revise these Terms and Conditions at any time and for any reason. Any such revised terms shall be posted on the Website and where such revisions are material they shall be notified to you by means of a notice on the Website indicating the date of revision and you shall be asked to confirm your acceptance to such revised Terms and Conditions by clicking on an acceptance icon.[828]

Gentle's clause also allows the company to alter terms 'at any time' and without notification it purports to bind the consumer as soon as changes are made as follows:

> Article 14 General Provisions
>
> (6). Modification of Terms of Service. Gentle has the right to modify the Terms of Service at any time and the Customer agrees that the new Terms of Service are applicable to all Services delivered after the modification and publication of the Terms of Service on the Website.[829]

(b) Choice of Law and International Jurisdiction

The question of the jurisdiction that is to govern disputes arising between companies and consumers is an important matter, especially in relation to affording adequate protection to both parties. It is common practice for companies to specify their governing

826 Cancer Genetics Inc, TOU
827 DNA Spectrum, TOS
828 GenePlanet, T&C
829 Gentle, TOS

jurisdiction of choice in their contracts. Such clauses stipulate that the law of a particular jurisdiction should govern any disputes, which might arise between the company and consumer. In the context of DTCGT, the jurisdiction that will govern disputes arising between companies and consumers varies widely.

However, for disputes involving UK based consumers, if provisions of the Consumer Rights Act were to apply and clauses were deemed to be unfair, English law would probably apply to any dispute that arose between the company and consumer. Specifically, this is addressed in section 32 of the Act and also in section 20 of Schedule 2. In accordance with these provisions it is likely that a clause purporting to bind a UK based consumer to have to resolve any potential disputes in another jurisdiction would not be enforceable. This also seems more likely given that the only UK case on wrap contracts did involve an American company and was still litigated in the UK.[830]

Furthermore, it is also likely that many terms purporting to choose a jurisdiction outside the EU to govern disputes will be unenforceable in accordance with articles 17 to 19 of the Brussels I-Regulation.[831] This argument was made by Loos and Luzak in their recent study of the terms of internet service providers.[832] These articles 'create specific jurisdiction for consumer contracts'[833] and it seems that DTCGT services should fall within the scope of Article 17. Specifically, article 17 provides that:

> 1. In matters relating to a contract concluded by a person, the consumer, for a purpose which can be regarded as being outside his trade or profession, jurisdiction shall be determined by this Section, without prejudice to Article 6 and point 5 of Article 7, if:
>
> (a) it is a contract for the sale of goods on instalment credit terms;
>
> (…)

830 *Spreadex Ltd v Cochrane* [2012] EWHC 1290

831 Regulation (EU) No 1215/2012 of the European Parliament and of the Council of 12 December 2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (recast) OJ 2012, L 251/1

832 Loos and Luzak (n 805) 19.

833 ibid (n 805) 19

> (c) in all other cases, the contract has been concluded with a person who pursues commercial or professional activities in the Member State of the consumer's domicile or, by any means, directs such activities to that Member State or to several States including that Member State, and the contract falls within the scope of such activities.

Loos and Luzak then cited the joint declaration of the Council and Commission on article 15 of the equivalent provision of the previous Brussels I Regulation, which:

> stated, inter alia, that for the specific rules of the Brussels I-Regulation pertaining to consumer contracts to apply, the contract concluded must fall within the framework of the targeted activities, and that the mere fact that an Internet site is accessible from the consumer's place of residence is not sufficient for their applicability (Cordera 2001, pp. 249-250; Trstenjak 2013, pp. 473-475). This joint declaration identifies as relevant factors in determining whether the requirements of (then) Article 15 of the Brussels I-Regulation are met the fact that the Internet site solicits the conclusion of contracts by consumers at a distance and that the contract is in fact concluded at a distance.[834]

It seems likely that many DTCGT companies would fall within the Regulation's remit, as many DTCGT websites do solicit sales from UK consumers and from consumers in other EU countries.

In the context of choice of law clauses, Loos and Luzak also refer to the Rome I Regulation[835], which under article 3, paragraph 1 allows for 'parties to a contract' to choose the law they wish to govern their contract, so long as 'the choice is made 'expressly or clearly demonstrated by the terms of the contract of the circumstances of the case'. They argue that:

> could suggest that a choice-of-law clause included in standard contract terms would not suffice to prescribe a valid choice for the applicable law, unless the trader has specifically drawn the consumer's attention to the term, e.g., by indicating that a choice-of-law clause is included in the standard contract terms. According to Articles 3, paragraph 5, and 10 Rome I-Regulation the existence and the validity of the consumer's consent to a choice-of-law clause is to be decided on the basis of the chosen law. This implies that the consent may be void or voided under the

834 ibid (n 805) 19

835 Regulation (EC) No 593/2008 of the European Parliament and of the Council of 17 June 2008 on the law applicable to contractual obligations (Rome I)

> chosen applicable law in cases of, for instance, duress, fraud or other vices of consent, but also by virtue of the rules on the incorporation of standard terms or those on unfair contract terms.[836]

Such clauses even where validly incorporated are also potentially unfair in accordance with Article 3 of the Unfair Terms Directive, as they may give:

> the false impression to the consumer that her national law is irrelevant for the dispute she has with the online service provider, for instance by falsely claiming that the law of the country where the service provider is located is applicable with the exclusion of any other law.[837]

In the context of DTCGT contracts, which are all standard form contracts, it seems likely that many companies are not providing sufficient notice of their choice of law clauses for them to be effective.

(i.) Summary of review of jurisdictional clauses

Overall, there is much commonality in the language used in these clauses regardless of what jurisdiction is specified. Of the 102 companies offering health related testing, 55 have their offices based in the USA. Usually, the company will specify its home jurisdiction as the forum for settlement of all disputes. American companies normally specify their home state's law.

Of the 71 companies with terms available, 51% do have a choice of law clause. Of the companies, which specify their forum of choice, the jurisdiction most commonly chosen is that of the state of California with 13% of companies choosing this. This is consistent with the fact that California is also the state in the USA which has more DTCGT companies based in it than any other state with 24% (17) companies in total. The companies that choose to be governed by Californian law in their contracts are:

836 Loos and Luzak (n 805) 22
837 ibid (n 805) 23

23andMe[838]; Counsyl;[839]; DNA Direct; DNA Plus; Genomic Health Inc[840]; myDNA; Navigenics; Pathway Genomics[841]; and Test Country[842]. Those companies based in California which do not specify California as their jurisdiction of choice are: Athleticode[843] ; Diagnomics; [844]; easyDNA[845] (note: its administration office is in California and its registered office is in the British Virgin Islands); Genomic Express Inc[846]; MEDomics[847]; PHENOM Biosciences Inc[848]; ; vuGene[849]; ; and DeCODEme[850].

Two companies specify their choice of law as that of the state of Massachusetts and 2 specify Texas as their choice of law. However, there are 6 companies located in Massachusetts and the only 2 specifying Massachusetts law are Perkin Elmer and Inherent Health. The other companies located in Massachusetts are: Interleukin Genetics, Inc[851]; Knome[852]; PerioPredict™ Genetic Risk Test[853]; and Progenika Inc[854]. The 3

838 23andMe, <https://www.23andme.com/health/> accessed 5 January 2013. [Checked again 22 January 2014 and still operating]. [Checked again 24 April 2014]. [Checked again 28 September 2014].

839 Counsyl, <https://www.counsyl.com> accessed 28 January 2014. [Checked again 10 April 2014].

840 Genomic Health Inc, <http://www.genomichealth.com/en-US.aspx#.UuuKSv07S44> accessed 15 January 2014. [Checked again 31 January 2014 and still operating]. [Checked again 14 April 2014]. [Checked again 28 September 2014]. [Checked again 28 September 2014].

841 Pathway Genomics, <https://www.pathway.com/about-us/management> accessed 11 February 2013. [Checked again 24 April 2014].

842 Test Country, <http://www.testcountry.com> accessed 10 August 2013. [Checked again 24 April 2014].

843 Athleticode, <http://athleticode.com> accessed 10 August 2013. [Checked again 22 January 2014 and still operating]. [Checked again 9 April 2014]. [Checked again 28 September 2014].

844 Diagnomics, <http://www.diagnomics.com> accessed 27 January 2014. [Checked again 28 September 2014].

845 easyDNA, <http://www.easy-dna.com> accessed 5 August 2014. [Checked again 28 September 2014]. [Checked again 28 September 2014].

846 Genomic Express Inc, <https://secure.genomicexpress.com/home.html> accessed 27 January 2014. [Checked again 28 January 2014 and still operating]. [Checked again 28 September 2014].

847 MEDomics, <http://www.medomics.com> [Checked again 29 January 2014 and still operating]. [Checked again 22 April 2014]. [Checked again 28 September 2014].

848 PHENOM Biosciences, <http://www.phenombio.com/about-us> accessed 30 April 2014.

849 vuGene, <http://www.mygenesdirect.com> accessed 2 January 2013. [Checked again 29 January 2014 and website not displaying]. [Checked again 24 April 2014].

850 DeCODEme, <http://www.decodeme.com> accessed 22 August 2013. [Checked again 28 January 2014 and still operating].

851 Interleukin Genetics, <http://ilgenetics.com/content/products-services> accessed 15 April 2014.

852 Knome, <http://www.knome.com/knome-blog/direct-to-consumer-genomics-reinvents-itself/> accessed 10 August 2013. [Checked again 16 April 2014].

853 PerioPredict™, 'What is PerioPredict™?' <http://periopredict.com/patient/about.php> accessed 15 April 2014.

companies located in Texas are: Gene by Gene; DNA DTC; and DNA Traits. It should be noted that Gene By Gene in fact owns both these latter companies.

Five companies specify that English or UK law should govern, whereas there are actually 11 companies located in the UK. The companies that choose for their disputes to be governed by English law are: BioClinics; DNAFit; DNA Genie; International Biosciences; and Test Diagnostics. The companies which are in fact located in the UK, but which do not specify their jurisdiction of choice in their contracts are: BioClinics (Genetic Health Management); easyDNA; Genetic Health; ION (Institute for Optimal Nutrition); Matt Roberts; My Gene Diet (Natures Remedies Ltd); and Nimble Diagnostics.

The two companies that are in fact located in Germany (Bio Logis and Genosense) both specify German law as their jurisdiction of choice. Of the two companies located in Slovenia, GenePlanet and LifeGenetics, LifeGenetics specifies that Slovenian law should govern disputes, whereas GenePlanet relies on Irish law.

There are 9 companies actually located in Australia. However, all 9 companies either have no terms available or no choice of law, so no available contract specifies Australian law as its jurisdiction of choice. The companies based in Australia are: Darwin Dieticians[855]; DNA Bioservices[856]; DNAFit[857]; FitGenes[858]; Lumigenix[859]; Molecular Diagnostic Services (PTY) LTD[860]; MyGene[861]; Remede[862]; Smart DNA[863].

---

854 Progenika Inc, <http://www.progenika.com/us/index.php> [Checked again 29 January 2014 and still operating]. [Checked again 24 April 2014].

855 Darwin Dietitians, <http://www.darwindietitians.com.au> accessed 22 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 10 April 2014]. [Checked again 28 September 2014].

856 DNA Bioservices, <http://www.dnabioservices.com.au/> accessed 13 May 2014. [Checked again 28 September 2014].

857 DNAFit, <http://www.dnafit.com/uk/> accessed 15 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 11 April 2014]. [Checked again 28 September 2014].

858 FitGenes, <http://www.fitgenes.com> accessed 27 January 2014. [Checked again 28 January 2014 and still operating]. [Checked again 14 April 2014]. [Checked again 28 September 2014].

Similarly, no companies based in Canada specify that Canadian law should govern their disputes. This is despite the fact that there are four companies located in Canada. These are: Accu-metrics Viaguard; C2DNA (Canadian Centre for DNA Diagnostics)[864]; DNA Testing Centres of Canada[865]; and YOUology[866].

(ii.) Examples of jurisdiction clauses

23andMe specifies its forum of choice in section 28 (b) of its Terms of Service:

> Applicable law and arbitration.
>
> Except for any disputes relating to intellectual property rights, obligations, or any infringement claims, any disputes with 23andMe arising out of or relating to the Agreement ("Disputes") shall be governed by California law regardless of your country of origin or where you access 23andMe, and notwithstanding of any conflicts of law principles and the United Nations Convention for the International Sale of Goods. Any Disputes shall be resolved by final and binding arbitration under the rules and auspices of the American Arbitration Association, to be held in San Francisco, California, in English (…)[867]

Although DNA DTC specifies a different jurisdiction as its forum of choice, the wording of section 21 in its Terms and Conditions is remarkably similar:

> Applicable law and arbitration.

---

859 Note: this company no longer appears to be operating.

860 Molecular Diagnostic Services (PTY) LTD, <http://www.mdsafrica.net/site/default.asp> accessed 27 January 2014. [Checked again 28 September 2014].

861 My Gene, <http://www.mygene.com.au> accessed 13 August 2013. [Checked again 29 January 2014 and website suspended]. [Checked again 22 April 2014]. [Checked again 28 September 2014].

862 Remede, <http://remede.com.au/dna-profiles-nutrigenomics/> accessed 7 April 2014. [Checked again 24 April 2014]. [Checked again 28 September 2014].

863 Smart DNA, <http://www.smartdna.net.au/howitworks.html> accessed 13 August 2013. [Checked again 28 September 2014].

864 C2DNA, <http://www.c2dna.com/index.html> accessed 28 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 10 April 2014]. [Checked again 28 September 2014].

865 DNA Testing Centres of Canada, <http://dnatestingcanada.com/about-us/> accessed 7 April 2014. [Checked again 12 April 2014]. [Checked again 28 September 2014].

866 YOUology, <http://www.youology.com/about-youology.html> accessed 7 April 2014. [Checked again 24 April 2014]. [Checked again 28 September 2014].

867 23andMe, TOS

> Except for any disputes relating to intellectual property rights, obligations, or any infringement claims, any disputes with DNA DTC arising out of or relating to the Agreement ("Disputes") shall be governed by Texas law regardless of your country of origin or where you access DNA DTC, and notwithstanding of any conflicts of law principles and the United Nations Convention for the International Sale of Goods. Any Disputes shall be resolved by final and binding arbitration under the rules and auspices of the American Arbitration Association, to be held in Houston, Texas, in English, with a written decision stating legal reasoning issued by the arbitrator(s) at either party's request, and with arbitration costs and reasonable documented attorneys' costs of both parties to be borne by the party that ultimately loses. Either party may obtain injunctive relief (preliminary or permanent) and orders to compel arbitration or enforce arbitral awards in any court of competent jurisdiction.[868]

(c) Indemnity clauses

(i.) Summary of review of indemnity clauses

Broad indemnity clauses are also very common in DTCGT contracts with 44% of companies requiring the consumer to indemnify the company. Overall 37% of companies go so far as to require the consumer to indemnify the company against third party actions, which might arise through the consumer sharing test results with a healthcare practitioner.

In accordance with the CMA's *Draft Guidance* and its *Final Guidance* it is likely that such indemnity clauses would be deemed unfair, as they either allow a company to protect itself from the consequences of its negligence 'or (…) transfer a risk to the consumer when the business can insure against it and the consumer cannot'.[869] These terms are also dealt with in the Grey List of the CRA in sections 10 and 11 of Schedule 2.

(ii.) Examples of indemnity clauses

Again the clauses of the most prominent DTCGT companies are remarkably similar and particularly broad in scope. It should be noted that were 23andMe's clause to be effective

---

868 DNA DTC, T&C– Individual User

869 (CMA) paras 82-3.

it would require the consumer to indemnify its affiliates, which would now include its pharmaceutical partners together with the other platforms it has purchased such as Cure Together.

23andMe's section 14 of its Terms of Services specifies that:

> You agree to defend and hold 23andMe, and its subsidiaries, affiliates, officers, agents, contractors, partners, employees, successors, and assigns harmless from any claim, or demand, including reasonable attorneys' fees, made by any third party due to or arising out of User Content you submit, post to, or transmit through the Service; your use of the Service; your connection to the Service; your violation of the TOS; or your violation of any rights of another. If you have submitted a saliva sample or otherwise provided your own Genetic Information, you will defend and hold harmless 23andMe, its employees, contractors, successors, and assigns from any liability arising out of the use or disclosure of any information obtained from genotyping your saliva sample and/or analysing your Genetic Information, which is disclosed to you consistent with our Privacy Statement or results from any third-party add-ons to tools we provide. In addition, if you choose to provide your Genetic and/or Self-Reported Information to third parties – whether individuals to whom you facilitate access, intentionally or inadvertently, or to third parties for diagnostic or other purposes - you agree to defend and hold harmless 23andMe, its employees, contractors, successors, and assigns from any and all liability arising from such disclosure or use of your Genetic and/or Self-Reported Information.[870]

DNA DTC's clause contained in Terms and Conditions closely resembles that of 23andMe:

> 7. Indemnity
>
> You agree to defend and hold DNA DTC, and its subsidiaries, affiliates, officers, agents, contractors, partners, employees, successors, and assigns harmless from any claim, or demand, including reasonable attorneys' fees, made by any third party due to or arising out of any information you submit, misuse of the results delivered to you, violation of the Terms and Conditions, or your violation of any rights of another party. If you have submitted a saliva sample or otherwise provided your own personal information, you will defend and hold harmless DNA DTC, its employees, contractors, successors, and assigns from any liability arising out of the use or disclosure of any information obtained from genotyping your saliva sample and/or analyzing your results, which is disclosed to you consistent

[870] 23andMe, TOS

> with our Privacy Statement or results from any third-party add-ons to tools we provide. In addition, if you choose to provide your results and personal information to third parties – whether individuals to whom you facilitate access, intentionally or inadvertently, or to third parties for diagnostic or other purposes - you agree to defend and hold harmless DNA DTC, its employees, contractors, successors, and assigns from any and all liability arising from such disclosure or use of your results and personal information.[871]

Similarly, section 13 of myDNA's Terms and Conditions reads as follows:

> If you have submitted a DNA sample or otherwise provided your own Genetic Information, you will defend and hold harmless myDNA, its employees, contractors, successors, and assigns from any liability arising out of the use or disclosure of any information obtained from genotyping your DNA sample and/or analysing your Genetic Information, which is disclosed to you (…)
>
> In addition, if you choose to provide your Genetic and/or Self-Reported Information to third parties - whether individuals to whom you facilitate access, intentionally or inadvertently, or to third parties for diagnostic or other purposes - you agree to defend and hold harmless myDNA, its employees, contractors, successors, and assigns from any and all liability arising from such disclosure or use of your Genetic and/or Self-Reported Information.[872]

Likewise, C2DNA includes the following clause in its Terms of Use:

> You expressly agree that use of this Site is at your sole risk and agree to indemnify, hold harmless and defend C2DNA and its respective directors, officers, employees, consultants and agents from and against any and all losses, claims, demands, expenses (including lawyers fees) or liabilities of whatever nature or kind asserted by, suffered or incurred by third parties arising out of your use of the content on this Site.[873]

(d) Exclusion clauses

(i.) Summary of review of exclusion clauses

Overall, exclusion clauses broadly disclaiming liability are very common with 80% of companies including such a clause. 14% of DTCGT company contracts examined herein disclaim liability for personal injury or death caused by their negligence.[874] This is a term

---

871 DNADTC, T&C

872 myDNA, T&C

873 C2DNA, TOU

874 These are: Asper Biotech; BioClinics; DDC Diagnostics Centre; DeCODEme; DNA Traits (owned by Gene By Gene); Test Diagnostics; and The Makings of Me.

of a type that is blacklisted in section 65 of the Consumer Rights Act and is consequently automatically void and unenforceable.

Meanwhile, 38% of companies disclaim liability for fitness for purpose and 44% specify that their services are provided on an 'as is' basis and 30% also specify that they provide 'no warranty' for their services.[875] It is quite likely that many of the terms of this type would be deemed to be unfair in accordance with the Act. Specifically, the Act implies certain terms into consumer contracts which include that contract for either the supply of services, goods, or digital content must in fact be 'fit for purpose' clauses disclaiming liability for 'fitness for purpose' are likely to be unenforceable. Section 10 requires that goods must be fit for a particular purpose and section 31 includes this as a type of liability that cannot be excluded in section 31 (1)(b).

(ii.) Examples of disclaimer clauses

23andMe's disclaimer clauses are to be found in section 7 and section 23 of its Terms of Service. Section 7 reads as follows:

> Account Creation, Customer Account, Password, and Security Obligations
>
> After you have purchased our Service, you will create a password and account designation. You are responsible for maintaining the confidentiality of the password and account, and are fully responsible for all activities that occur under your password or account. If you allow third parties to access 23andMe's website through your username and password, you will defend and indemnify 23andMe and its affiliates against any liability, costs, or damages, including attorney fees, arising out of claims or suits by such third parties based upon or relating to such access and use. You agree to (a) immediately notify 23andMe of any unauthorized use of your password or account or any other breach of security, and (b) ensure that you exit from your account at the end of each session. 23andMe cannot and will not be liable for any loss or damage arising from your failure to comply with this Section.[876]

Section 23 reads:

---

875 Phillips, 'Think Before You Click Ordering A Genetic Test Online'

876 23andMe, TOS

Disclaimer of Warranties YOU EXPRESSLY ACKNOWLEDGE AND AGREE THAT: (1) YOUR USE OF THE SERVICES ARE AT YOUR SOLE RISK. THE SERVICES ARE PROVIDED ON AN "AS IS" AND "AS AVAILABLE" BASIS. 23ANDME EXPRESSLY DISCLAIMS ALL WARRANTIES OF ANY KIND, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NONINFRINGEMENT. (2) 23ANDME MAKES NO WARRANTY THAT (a) THE SERVICES WILL MEET YOUR REQUIREMENTS; (b) THE SERVICES WILL BE UNINTERRUPTED, TIMELY, UNFAILINGLY SECURE, OR ERRORFREE; (c) THE RESULTS THAT MAY BE OBTAINED FROM THE USE OF THE SERVICES WILL BE ACCURATE OR RELIABLE; (d) THE QUALITY OF ANY PRODUCTS, SERVICES, INFORMATION, OR OTHER MATERIAL PURCHASED OR OBTAINED BY YOU THROUGH THE SERVICES WILL MEET YOUR EXPECTATIONS AND (e) ANY ERRORS IN THE SOFTWARE WILL BE CORRECTED. (3) ANY MATERIAL DOWNLOADED OR OTHERWISE OBTAINED THROUGH THE USE OF THE SERVICES IS DONE AT YOUR OWN DISCRETION AND RISK AND THAT YOU WILL BE SOLELY RESPONSIBLE FOR ANY DAMAGE TO YOUR COMPUTER SYSTEM OR LOSS OF DATA THAT RESULTS FROM THE DOWNLOAD OF ANY SUCH MATERIAL. (4) NO ADVICE OR INFORMATION, WHETHER ORAL OR WRITTEN, OBTAINED BY YOU FROM 23ANDME OR THROUGH OR FROM THE SERVICES SHALL CREATE ANY WARRANTY NOT EXPRESSLY STATED IN THE TOS. (5) YOU SHOULD ALWAYS USE CAUTION WHEN GIVING OUT ANY PERSONALLY IDENTIFYING INFORMATION ABOUT YOURSELF OR THOSE FOR WHOM YOU HAVE LEGAL AUTHORITY. 23ANDME DOES NOT CONTROL OR ENDORSE ANY ACTIONS RESULTING FROM YOUR PARTICIPATION IN THE SERVICES AND, THEREFORE, 23ANDME SPECIFICALLY DISCLAIMS ANY LIABILITY WITH REGARD TO ANY ACTIONS RESULTING FROM YOUR PARTICIPATION IN THE SERVICES.24. Limitation of Liability WITHIN THE LIMITS ALLOWED BY APPLICABLE LAWS, YOU EXPRESSLY ACKNOWLEDGE AND AGREE THAT 23ANDME SHALL NOT BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, SPECIAL, CONSEQUENTIAL, OR EXEMPLARY DAMAGES, INCLUDING BUT NOT LIMITED TO, DAMAGES FOR LOSS OF PROFITS, GOODWILL, USE, DATA OR OTHER INTANGIBLE LOSSES (EVEN IF 23ANDME HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES), RESULTING FROM: (a) THE USE OR THE INABILITY TO USE THE SERVICES; (b) ANY ACTION YOU TAKE BASED ON THE INFORMATION YOU RECEIVE IN THROUGH OR FROM THE SERVICES, (v) YOUR FAILURE TO KEEP YOUR PASSWORD OR ACCOUNT DETAILS SECURE AND CONFIDENTIAL, (d) THE COST OF PROCUREMENT OF SUBSTITUTE GOODS AND SERVICES RESULTING FROM ANY GOODS, DATA, INFORMATION, OR SERVICES PURCHASED OR

> OBTAINED OR MESSAGES RECEIVED OR TRANSACTIONS ENTERED INTO THROUGH OR FROM THE SERVICES; (e) UNAUTHORIZED ACCESS TO OR ALTERATION OF YOUR TRANSMISSIONS OR DATA; (f) THE IMPROPER AUTHORIZATION FOR THE SERVICES BY SOMEONE CLAIMING SUCH AUTHORITY; or (g) STATEMENTS OR CONDUCT OF ANY THIRD PARTY ON THE SERVICES.[877]

Meanwhile, Counsyl's clause is included in section 11 of their Terms of Service:

> YOU EXPRESSLY UNDERSTAND AND AGREE THAT COUNSYL SHALL NOT BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, SPECIAL, CONSEQUENTIAL, OR EXEMPLARY DAMAGES, INCLUDING BUT NOT LIMITED TO, DAMAGES FOR LOSS OF PROFITS, GOODWILL, USE, DATA OR OTHER INTANGIBLE LOSSES (EVEN IF COUNSYL HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES), RESULTING FROM: (1) THE USE OR THE INABILITY TO USE THE SERVICES; (2) ANY ACTION YOU TAKE BASED ON THE INFORMATION YOU RECEIVE THROUGH OR FROM THE SERVICES; (3) YOUR FAILURE TO KEEP YOUR PASSWORD OR ACCOUNT DETAILS SECURE AND CONFIDENT; (4) THE COST OF PROCUREMENT OF SUBSTITUTE GOODS AND SERVICES RESULTING FROM ANY GOODS, DATA, INFORMATION, OR SERVICES PURCHASED OR OBTAINED OR MESSAGES RECEIVED OR TRANSACTIONS ENTERED INTO THROUGH OR FROM THE SERVICES; (5) UNAUTHORIZED ACCESS TO OR ALTERATION OF YOUR TRANSMISSIONS OR DATA; OR (6) THE STATEMENTS OR CONDUCT OF ANY THIRD PARTY ON THE SITE OR IN CONNECTION WITH THE SERVICES. SOME JURISDICTIONS DO NOT ALLOW THE EXCLUSION OF CERTAIN WARRANTIES OR THE LIMITATION OR EXCLUSION OF LIABILITY FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES. ACCORDINGLY, SOME OF THE LIMITATIONS DESCRIBED IN SECTIONS 10 AND 11 MAY NOT APPLY TO YOU.[878]

---

877 23andMe, TOS

878 Counsyl, TOS

(e) Arbitration Clauses

(i.) Summary of review of arbitration clauses

Arbitration clauses are often included in wrap contracts and these are normally included in order to place limitations on how disputes between consumers and companies are to be resolved. Often these clauses will specify that any disputes must be resolved through arbitration proceedings and they will also specify the jurisdiction where claims should be brought. While most clickwrap and browsewrap contract disputes have centred on such clauses,[879] only 13% (9) out of 71 companies reviewed actually include such a clause. This can be compared with 15% (10) out of 68 for ancestry testing companies. However, although they may not be particularly common, 23andMe does include such a clause and this clause has been central to the class action litigation against 23andMe previously mentioned in chapter four.

The nine companies which include arbitration clauses are: 23andMe; Any Lab Test Now; Counsyl; DNA DTC (owned by Gene By Gene); DNA Spectrum; Foundation Medicine Inc; Genetic Testing Laboratories Inc; myDNA; and Pathway Genomics. Overall, the clauses are very similar in their wording, despite differences in the jurisdiction specified for where claims are to be brought. Of these 9, 4 specify that the proceedings are to be brought in the state of California, with 23andMe and myDNA allowing for claims to be brought in San Francisco. Pathway specifies San Diego and Counsyl specifies Santa Clara County. Of the other 5, 4 specify another American state as their venue of choice. Only one, Foundation Medicine, does not limit the jurisdiction,

[879] Manwaring (n 773) 13

allowing for dispute resolution to be 'facilitated by the International Centre for Dispute Resolution/ American Arbitration Association'.[880]

(ii.) Examples of arbitration clauses

What follows is the text of the arbitration clauses of 23andMe, Any Lab Test Now (which relies on PayPal's User Agreement), Counsyl, DNA DTC, and Pathway Genomics. 23andMe's arbitration clause is contained in section 28(b) of its Terms of Service:

> Applicable law and arbitration. Except for any disputes relating to intellectual property rights, obligations, or any infringement claims, any disputes with 23andMe arising out of or relating to the Agreement ("Disputes") shall be governed by California law regardless of your country of origin or where you access 23andMe, and notwithstanding of any conflicts of law principles and the United Nations Convention for the International Sale of Goods. Any Disputes shall be resolved by final and binding arbitration under the rules and auspices of the American Arbitration Association, to be held in San Francisco, California, in English, with a written decision stating legal reasoning issued by the arbitrator(s) at either party's request, and with arbitration costs and reasonable documented attorneys' costs of both parties to be borne by the party that ultimately loses. Either party may obtain injunctive relief (preliminary or permanent) and orders to compel arbitration or enforce arbitral awards in any court of competent jurisdiction.[881]

Any Lab Test Now relies on the PayPal User Agreement and the relevant sections are 14 (3)(a) – (c):

> Agreement to Arbitrate. You and PayPal each agree that any and all disputes or claims that have arisen or may arise between you and PayPal shall be resolved exclusively through final and binding arbitration, rather than in court, except that you may assert claims in small claims court, if your claims qualify. The Federal Arbitration Act governs the interpretation and enforcement of this Agreement to Arbitrate. Agreement to Arbitrate.
>
> a. Prohibition of Class and Representative Actions and Non-Individualized Relief. (…)
>
> b. Arbitration Procedures.

---

880 Foundation Medicine, TOU

881 23andMe, TOS

Arbitration is more informal than a lawsuit in court. Arbitration uses a neutral arbitrator instead of a judge or jury, and court review of an arbitration award is very limited. However, an arbitrator can award the same damages and relief on an individual basis that a court can award to an individual. An arbitrator also must follow the terms of this User Agreement as a court would. The arbitration will be conducted by the American Arbitration Association ("AAA") under its rules and procedures, including the AAA's Supplementary Procedures for Consumer-Related Disputes (as applicable), as modified by this Agreement to Arbitrate. The AAA's rules are available at www.adr.org. A form for initiating arbitration proceedings is available on the AAA's website at http://www.adr.org. The arbitration shall be held in the county in which you reside or at another mutually agreed location. If the value of the relief sought is $10,000 or less, you or PayPal may elect to have the arbitration conducted by telephone or based solely on written submissions, which election shall be binding on you and PayPal subject to the arbitrator's discretion to require an in-person hearing, if the circumstances warrant. Attendance at an in-person hearing may be made by telephone by you and/or PayPal, unless the arbitrator requires otherwise.

The arbitrator will decide the substance of all claims in accordance with the laws of the State of Delaware, including recognized principles of equity, and will honor all claims of privilege recognized by law. The arbitrator shall not be bound by rulings in prior arbitrations involving different PayPal users, but is bound by rulings in prior arbitrations involving the same PayPal user to the extent required by applicable law. The arbitrator's award shall be final and binding, and judgment on the award rendered by the arbitrator may be entered in any court having jurisdiction thereof.

c. Costs of Arbitration.

Payment of all filing, administration, and arbitrator fees will be governed by the AAA's rules, unless otherwise stated in this Agreement to Arbitrate. If the value of the relief sought is $10,000 or less, at your request, PayPal will pay all filling, administration, and arbitrator fees associated with the arbitration. Any request for payment of fees by PayPal should be submitted by mail to the AAA along with your Demand for Arbitration and PayPal will make arrangements to pay all necessary fees directly to the AAA. If the value of the relief sought is more than $10,000 and you are able to demonstrate that the costs of arbitration will be prohibitive as compared to the costs of litigation, PayPal will pay as much of the filing, administration, and arbitrator fees as the arbitrator deems necessary to prevent the arbitration from being cost-prohibitive. In the event the arbitrator determines the claim(s) you assert in the arbitration to be frivolous, you agree to reimburse PayPal for all fees associated with the arbitration paid by PayPal on your behalf that you otherwise would be obligated to pay under the AAA's rules.

e. Opt-Out Procedure.

You can choose to reject this Agreement to Arbitrate ("opt out") by mailing us a written opt-out notice ("Opt-Out Notice"). For new PayPal

users, the Opt-Out Notice must be postmarked no later than 30 Days after the date you accept the User Agreement for the first time. If you are already a current PayPal user and previously accepted the User Agreement prior to the introduction of this Agreement to Arbitrate, the Opt-Out Notice must be postmarked no later than December 1, 2012.[882]

Counsyl's Terms of Service includes the following clause:

15. General Legal Term

These Terms and any Counsyl Informed Consent that you have agreed to, constitute the entire agreement between Counsyl and you (this "Agreement"); provided, however, that certain provisions of these Terms may be superseded by expressly designated legal notices or terms located on particular pages within this Site. This Agreement and the resolution of any dispute related to this Agreement, including your use and access to Site, the Services, your Results or any other Content shall be governed by and construed in accordance with the laws of California, without regard to its conflicts of law principles. Any legal action or proceeding between Counsyl and you related to this agreement will be governed exclusively by the laws of the state of California. Any dispute, claim, or controversy in connection with or arising under the use of our Service or this agreement, its construction, existence, interpretation, validity, or any breach hereof which cannot be amicably settled between the parties, shall be finally and exclusively resolved by binding arbitration under the Rules of Arbitration of the American Arbitration Association then prevailing. The use of arbitration on an individual basis to resolve disputes is required; the right to class arbitrations and class actions is waived under the terms of this Agreement. The arbitration proceedings shall be held in Santa Clara County, California, U.S.A.; the intentions of the parties as stated herein, international commercial practice, and the governing law of this agreement.[883]

DNA DTC's clause in its Terms and Conditions reads as follows:

Applicable law and arbitration.

Except for any disputes relating to intellectual property rights, obligations, or any infringement claims, any disputes with DNA DTC arising out of or relating to the Agreement ("Disputes") shall be governed by Texas law regardless of your country of origin or where you access DNA DTC, and notwithstanding of any conflicts of law principles and the United Nations Convention for the International Sale of Goods. Any Disputes shall be resolved by final and binding arbitration under the rules and auspices of

882 Any Lab Test Now, Agreement
883 Counsyl, TOS

> the American Arbitration Association, to be held in Houston, Texas, in English, with a written decision stating legal reasoning issued by the arbitrator(s) at either party's request, and with arbitration costs and reasonable documented attorneys' costs of both parties to be borne by the party that ultimately loses. Either party may obtain injunctive relief (preliminary or permanent) and orders to compel arbitration or enforce arbitral awards in any court of competent jurisdiction.[884]

Pathway Genomics' clause:

> All disputes between Pathway and you arising under these Terms and Conditions shall be decided by arbitration in accordance with the rules of the American Arbitration Association by a single arbitrator in San Diego, California, U.S. The award rendered by the arbitrator shall be final. In the event of any legal action or proceeding related to this website, such action or proceeding shall be brought exclusively in a federal or state court of competent jurisdiction sitting in California.[885]

(f) Consent, Assent, and Acceptance of Terms

(i.) Summary of review of consent, assent, and acceptance clauses

It should also be noted that consent, assent, and acceptance of contractual terms are quite separate things. These concepts are covered in greater depth in the next chapter. Consent and assent and/or acceptance are often conflated in the contracts and privacy policies of DTCGT companies. This conflation is another factor highlighting the consequences of the paradigm shift from patient to consumer in the DTCGT context. In a clinical or research setting the emphasis is normally on obtaining valid consent and a patient will be asked to provide appropriate consent before undergoing any form of medical treatment. Likewise, a research participant is also required to give adequate consent to participate in research. As previously mentioned: the Human Tissue Act also sets requirements for consent and creates an offence for non-consensual DNA analysis. This means that DTCGT companies that are not meeting appropriate standards may face prosecution; and

884 DNA DTC, T&C
885 Pathway Genomics, T&C

the recent ruling in *Montgomery v Lanarkshire Health Board*[886] may mean that DTCGT companies providing tests for health purposes or engaging in health research may need to have better consent mechanisms and provide more comprehensive information to their consumers. Prior to the advent of DTCGT patients were also expected to provide appropriate consent before undergoing genetic testing and also undergo pre and post-test genetic counselling. This continues to be a requirement of genetic testing carried out in a clinical setting.

In contrast, in a normal commercial setting where terms are agreed upon in a contract, the emphasis in contract law has been on demonstrating assent or acceptance of the terms of the contract and what constitutes that assent or acceptance. Of the 71 companies with terms available, 31% do not have specific clauses addressing consent. The remaining 69% (49 companies) do have some clause addressing consent or acceptance of terms.[887] However, consent and assent are often treated as synonymous in DTCGT contracts and the way in which both are treated in the contracts is problematic. For instance, of the 49 companies, 53% deem either acceptance, agreement or consent to their terms merely through use or viewing of the website (this is representative of 35% of the total 71 companies examined). 22% have clauses deeming acceptance or agreement and 13% have clauses deeming consent.

The companies that include clauses that deem acceptance of their terms or agreement with their terms through use or viewing of their website or services include: 23andMe; 23DNA; DNA Direct; easyDNA; GenePlanet; Genomic Health; GTL; GenoVive; Inherent Health; International Biosciences; Indian Biosciences; Map My Genome; My Gene Diet; myDNA; Personal Genome Diagnostics; Phenom; and VuGene.

886 (Scotland) [2015] UKSC 11; Mark Campbell, 'Montgomery v Lanarkshire Health Board' (2015) 44(3) Common Law World Review 222-228.

887 Phillips, 'Think Before You Click Ordering A Genetic Test Online'

The 9 companies that include clauses that deem consent through use or viewing of the website are: ARUP; Cancer Genetics Inc; DNADTC; DNA Spectrum; Genomic Health; Halo Health; Inherent Health; Life Genetics; and the Makings of Me.

Only 10 companies mention 'informed consent' anywhere in their contracts and privacy policies. These companies are: Counsyl; DeCODEme; DNA Spectrum; DNA Traits; easyDNA; GenePeeks; Gentle; Inherent Health; Map My Gene; and Navigenics.[888] Only a small minority of companies that have consent clauses also have separate consent documents. The best examples are: 23andMe; Gene by Gene's DNA DTC; Counsyl; Navigenics (which is no longer DTC); and myDNA.

In the context of DTCGT where test results may have relevance for a person's health, it seems unacceptable for companies to deem consent merely through use or visiting of the website, as visiting a website does not necessitate viewing of terms. It does seem desirable that more information and resources to assist with understanding contractual terms be provided and doing this on the web is not difficult or particularly costly.

There are several issues, which need to be considered in examining acceptance and consent mechanisms in the DTCGT context. These include: the level of consumers' understanding of terms in DTCGT contracts; whether they have in fact given consent to the contract; the limits of their consent – for instance have they provided adequate consent for their data be used in research and shared by the company with third parties; and whether the consumer has capacity to consent – for instance as genetic information is shared between family members, ought all relevant family members to give their consent before one individual is tested; an also whether they have in fact given valid assent or acceptance of terms It is submitted that the current practice of deeming either acceptance

888 Please note that Navigenics is no longer offering DTC services

or consent through viewing or visiting a website provides insufficient protection for consumers and unnecessarily favours companies. While in more conventional e-commerce this may be permissible to some extent DTCGT companies are collecting large amounts of potentially sensitive information from their consumers including information that would more usually be recorded in a patient's medical records.

Furthermore, in accordance with the provisions of the Consumer Rights Act it is likely that deemed consent or assent clauses might be deemed to be unfair terms in accordance with the Grey List in Schedule 2, as such terms seem to be within the remit of section 10 which deals with terms that have 'the object or effect of irrevocably binding the consumer to terms with which the consumer has had no real opportunity of becoming acquainted before the conclusion of the contract'.

(ii.) Examples of consent clauses

23andMe's Terms of Service includes the following clause in section 6:

> User Representations
>
> By accessing 23andMe Services, you agree to, acknowledge, and represent as follows:
>
> a. You understand that information you learn from 23andMe is not designed to diagnose, prevent, or treat any condition or disease or to ascertain the state of your health and that you understand that the 23andMe services are intended for research, informational, and educational purposes only. You acknowledge that 23andMe urges you to seek the advice of your physician or other health care provider if you have questions or concerns arising from your Genetic Information.
>
> 6 (i). You take responsibility for all possible consequences resulting from your sharing with others access to your Genetic Information and your Self-Reported Information.[889]

Meanwhile, 23andMe's Consent Document also covers how consent is to be manifested:

[889] 23andMe, TOS

1. What am I agreeing to if I consent?

Giving consent by checking the appropriate box below means that you agree to let 23andMe investigators use your Genetic & Self-Reported Information for 23andWe research, as described above.

"Genetic & Self-Reported Information" refers to:

Your genetic data

Information you enter into surveys and forms Information you enter via features labeled with the 23andWe research logo Data you authorize us to import for research Your age and ethnicity Self-Reported Information includes any information you submitted prior to giving consent. If you have elected to have your saliva sample stored, we may also use the results of further analysis of your sample in 23andWe research. To protect your privacy, your Genetic & Self-Reported Information does not include identifying Registration Information you provided when you purchased the Personal Genome Service® or created an account (such as name, address, email address, user ID, password, or credit card information).[890]

Whereas, DNA DTC's Consent Document contains the following clause:

From its inception, in April of 2000, DNADTC. (the "Company") through its first business unit, Family Tree DNA, opened the path for its customers to participate directly in the development of this field. Many of the advances that we have seen in the field of genetic genealogy and population genetics were a direct contribution of what is termed citizen science.

Along those lines, and as the Company started moving towards other areas of DNA testing which allows the discovery of health conditions, we believe that here as well, through RUO tests, individual consumers can play a significant role in advancing the discovery of genetic factors behind diseases and traits.

In view of that, by checking the box below, and by ordering an RUO DNA test for your own use, you agree to participate in the research and development initiatives as stated in the Company's and Terms and Conditions and Privacy Document below[891]

(iii.) Examples of acceptance clauses

DNA DTC in its Terms and Conditions covers its requirements for acceptance of terms:

DNADTC.com is a division of DNADTC Ltd, ("Company"). DNADTC.com is in the business of providing Research Use Only (RUO) DNA tests. This document has the purpose of informing about the DNADTC.com's Terms and Conditions as it relates to your record,

890 23andMe, Consent

891 DNA DTC, Consent Document

information and test results. This document supplements the content of the Company general Terms and Conditions.

The tests offered by DNADTC.com are processed in the Company's own lab, the Genome Research Center in Houston, TX. Before using DNADTC.com services or website, you must review and accept this and the general Agreement containing your rights and responsibilities as a user of the website and services operated and offered by DNADTC.com.

If you do not agree with any provision of this Agreement, you must not use the website and services offered by DNADTC.com.

8. Use and Storage

DNA DTC may establish limits concerning the maximum number of days that your results will be retained by the Company, the maximum disk space that will be allotted on the Company's servers on your behalf. You acknowledge and agree that DNA DTC has no responsibility or liability for the deletion of or failure to store any of your results or for the loss of those results due to malfunction or destruction of data servers or other catastrophic events.[892]

Inherent Health includes the following clause in its Privacy Policy:

NOTICE TO VISITORS OUTSIDE OF THE UNITED STATES

You should be aware that the United States and other countries have not harmonized their privacy regulations. Because Interleukin and its servers is located in the United States, we have written our Privacy Policy to satisfy United States regulations. By registering as a customer, you expressly agree to the transfer into and out of the United States and the use of your personally identifiable information as necessary to provide the services that you request. You also agree to the level of privacy protection set out in this Privacy Policy.[893]

Meanwhile DNA Direct in section 15 of its Terms of Use includes the following clause:

(…) You and DNA Direct expressly agree to submit to the exclusive jurisdiction and venue of the courts in California in all disputes arising out of or relating to the use of this Service.[894]

(iv.) Examples of deemed consent clauses

ARUP's Online Privacy Policy:

Your Consent

892 DNA DTC, T&C
893 Inherent Health, Privacy
894 DNA Direct, TOU

> By visiting and using ARUP's website and the contents therein, you consent to the collection, use, and disclosure of information as described in this policy.[895]

23DNA's Privacy Policy:

> Our computer systems are currently based in the United States, so your personal data will be processed by us in the United States. As a visitor from outside the United States, by using the Site you agree to this privacy policy and you consent to the transfer of all such information to the United States and to the processing of that information as described in this privacy policy.[896]

(v.) Examples of deemed acceptance clauses

The Makings of Me includes two clauses deeming consent. These are contained in section 6 of its Terms of Use and a section of its Privacy Policy. Section 6 reads:

> By using this Site and/or any of its Services, you agree to these Terms, including any modifications we make, and further waive any rights or claims you may have against us.[897]

And its Privacy Policy includes the following section:

> What if you do not agree with our Privacy Policy?
>
> By visiting our website and voluntarily providing personal information to the website, you agree to the terms of the online Terms of Use Agreement and this Privacy Policy. (…)[898]

Whereas Perkin Elmer includes the following clause:

> By using this site or downloading materials from this site, you agree to these terms and conditions. If you do not agree to be bound by these terms and conditions, please do not use this site or download materials from this site.[899]

Genomic Health in its section on Governing Law includes the following:

> By choosing to visit our Websites or otherwise provide information to Genomic Health, you agree (…)[900]

---

895 Arup, Privacy
896 23DNA, Privacy
897 The Makings of Me, TOU
898 The Makings of Me, Privacy
899 Perkin Elmer, T&C
900 Genomic Health Inc, Legal

(g) Scope of purpose

(i.) Summary of review of scope of purpose clauses

While in the context of DTCGT conducted for purposes that are not health related, it may appear reasonable that a company is not providing medical advice or medical information, the situation is less clear where tests are carried out for health purposes. This is accentuated when DTCGT companies are also engaged in medical research, which as previously noted is true of all the most prominent DTCGT companies.

Of the 71 companies examined, 51% have clauses of this type. Of these 12 companies specifically state that their services are provided for 'informational purposes'. 45% of companies overall include a statement indicating that they do not provide or intend to provide medical advice with 15% also stating that their services are not intended to be a substitute for medical advice and 27% indicate in some way that their services are not intended as medical advice. Three companies specifically use the phrase 'we do not provide medical advice' (23andMe, DNA DTC, and The Makings of Me). 20% mention that their services are not intended as diagnoses.

It is likely that such terms may be deemed to be unfair under the CRA, as the Act implies obligations into contracts for services and the supply of digital content. Specifically, digital content, which in this case would include genetic test results, should be fit for purpose (section 35), should match description (section 36) and should be of satisfactory quality (section 34). In relation to scope of purpose clauses the provision requiring services section 36, which requires digital content to match description is key. In the context of DTCGT companies providing health tests, where website content encourages consumers to believe they are buying tests that have a medical purpose or

will be relevant for medical treatment decisions, a scope of purpose clause suggesting that services are not for medical purposes may be deemed to be unfair.

(ii.) Examples of scope of purpose clauses

23andMe's clause reads:

> 5. 23andMe Services are for research, informational, and educational use only. We do not provide medical advice.
> The Genetic Information provided by 23andMe is for research, informational, and educational use only. This means two things. First, many of the genetic discoveries that we report have not been clinically validated, and the technology we use, which is the same technology used by the research community, to date has not been widely used for clinical testing. Second, in order to expand and accelerate the understanding and practical application of genetic knowledge in health care, we invite all genotyped users to participate in 23andWe Research. Participation in such research is voluntary and based upon an IRB-approved consent document. As a result of the current state of genetic knowledge and understanding, our Services are for research, informational, and educational purposes only. The Services are not intended to be used by the customer for any diagnostic purpose and are not a substitute for professional medical advice. You should always seek the advice of your physician or other health care provider with any questions you may have regarding diagnosis, cure, treatment, mitigation, or prevention of any disease or other medical condition or impairment or the status of your health. 23andMe does not recommend or endorse any specific course of action, resources, tests, physician or other health care providers, drugs, biologics, medical devices or other products, procedures, opinions, or other information that may be mentioned on our website.[901]

DNA DTC's clause is remarkably similar:

> 1. (…) DNA DTC RUO tests are for research, informational and educational use only. We do not provide medical advice. In other words, some of the genetic information that is reported may have not been clinically validated, and the technology we use, which is the same technology used by the research community, to date has not been widely used for clinical testing. For this reason, our customers are encouraged to participate in DNA DTC's research initiatives that may contribute to a better understanding of the results of genetic testing. The use of DNA DTC services or website information is solely at your own risk.
> 2. Client Representations and Warranties.
> By accessing DNA DTC Services, you agree to, acknowledge, and represent as follows:
> You understand that information you learn from DNA DTC is not

[901] 23andMe, TOS

> designed to diagnose, prevent, or treat any condition or disease or to ascertain the state of your health and that the DNA DTC services are intended for research, informational, and educational purposes only. You acknowledge that DNA DTC urges you to seek the advice of your physician or other health care provider if you have questions or concerns arising from your Genetic Information.[902]

Meanwhile, the wording of Genetic Performance and Gonidio are also very similar. Genetic Performance's clause reads:

> It is not the intention of genetic performance to provide specific medical advice but rather to provide you with information to better understand your genetic predispositions. Specific medical advice will not be provided, and genetic performance urges you to consult with a qualified physician for diagnosis and for answers to your personal questions. (…)
> Individuals with specific concerns about their health status or genetic testing should consult with a doctor or a genetic counselor.[903]

Whereas, Gonidio's clause reads:

> It is not the intention of Gonidio to provide specific medical advice but rather to provide you with information to better understand the health risks and benefits associated with your genotype. Specific medical advice will not be provided, and Gonidio urges you to consult with a qualified physician for diagnosis and for answers to your personal questions. (…)
>
> Individuals with specific concerns about their health status or genetic testing should consult with a doctor or a genetic counselor.[904]

(h) Property and Intellectual Property

(i.) Summary of review of intellectual property and property clauses

It is also common for companies to include broad clauses on intellectual property and property more generally, such as a clause waiving the consumers' property rights in their genetic information. While a person does not normally retain property rights in their excised tissue or DNA there are important privacy[905] and security issues raised by

---

902 DNA DTC, T&C

903 Genetic Performance, T&C

904 Gonidio, TOS

905 Hsiao-Ying Huang, and Masooda Bashir, 'Direct-to-consumer genetic testing: contextual privacy predicament' Proceedings of the 78th ASIS&T Annual Meeting: Information Science

DTCGT companies' use, storage, and potential sharing or sale of consumers' data. These clauses as currently framed are often unnecessarily broad in scope and are likely to fail the requirements of transparency under the CRA and the Unfair Terms Directive terms. They are also likely to be in breach of data protection law and not be consistent with the Human Tissue Act. As DTCGT companies are commercial entities and their main assets consist of the sequenced information collected from consumers together with their research ventures it seems that companies do need to be more transparent about the property rights they are allocating to themselves. At present, these clauses are very similar to the clauses used by social networking websites meaning that companies also often acquire licences to use user generated content, which in this context may actually include a person's health information and information which would normally be included in a medical record and which would ordinarily be subject to confidentiality protection. It is possible that at present many consumers are not necessarily aware of the implications, which such clauses may have upon their rights in their sequenced genetic information and other types of personal information.

(ii.) Examples of property waiver clauses

23andMe's Terms of Service includes the following clause:

> 6. (k). **Waiver of Property Rights:** You understand that by providing any sample, having your Genetic Information processed, accessing your Genetic Information, or providing Self-Reported Information, you acquire no rights in any research or commercial products that may be developed by 23andMe or its collaborating partners. You specifically understand that you will not receive compensation for any research or commercial products that include or result from your Genetic Information or Self-Reported Information.[906]

Meanwhile, Gene by Gene's DNA DTC's Terms and Conditions includes the following clauses:

---

with Impact: Research in and for the Community (2015) American Society for Information Science 50.

906 23andMe, TOS

2. **Client Representations and Warranties**

(…)Waiver of Property Rights: You understand that by providing any sample, having your sample processed, accessing your results, or providing personal information, you acquire no rights in any research or commercial products that may be developed by DNA DTC or its collaborating partners. You specifically understand that you will not receive compensation for any research or commercial products that include or result from your sample, results or personal record. You agree that you have the authority, under the laws of the state or jurisdiction in which you reside, to provide these representations. In case of breach of any one of these representations you will defend and indemnify the Company against any liability, costs, or damages arising out of the breach of the representation.

6. Your Proprietary Rights Your sample, once submitted to and analyzed by us, cannot be returned to you. Any test results derived from your sample remains your information, subject to rights as established under the Terms and Conditions and Privacy Statement. You understand that you should not expect any financial benefit from DNA DTC as a result of having your results processed; made available to you; or, as provided in our Privacy Statement and Terms of Service, shared with research partners, including commercial partners.

Waiver of Property Rights. As stated above, you understand that by providing any sample, having your sample processed, accessing your results, or providing personal information, you acquire no rights in any research or commercial products that may be developed by DNA DTC or its collaborating partners. You specifically understand that you will not receive compensation for any research or commercial products that include or result from your sample, results or personal record.[907]

(iii.) Examples of Intellectual Property clauses

23andMe's clause:

22. 23andMe's Proprietary Rights

You acknowledge and agree that 23andMe (or 23andMe's licensors, as applicable) own all legal right, title, and interest in and to the Services, including any intellectual property rights which subsist in the Services (whether those rights happen to be registered or not, and wherever in the world those rights may exist).

You further acknowledge that the Services may contain information which is designated confidential by 23andMe and that you shall not disclose such information without 23andMe's prior written consent. You further acknowledge and agree that the Services and any necessary software used in connection with the Services ("Software") contain proprietary and confidential information that is protected by applicable intellectual

907 DNA DTC, T&C

property and other laws. You further acknowledge and agree that information presented to you through the Services or sponsors is protected by copyrights, trademarks, service marks, patents, or other proprietary rights and laws. Except as expressly authorized by 23andMe, you agree not to-and not to permit anyone else to-modify, rent, lease, loan, sell, distribute, or create derivative works of, reverse engineer, decompile, or otherwise attempt to extract the source code of the Services or Software or any part thereof, in whole or in part. Software, if any, that is made available to download from the Services, excluding software that may be made available by end-users through the Services, is the copyrighted work of 23andMe and/or its suppliers. Your use of the Software is governed by the terms of the end user license agreement, if any, which accompanies or is included with the Software ("License Agreement"). You may not install or use any Software that is accompanied by or includes a License Agreement unless you first agree to the License Agreement terms. 23andMe, Inc., 23andMe, and other 23andMe logos and product and service names are trademarks of 23andMe and these marks together with any other 23andMe trade names, service marks, logos, domain names, and other distinctive brand features are the "23andMe Marks". Unless you have agreed otherwise in writing with 23andMe, other than through the Limited License in Section 9, nothing in the TOS gives you a right to use any 23andMe Marks and you agree not to display, or use in any manner, 23andMe Marks.

You agree that you shall not remove, obscure, or alter any proprietary rights notices (including copyright and trade mark notices) that may be affixed to or contained within the Services. Unless you have been expressly authorized to do so in writing by 23andMe, you agree that in using the Services, you will not use any trade mark, service mark, trade name, logo of any company or organization in a way that is likely or intended to cause confusion about the owner or authorized user of such marks, names, or logos. For any Software not accompanied by a License Agreement, 23andMe grants you a personal, non-transferable, and non-exclusive right and license to use the object code of its Software on a single computer. You may not (and may not allow any third party to) copy, modify, create a derivative work of, reverse engineer, reverse assemble, or otherwise attempt to discover any source code, sell, assign, sublicense, grant a security interest in, or otherwise transfer any right in the Software unless this is expressly permitted or required by law, or unless you have been specifically told that you may do so by 23andMe, in writing. This license is for the sole purpose of enabling you to use and enjoy the benefit of the Services as provided by 23andMe, in the manner permitted by the TOS. Unless 23andMe has given you specific written permission to do so, you may not assign (or grant a sublicense of) your rights to use the Software, grant a security interest in or over your rights to use the Software, or otherwise transfer any part of your rights to use the Software. You agree not to modify the Software in any manner or form, or to use modified versions of the Software, including (without limitation) for the purpose of obtaining unauthorized access to the Service. You agree not to access the Service by any means other than through the interface

that is provided by 23andMe for use in accessing the Service. Any rights not expressly granted herein are reserved.[908]

(iv.) Examples of licence clauses

23andMe includes the following clauses in its TOS:

> 9. Limited License
>
> You acknowledge that all User Content, whether publicly posted or privately transmitted, is the sole responsibility of the person from which such User Content originated. This means that you, and not 23andMe, are entirely responsible for all User Content that you upload, post, email, or otherwise transmit via the Service.
>
> You acknowledge that the Services content presented to you as part of the Services, whether original 23andMe Services content or sponsored content within the Services, is protected by copyright and/or other intellectual property rights that are owned by 23andMe and/or the sponsors who provide that content to 23andMe (or by other persons or companies on their behalf). 23andMe grants you a Limited License to copy and distribute free of charge, for noncommercial purposes only, any of the Services content with the exception of content from "MD's Perspectives" in the "For the Experts" section of the website and any other content marked as not subject to this Limited License on the website, provided you: (i) provide the Services content as it appears on the 23andMe website with no changes including but not limited to presenting selections which might tend to misrepresent the substance of the Services content; (ii) include the following attribution on the first page of any materials you distribute: © 23andMe, Inc. 2007- 2012. All rights reserved; distributed pursuant to a Limited License from 23andMe; (iii) agree you have no right to offer anyone else any further right with respect to this Services content. Aside from the Limited License provided in this paragraph, you may not modify, rent, lease, loan, sell, distribute, or create derivative works based on this Services content (either in whole or in part) unless you have been specifically told that you may do so by 23andMe or by the owners of that content, in a separate agreement.
>
> 13. Material Provided to 23andMe - Your Proprietary Rights
>
> **User Content**. 23andMe does not claim ownership of the User Content you provide to 23andMe (including feedback and suggestions) or post, upload, input, or submit to the Service. Unless otherwise specified, you retain copyright and any other rights you already hold over User Content that you create and submit, post, or display on or through the Services. However, by submitting, posting, or displaying User Content, you give 23andMe, its affiliated companies, sublicensees (including but not limited to sublicensees who avail themselves of the Limited License granted in

[908] 23andMe, TOS

> Section 9 above) and successors and assigns a perpetual, irrevocable, worldwide, royalty-free, and non-exclusive license to reproduce, adapt, modify, translate, publish, publicly perform, publicly display, distribute, reproduce, edit, reformat, and create derivative works from any User Content that you submit, post, or display on or through the Services. You acknowledge and agree that this license includes a right for 23andMe to make such User Content available to other companies, organizations, or individuals with whom 23andMe has relationships, and to use such User Content in connection with the provision of those services.
>
> You understand that 23andMe, in performing the required technical steps to provide the Services to our users, may (a) transmit or distribute your User Content over various public networks and in various media; and (b) make such changes to your content as are necessary to conform and adapt that content to the technical requirements of connecting networks, devices, services, or media. You acknowledge and agree that this license shall permit 23andMe to take these actions. You represent and warrant to 23andMe that you have all the rights, power, and authority necessary to grant the above license.[909]

The Makings of Me includes the following clause:

> **Waiver of Rights:** You agree to grant to Mapme a non-exclusive, worldwide, royalty-free, perpetual license, with the right to sublicense, to reproduce, distribute, transmit, create derivative works of, publicly display and publicly perform any materials and other information (including, without limitation, ideas contained therein for new or improved products or services) you submit to public areas of Mapme (such as BBSs, forums and chat rooms) by all means and in any media now known or hereafter developed. You hereby waive all rights, legal, moral or otherwise, in any such materials and information, and you hereby warrant that any such materials and information originate with you, or that you have the right to submit such materials and information. You agree that you shall have no recourse against Mapme for any alleged or actual infringement or misappropriation of any proprietary right in your public communication.[910]

DNA Spectrum's provision in the Intellectual Property clause of its TOS:

> While you retain any and all rights accruing to you with respect to your User-generated Content, you grant us, our agents and affiliates a worldwide, irrevocable, perpetual, non-exclusive, fully sub-licensable, transferable, royalty-free license to copy, reproduce, edit, adapt, modify, (publicly) display, publish, translate, distribute and otherwise use such content for any purpose in any existing or future form(s) or media.[911]

---

909 23andMe, TOS

910 The Makings of Me, TOU

911 DNA Spectrum, TOS

5 Conclusion

This chapter has presented a review of 71 contracts used by DTCGT companies engaged in the provision of health related services. As has been shown through the examples of actual clauses, there is overall a lack of transparency in the sense that DTCGT contractual terms may be construed not to be written in plain and intelligible language and maybe overly lengthy. There is also much commonality in the types of clauses used and also the language used by different companies, which might also indicate that companies are copying terms from their competitors. Companies may also be copying terms from other web-based industries, as many of the terms used resemble the contracts of companies engaged in other types of e-commerce. The similarities between different companies' contracts results in limitations on consumers' choices as it means that even where consumers are interested in purchasing genetic tests on terms that are more favourable, they may in fact find it difficult to find companies with better terms. Given this tendency it is hoped that the CMA will work with the industry to improve the terms or take enforcement action against it.

Certain types of terms commonly included in DTCGT contracts including: clauses allowing for unilateral variation of the contract; clauses disclaiming liability for fitness for purpose or for personal injury caused by the company's negligence; clauses limiting scope of purpose; clauses purporting to bind the consumer to resolve any disputes in another jurisdiction; and consent clauses are likely to be deemed unfair and regulators should take an interest in policing these terms. The frequency of these terms highlights the need for greater oversight of the industry and indicates that self-regulation may not be providing sufficient protection to consumers. It is also likely that consent mechanisms in particular may not be in compliance with either the Human Tissue Act or

the DPA and that where companies provide health tests they may in fact need to adhere to higher standards in line with the decision in *Montgomery*.[912]

The next chapter will consider legislation on unfair terms in the UK and how some terms commonly included in DTCGT contracts might be challenged on the grounds of potential unfairness under UK law. It is argued that many terms currently used do cause an imbalance in the rights of parties to the contract to the detriment of the consumer. It is also suggested that overall it is likely that many DTCGT contracts fail to meet the CRA's requirement for transparency and as transparency has also been frequently stressed in policy guidance, it is clear that there is a need for better practice.

It seems that in the context of the DTCGT industry the use of wrap contracts does need to be considered more carefully. As consumers are becoming habituated to agreeing to unseen terms online they are also likely to be underestimating any risks of potential harm from entering into such contracts.[913] While it might be argued that purchasing shoes on Amazon is not an activity likely to result in harm for that consumer, the DTCGT context is different and involves more potential risk. While an individual might provide quite significant amounts of personal information to a company when making an ordinary purchase online when a person orders a DTCGT she provides both a physical sample of herself and access to her genetic information. Genetic information can be used as a unique identifier of the individual tested, but it can also be used to identify her relatives. Where DTCGT companies are also engaged in health research they are also acquiring large amounts of health information about the consumer, which might be potentially sensitive and would normally only have been provided by the individual as part of medical treatment or participation in medical research. Given the length of DTCGT contracts and the language used it is possible that consumers will not necessarily

912 (Scotland) [2015] UKSC 11

913 Kim (n 227) 59

understand the legal information contained in these documents and they may also not be sufficiently cognizant of the implications of entering into a contract online.

Chapter Six – Understanding the Legal Significance of That Click

1 Introduction

The previous chapter reviewed the contracts of DTCGT companies providing tests for purposes, using a series of examples of terms from publicly available contracts. It suggested that several terms commonly included in DTCGT contracts are likely to be open to challenge on the grounds of potential unfairness under UK law. It also found that there was much similarity in the types of terms and the language used in DTCGT contracts, which is reflective of broader trends in the digital environment, where it is common for companies to copy terms from their competitors.[914] The present chapter begins with an overview of contract law as it relates to DTCGT contracts. It then examines how it might be possible to challenge certain types of terms included in DTCGT contracts on the grounds of their potential unfairness. It also discusses the newly formed Competition Markets Authority (CMA) and its potential role in improving DTCGT contracts through collaborating with the DTCGT industry or by challenging specific terms in the English courts, as its predecessor the Office of Fair Trading has successfully done. It examines the relevant provisions of the new Consumer Rights Act (CRA) and how these might impact upon the interpretation of specific terms included in DTCGT contracts. It also considers the previous unfair terms legislation and the Consumer Contracts (Information, Cancellation and Additional Charges) Regulations 2013.

Significantly, the CMA has recently completed a review of cloud service providers, assessing whether their contractual terms and business practices are in compliance with consumer protection law. For present purposes, their update on the compliance review lists a

914 ibid (n 227) 60- 61; and Radin (n 798) 41-2

number of types of terms and business practices that they are particularly concerned about. These include:

> terms that exclude or limit providers' liability for problems with their services;
>
> terms that allow providers to unilaterally vary contracts, prices and/or services;
>
> terms that allow providers to suspend or terminate services/contracts without notice to consumers;
>
> terms that provide for contracts to be automatically renewed;
>
> terms that require consumers to issue legal proceedings outside of their home country or apply non-UK law to contracts, such as a consumer having to make a claim in the US courts rather than in the UK; and
>
> the way some services are sold to consumers, eg customers are not always provided with necessary information before entering into the contract.[915]

In line with this update and the CMA's recent findings report for this compliance review, this chapter suggests that it is likely that the following types of terms commonly found in DTCGT contracts might be found to be in breach of consumer protection legislation, and specifically be deemed to be unfair terms. These terms are as follows:

- clauses allowing for unilateral variation of the contract;
- clauses disclaiming liability for fitness for purpose or for personal injury caused by the company's negligence;
- clauses limiting scope of purpose;
- clauses purporting to bind the consumer to resolve any disputes in another jurisdiction;
- and consent clauses.

It is argued in line with the work of Kim that the recognition of wrap contracts as valid contractual forms is problematic, as although they resemble more traditional standard form contracts, the nature of the online environment and the behaviour of people online impacts upon their perceptions of such documents in important ways. In light of special characteristics of wrap contracts and the digital environment it suggests

---

915 CMA, *Update on cloud storage consumer compliance review* (CMA, 1st April 2016) <https://assets.digital.cabinet-office.gov.uk/media/56fe3227ed915d117d000037/Investigation_update-1_April_2016.pdf> accessed 29 May 2016.

that their use may not be appropriate for genetic tests, especially those provided for health purposes.

It is important to note that for the most part, DTCGT contracts are typical wrap contracts and closely resemble the forms used in e-commerce more generally. For instance, many of the terms commonly found in DTCGT contracts are also found in the contracts of Amazon, Twitter, and Google and the language used is also very similar.[916] Given that wrap contracts have often been viewed as similar to other types of standard form contracts, it may be argued that contract law does not provide the best remedy for consumers in this context and that the use of wrap contracts does not pose special challenges. I do believe there are more general problems with the use of wrap contracts online for a variety of industries, but I would also emphasize that offering genetic tests, (especially those for health purposes) via the Internet given the complex nature of test results and the fact that they have previously been restricted to a medical setting means that we may need to look beyond contract law for a remedy and in that case, I recommend that in the UK, the ICO, the Human Tissue Authority, and the MHRA may all have role to play in improving regulation of the industry. The ICO and the Human Tissue Authority especially could assist with improving consent mechanisms in this context. However, the focus of this chapter is on how to challenge particular terms on the grounds of their unfairness under contract law in the UK, which is primarily through relying on consumer protection legislation on unfair terms.

A significant proportion of this research has involved analysis of these documents as texts and this chapter is primarily concerned with how DTCGT contracts ought to be interpreted and whether it is possible to argue that several terms commonly included therein ought to be construed as unfair and unenforceable. This investigation is premised

916 Loos and Luzak (n 805)

on the assumption that DTCGT contracts are likely to be deemed as prima facie valid contracts under UK law. It may be possible and desirable in line with Kim's work to challenge the validity of some DTCGT contracts in their entirety. However, as it is likely that many contracts are prima facie valid contracts then if the protection of consumer rights is to be ensured the best way to challenge the terms needs to be identified. Currently, it seems that the best way is to challenge these contracts is on the grounds of specific terms being unfair and also, that many contracts are on the whole failing transparency requirements.

2 An Overview of Contract Law As It Relates to DTCGT

(a) The nature of contract

Contracts at their most basic level can be defined as legally enforceable or legally binding promises. Central to the traditional conception of a contract are the concepts of offer and acceptance and consideration.[917] Here one person will make an offer, which is in turn accepted by another normally in exchange for something else 'consideration'. Contract law is the law of bargaining and there is a strong emphasis on freedom of will and an important purpose of contract law generally is 'to promote individual autonomy'.[918] There is much academic literature regarding the theoretical justifications for contract law and the legal enforcement of contracts.[919] For Radin, there are essentially 'two main branches: welfare theories and autonomy theories'.[920] Autonomy theories are centred on 'an exchange of promises, or on agreement'.[921] In such theories, 'in order for any

917 AS Burrows, *A Casebook on Contract* (4th edn, Hart Publishing 2013) 3-4.
918 Kim (n 227) 207
919 See generally Gregory Klass, George Letsas and Prince Saprai (eds), *Philosophical Foundations of Contract Law* (OUP 2014); and Radin (n 798) chapter 4
920 Radin 57
921 ibid 57

entitlement to be transferred (…) voluntariness of transfer is an indispensable premise of justice'.[922]

Unfortunately, while the model of parties agreeing on a bargain that is to their mutual advantage is still important today, especially in the online environment it does not always reflect reality. In wrap contracts specifically the element of voluntariness may be lacking. Generally, parties will be held to be bound by the agreements they have made and there are strong arguments concerned with autonomy, which are used to justify a cautious approach to questioning the validity of a bargain once made.[923] However, as will be seen in the following discussion on the nature of wrap contracts it might in fact be desirable for many wrap contracts not to be deemed valid contracts and in the context of the DTCGT industry especially in relation to the provision of genetic tests for health purposes, their use may not be desirable.

Much of the enforcement of contracts can also be justified on pragmatic grounds as it allows businesses to conduct their affairs with more certainty. It is this justification that has been largely relied upon by courts in enforcing standard form contracts and standard form contracts have developed as a consequence of industrialisation and the development of the mass market.[924]

In relation to the theoretical basis for enforcing wrap contracts Kim suggests that Eisenberg's dynamic theory of contracts[925] 'best reflects contract law doctrine'.[926] Eisenberg's theory holds that 'rather than establishing principles to support a given doctrine or theory, contract law should explain, establish, and uphold rules of behaviour. In other words, it should be adaptive, complex, substantive, and dynamic, rather than

922 ibid 59
923 Kim (n 227) 9-13
924 ibid (n 227) 20-6
925 ibid (n 227) 15
926 ibid (n 227) 15

stringent (…) and static'.[927] The principles of this theory are that, 'if appropriate conditions are satisfied, and subject to appropriate constraints, contract law should effectuate the objectives of parties to a promissory transaction' and:

> the rules that determine the conditions to, and the constraints on (…) objectives of parties to promissory transactions (…) should consist of the rules that would be made by a fully informed legislator who seeks to make the best possible rules of contract law by taking into account all relevant propositions of morality, policy, and experience.[928]

Kim argues that 'courts have increasingly adopted a view of contracts that is in accordance with dynamic principles', although 'this adoption (…) has not been consistent'.[929] She suggests that, 'although dynamic theory justifies the results in early landmark wrap contract cases, it does not justify subsequent cases or the doctrine that developed in the wake of the early cases'.[930] She argues that dynamic theory supports the existence of wrap contracts, 'but the doctrine is in dire need of rehabilitation'.[931]

In contract law the emphasis is normally on whether a person has given appropriate assent to the terms of the agreement. It should be noted that assent can be passive and sometimes may be implied from a course of dealing or on the basis of constructive or actual knowledge.[932] In the context especially of standard form contracts Courts have upheld the validity of contracts where one party has not in fact read the terms. Kim also views the way assent has been constructed in contracts of adhesion more generally as problematic. She writes that, 'assent in the context of adhesive contracts thus

---

927 ibid (n 227) 13-14, notes 32 and 33, citing Melvin Aron Eisenberg, 'Symposium on Law in the Twentieth Century: The Emergence of Dynamic Contract Law' (2000) 88 Cal L Rev, 1743, 1745 and 1753

928 ibid (n 227) 14 and note 34 citing Eisenberg

929 ibid (n 227) 15 and note 42 citing Eisenberg

930 ibid (n 227) 16

931 ibid (n 227) 16

932 Ewan McKendrick, *Contract law: text, cases, and materials* (5th edn, OUP 2012) 80-115, 313-37

became construed to mean acquiescence rather than active agreement (…) assent is often stripped of any requirement of volition or desire to enter into a contract.'[933]

However, in a clinical setting, the emphasis in genetic testing has been on individuals giving appropriate consent, which should be voluntary and informed.[934] More generally, in relation to medical treatment valid consent of the patient is required and it is possible that operating on a patient without appropriate consent could breach their rights under article 3 of the ECHR, which affords protection against 'torture or inhuman or degrading treatment'.[935] Valid consent in a medical setting arguably requires a much higher standard than contractual assent. Doctors are required to provide patients with information regarding the treatment they are considering before obtaining consent and when doctors provide information to patients regarding procedures, 'it is not enough to ensure this advice is provided – attempts must be made to make sure it is understood'.[936] This can be demonstrated by reference to the General Medical Council's guidance on consent, which suggests that in obtaining consent, doctors 'should check whether the patient needs any additional support to understand information, to communicate their wishes, or to make a decision'. [937] It is also far less likely that consent will be implied in the context of medical treatment, as the rights of patients to refuse treatment are afforded strong legal protection. The position in English law is that a person may 'refuse treatment even if without the treatment she or he will die'.[938] The importance of obtaining valid

933 Kim (n 227) 27

934 Herring (n 282) 155-62; and NHS Choices (n 303) provides that 'Consent is required from a patient regardless of the intervention – from a physical examination to organ donation'.

935 ibid (n 302) 149, citing *R (N) v Dr M, A Health Authority Trust and Dr O* [2002] EWHC 1911

936 ibid (n 302) 173

937 General Medical Council, Consent: patients and doctors making decisions together (General Medical Council, 2008) para 21

938 Herring (n 282) 552 citing *Re T (Adult: Refusal of Treatment)* [1992] 4 ALL ER 649, [652]-[653]; *Airedale NHS Trust v Bland* [1993] 1 All ER 821, [860] (Lord Keith), [866] (Lord Goff), [881 (Lord Browne-Wilkinson), and [889 (Lord Mustill); *Re AK* [2001] 1 FLR 129

consent to treatment was reaffirmed in the recent case of *Montgomery (Appellant) v Lanarkshire Health Board (Respondent) (Scotland)*.[939]

Yet, DTCGT contracts and many other Internet companies tend to treat the concepts of consent and assent interchangeably and sometimes in the context of a Terms of Service agreement companies will mention consent to the contract rather than assent or acceptance. This practice may potentially be more common also due to the broader trend of Internet industries borrowing or copying the terms of their competitors.[940] This conflation is problematic and is another feature highlighting the paradigm shift from patient to consumer apparent in the DTCGT context and the potential inadequacy of current consent mechanisms if these are compared to the requirements for consent in a medical setting.

On the matter of the validity of DTCGT contracts, it is also possible that an argument could be made against the validity of wrap contracts in this context on the basis that many DTCGT companies are providing insufficient notice of their terms.[941] Such an argument would rely on the position established in *Parker v South Eastern Railway Co,* [942] and affirmed in the case law since, which is:

> that a term will only become incorporated in the contract if notice of the term has been given and that notice is reasonably sufficient in all the circumstances. This is a question of fact, "in answering which the tribunal must look at all the circumstances and the situation of the parties"[943]

While as will be discussed later in this chapter there is very limited case law in the UK on the validity of wrap contracts, it seems possible that some DTCGT contracts may not be held to be valid in their entirety.

---

939 [2015] 2 All ER 1031, [2015] UKSC 11
940 Kim (n 227) 60- 61
941 Lawson 9-12
942 (1877) LR 2 CPD 416
943 Lawson (n 941) 9-10

(b) Clickwrap, Browsewrap, and DTCGT

The contracts used by DTCGT companies are mass consumer standard form contracts, (sometimes referred to as 'boilerplate') also referred to as contracts of adhesion. Adhesion contracts have terms that are offered on a 'take it or leave it' basis.[944] The online environment has given rise to a new type of adhesion contract known as the wrap contract, which has two main forms: clickwrap and browsewrap. However, while wrap contracts might be treated as adhesion contracts, as will be seen they are not necessarily the same as older forms of adhesion contracts and may represent a separate class of contract.[945] All DTCGT companies use either clickwrap or browsewrap agreements and most DTCGT contracts take the same forms, regardless of whether they are called Terms of Service, Terms and Conditions, or Privacy Statements.

Both clickwrap and browsewrap have developed from shrink-wrap agreements (also referred to as shrink-wrap licences), which were originally conceived in order to protect the rights of software developers. Shrink-wrap contracts are included on the packaging of software products and a person normally signals their assent to be bound by these contracts by ripping the packaging open.[946] There are now also 'Tapwraps', which are the contracts encountered on mobile devices, which allow a person to agree to terms with a tap of the finger.[947] Companies also often engage in the practice of 'multiwrapping', which Kim uses to refer to 'the use of more than one type of Wrap contract'.[948]

Wrap contracts will be encountered by many people on a daily basis. They are used both on websites and in the sale and installation of software. It is increasingly the

944 Kim (n 227) 4-5.
945 See generally ibid (n 300)
946 ibid (n 227)
947 ibid 3.
948 ibid 93

case that companies operate on the assumption that the majority of their consumers will not read their contracts or privacy policies. In turn, this has given rise to the practice of including additional clauses in contracts that bear no relation to the original purpose of the contract and are intended to give the company additional advantages. This practice has been dubbed by Kim as the inclusion of 'crook' provisions and is a feature that distinguishes wrap contracts from other types of adhesion contract.[949] Perhaps the most extreme example was Gamestation's inclusion of a clause, which purported to compel you to relinquish your immortal soul to the company, although this was actually included as an experiment.[950]

It is argued here that in line with Kim suggestions that due to special aspects relating to both the form and substance of wrap contracts, they ought to be treated as distinct from other types of contracts of adhesion.[951] Most significantly, whereas with paper contracts a person would normally be aware of the fact that she was entering a legally binding agreement, the proliferation of wrap contracts in e-commerce has meant that consumers may not be aware that they are entering into a legally binding agreement when they purchase a product online or browse a website.[952] As Kim notes:

> In the physical world, customers are typically asked to sign lengthy, multipage contracts only for significant transactions, such as the purchase of a house, or for transactions where the drafting party has a continuing property interest, such as a car rental agreement or a lease agreement. Online, a customer may be deemed to have assented to a thirty-page document simply by visiting a website.[953]

---

949 ibid (n 300) 51-2; Nancy S Kim, 'Contract's Adaptation and the Online Bargain' (2010) 79 U Chi L Rev 1327

950 Marc Perton, 'Read Fine Print Or GameStation May Own Your Soul' Consumerist <http://consumerist.com/2010/04/16/read-fine-print-or-gamestation-may-own-your-soul/> accessed 8 September 2014; Brendon Behesti, 'Cross-Jurisdictional Variation in Internet Contract Regulation' (2013) 51.

951 Kim, *Wrap Contracts: Foundations and Ramifications* (n 227) chapters 6 and 7

952 ibid (n 227)53-69, 126-46

953 ibid (n 227) 59

While it might be desirable that consumers do read these documents the reality is that due to the length and frequency of such documents, most people actually do not have time to read them, even were they so inclined.[954] A recent study 'estimated that it would cost the average American Internet user 201 hours or the equivalent of $3,534 a year to read the privacy policies of each website that he or she visits'.[955] Even where consumers do choose to read such contracts there is evidence to suggest they will not necessarily understand their content due to the complex nature of the language used, which may require a high level of education to comprehend.[956] Furthermore, as companies often do not expect consumers to read such documents, it may also be difficult for a consumer to locate terms on a website.[957] This was actually apparent in conducting this research, as sometimes it was in fact difficult to find terms on DTCGT websites.

As evidenced by the examples of contract terms provided in chapter five, there is much commonality between companies in their contracts meaning that the idea that consumers can choose between companies with more favourable terms is largely illusory.[958] As Kim writes:

> Contrary to what courts have too often ruled, choice of terms online is a fantasy that exists only in an alternative contracting universe. Not only does one party lack bargaining power with respect to a particular transaction or party, but one class of parties lacks bargaining power within a contracting environment.77 It is not a viable option for the consumer to decline the terms of any particular agreement if the consumer wishes to engage in online activity. The party's "assent" is void of volition and merely reflects a refusal on the part of the consumer to resist market forces through self-deprivation that would have profound social and economic consequences.

954 Plaut and Bartlett III

955 Kim, *Wrap Contracts: Foundations and Ramifications* (n 227)213 citing Aleecia M McDonald and Lorrie Faith Cranor, 'The Cost of reading privacy policies' (2008) 4 I/S A Journal of Law and Policy For the Information Society at 562

956 Ian Ayres and Alan Schwartz, 'The No-Reading Problem in Consumer Contract Law' (2014) 66 Stan L Rev 545; Loos and Luzak (n 805)

957 Kim, *Wrap Contracts: Foundations and Ramifications* (n 227)

958 ibid (n 300)206-7.

> This situation is quite different from the model contract scenario that is assumed by contract doctrine and differs even from the model adhesive contract scenario. Given the importance of online activity in our daily lives, it is highly unlikely that even the most ardent supporter of contractual autonomy would forego an ill-advised "click" on the basis of principle and an understanding of contract law alone. A refusal to accept standardized contractual terms is simply unrealistic in many types of transactions. Refusing to visit websites or use products and services that utilize wrap contracts means opting out of the use of the Internet, computers, and smartphones and essentially shutting oneself out of important economic and civic activities.[959]

As Kim suggests choosing to avoid websites with wrap contracts is not a real option for most people. I suggest that in the context of DTCGT given the complex and ambiguous nature of genetic test results and the uses to which genetic information can be put, the use of wrap contracts to govern the transaction may not be appropriate. However, as it also seems unlikely that the industry's reliance on wrap contracts will decrease in the near future, it is desirable that the CMA takes a compliance review of DTCGT contracts and practices and seeks to reform DTCGT contracts.

(i.) *Clickwrap Contracts*

Clickwrap contracts 'do not permit a user to progress until and unless the user clicks on a box containing the words "I agree" or some similar expression of agreement'[960]. Such contracts are now familiar to many and a large number of people will encounter them on a wide variety of websites, but it is possible that many people may not view clickwrap contracts in the same way as they would treat a lease on an apartment or a contract for the sale of a car.[961] This is to a large extent a problem of perception. Often when active online individuals will not be aware of the fact that they are entering into a contract when they purchase a product or service. This is in large part because people are often influenced by more traditional ideas about the formalities that might accompany the

959 ibid (n 300) 207.

960 ibid 35; Nancy S Kim, 'Exploitation by Wrap Contracts-Click' (2014) 39 California Bar IP Journal, New Matter 10

961 Kim, *Wrap Contracts: Foundations and Ramifications* (n 227) 1-5; Manwaring (n 809)

formation of a contract, such as the act of physically signing the document. Although a person might click 'I agree' she may not necessarily 'click' on to the legal implications that flow from this clicking of the mouse.[962]

(ii.) ***Browsewrap Contracts***

''Browsewrap' is agreement proved by the simple fact that one party browsed the other's site'.[963] As Kim notes:

> An analogy would be stopping to browse at a shop and being asked to sign a lengthy agreement prior to entering. (A more precise analogy to browsewraps would be one where you walk into the store and are deemed to have agreed to that agreement simply by setting foot in the door and not immediately exiting.)[964]

These agreements are similar to clickwrap, except that browsewrap contracts normally have their terms only accessible by means of a hyperlink to another page or another website. Significantly, this means that it is possible for a consumer to enter into a browsewrap contract without necessarily being required to view the terms at all.[965] However, the lines between what is considered to be a browsewrap and what is considered to be a clickwrap agreement are blurred, with commentators sometimes disagreeing on the appropriate classification of the same agreement.[966]

With DTCGT perhaps it might be expected that a person ordering some form of health test online might be more inclined to pause and read the contract more carefully, but the reality is that many consumers are still not in fact doing this.[967] The following

---

962 Manwaring (n 809)

963 Hedley (n 820) 249

964 Kim, *Wrap Contracts: Foundations and Ramifications* (n 227) 59

965 ibid (n 227) 59-60; Daniel D Barnhizer, 'Escaping Toxic Contracts: How We Have Lost the War on Assent in Wrap Contracts' (2014) 44 Sw L Rev 215; Ian Ayres and Alan Schwartz, 'No-Reading Problem in Consumer Contract Law, The' (2014) 66 Stan L Rev 545; Thompson; Kacen, Hess and Kevin Chiang Plaut and Bartlett III (n 801)

966 Manwaring (n 809) 1, footnote 2

967 Two colleagues (Teresa Finlay and Jan Charbonneau) are working on research projects investigating consumer understanding of genetic test results and consumers' perceptions of the DTCGT industry. In interviews some consumers likened DCTGT contracts to their iTunes agreements and admitted that they did not read these documents.

quotes from Teresa Finlay's research interviewing clinicians and consumers about DTCGT highlight some of the problems of relying on wrap contracts in this context. The first quote is from a clinician dubbed CP3 scientist. Their comment is as follows:

> There's probably a long Terms and Conditions like (…) that you scroll down to the bottom and tick a box like I always do whenever I'm supposed to sign up for something. Yes of course I agree. Go away, I want to get to the next bit.[968]

Meanwhile a consumer called Fiona comments thus:

> I suspect they don't give people very much information but I'm not sure whether giving people more information would actually improve people's understanding of what they were doing… because most of the time when you're given a long electronic document most of us read the top few lines and then don't look at the rest of it anyway Because I'd already somewhat made up my mind I never really looked into how well they communicate before you're going to make the decision. [969]

Finally, Jane says:

> Well there was written information but like a lot of people you don't always go through all the small print. I understand contracts but when so many demands are made on you to go through a contract like that and to read all the small print, it's hard to take it all in (…) So, I think that to read the small print and really consider it and understand it, you have to be a very unusual person. [970]

Of course it is not necessary for a person to have read a contract in order to be bound to it. In the UK *L'Estrange v Graucob*[971] is good authority for the significance of a person's signature binding them to an agreement regardless of whether they have in fact read the terms contained in it. However, it is possible that wrap contracts should not be treated in the same way as more traditional standard form contracts. Kim's work is very persuasive in this context as she convincingly argues there are some features of the

---

968 Finlay (n 377); and quotes taken from conference slides Phillips and Finlay, '"DNA a click away" -Workshop on 'agreements' in DTCGT' (n 291)

969 ibid (n 377); and quotes taken from conference slides Phillips and Finlay, '"DNA a click away" - Workshop on 'agreements' in DTCGT'

970 Finlay (n 377); and quotes taken from conference slides Phillips and Finlay, '"DNA a click away" -Workshop on 'agreements' in DTCGT'

971 *L'Estrange v F Graucob Ltd* [1934] 2 KB 394

digital environment and the substance of wrap contracts, which may mean that the enforceability of some wrap contracts is questionable and these should not necessarily be treated as synonymous with other types of adhesion contracts.[972] Most significant here is the nature of the Internet itself. Wrap contracts are normally presented in digital form, which means that companies can now create significantly longer contracts at greatly reduced cost. Previously, with other types of standard form contracts, which were typically presented to the consumer in paper form if a document was significantly lengthy, when the transaction was minor this might have alerted the consumer's suspicion even if they did not read the contract. In the online environment it is possible that many people are becoming habituated to clicking "I Agree" without necessarily even realizing they are entering into a legal agreement.[973] There are less visual cues regarding contract length in the online environment. Where a person might balk at being presented with a 100 page contract in paper form they may not even notice the length of a wrap contract, particularly in the context of browsewrap where it is possible that the individual may not ever click on the hyperlink containing terms. There is also research suggesting that people do not necessarily comprehend what they read in the same way when they read it on a screen as opposed to on paper.[974]

In the context of online business generally the use of wrap contracts can allow business to engage in what is essentially a form of private legislation.[975] If DTCGT is viewed as disruptive technology, then as Kim writes:

> The boundaries of acceptable practices are undefined when it comes to new marketplace innovations. Contracts serve a dual purpose in this context in that not only do they set forth the legal obligations of the

---

[972] Kim, *Wrap Contracts: Foundations and Ramifications* (n 227) chapters 6 and 7

[973] ibid (n 227) 59-61

[974] Anne Mangen, Bente R Walgermo and Kolbjørn Brønnick, 'Reading linear texts on paper versus computer screen: Effects on reading comprehension' (2013) 58 International Journal of Educational Research 61

[975] Hedley (n 820) 248; Kim, *Wrap Contracts: Foundations and Ramifications* (n 227) 71-6

> parties, they legitimate new practices. A new business that is socially and legally questionable, but not yet regulated gains legitimacy through the notion that the practice has been consented to via contract.[976]

The use of these contractual forms also takes:

> the user further away from actual assent than contracts of adhesion; it is not merely the issue of non-negotiability that is at stake. It is the issue of autonomy itself. The justification for state intervention in what is essentially a private matter is that the parties agreed to it; their consent is the starting point. Without consent, judicial enforcement of contracts is state coercion. Courts justify wrap contracts by claiming that the nondrafting party manifested consent, but their construction of what constitutes manifestation of consent has wandered too far from the truth. Nonconsent does not become consent simply by claiming it is. Consent has meaning in our society and in the law, and it is a different one than that used by courts to establish assent to wrap contracts.[977]

The reality is that often consumers do not read these contracts and given the nature of DTCGT services this is problematic and it should cause concern given the real likelihood of companies using consumers' genetic data in research and sharing it with their partners and affiliates.

It is possible to make a comparison here with the consumers' behaviour regarding software installation. In the context of the installation of software it has been found that while many consumers do not read End User Licence Agreements (EULA) this can result in harm to consumers, especially in the context of the installation of spyware. Spyware 'presents users with a trade-off: users gain the functionality of software in exchange for giving up private data, tolerating advertising messages, or both'.[978] Good et al conducted a study on the impact of using short summary notice on users' behaviour regarding installation of spyware. Their work validated 'the use of short summary notices as a mechanism for reducing the installation of unwanted software' and they also found that

---

976 ibid 73

977 ibid 211

978 Nathaniel S Good et al, *Noticing notice: a large-scale experiment on the timing of software license agreements* (ACM 2007) 607

providing a notice after installation with the option for uninstallation was also helpful for consumers.[979] They suggest that:

> Users might be well-served by systems that "pretend" to install software, then warn about the consequences before really completing the installation. (This approach could be a variant of the "to finish installation, you must reboot" barrier.) Or in some cases, it may even be worth preventing immediate use of software to provide a period of reflection. Efforts in the private sector to create virtual machines or sand boxes of sort that would allow consumers to test out software without allowing it fully onto their machine appear promising.[980]

The use of short summary notices could be useful in the DTCGT context, as it might aide consumer understanding and the possibility of companies allowing for a cooling off period in the context of the purchase of genetic tests might also be desirable.

At present, while some relevant case law will be considered later in this chapter, it should be stressed that the jurisdiction with the most significant body of case law concerning wrap contracts to date is that of the USA and future research will consider the US case law. Before moving on though, it should be noted that in the USA Courts have tended to treat clickwrap and browsewrap differently, but increasingly they focus primarily on whether the customer had notice.[981] If a consumer has sufficient notice of terms it may be difficult to challenge the enforceability of terms. Sometimes, the availability of a privacy policy on a website has been held to constitute sufficient notice regardless of whether the consumer read the policy. However, there have also been cases, such as *Pollstar v Gigmania Ltd*[982] where courts have 'refused to enforce the terms of an online license agreement because the link to it was hard to read and unidentifiable as a hyperlink.'[983] The Court was primarily concerned with the formatting of the terms and if

979 ibid 615
980 ibid 615
981 Kim, *Wrap Contracts: Foundations and Ramifications* 41-2
982 ibid 42; 170 F Supp 2d 974 (ED Cal 2000)
983 ibid 42

they had been presented in another format the Court might have enforced them.[984] Some DTCGT contracts and privacy policies are also presented in difficult to read forms and it is possible that some terms contained in DTCGT contracts may be held to be unenforceable on the grounds of insufficient notice.

3 Regulatory Action

(a) The Office of Fair Trading

The OFT before its closure had quite a lot of success in enforcing the UTCCR and altering companies' terms. For instance, between 2000 and 2005, 'more than 5,000 terms were changed or abandoned following investigation by the OFT'.[985] The terms most often challenged for unfairness were, 'those excluding or limiting liability for shortcomings in the quality of goods or services, those imposing financial penalties, and failure to use plain and intelligible language'.[986] Most changes were accomplished through direct negotiations with companies and it was rare for litigation to be necessary. McKendrick notes, '[t]he real enforcement of the Regulations is not taking place in the courts but in the Office of Fair Trading'.[987] Furthermore, Bright notes, 'as most of the work done by the Regulations' – meaning the UTCCR – 'is through the pre-emptive work of the OFT it is their approach to investigating cases that is more significant for the consumer. (…) businesses appear on the whole to have been happy to work with the OFT rather than to resist and challenge'.[988] The discussion about the meaning of unfairness under the UTCCR has centred on two main issues:

---

984 ibid 42

985 Susan Bright, 'Unfairness and the Consumer Contract Regulations' in Andrew Burrows and Edwin Peel (eds), *Contract Terms* (Hart 2007) 176

986 ibid 176

987 McKendrick (n 932) 489

988 Bright (n 985)178

> First, is there a procedural component to the good faith requirement in Regulation 5(1)? If so, it is argued by some that unfairness must operate differently at the general use and ex casu stages as there is no procedure to be looked at in general use challenges. Several leading figures have suggested that general use challenges are primarily concerned with substantive issues (…)
>
> Second, if procedure does have a role to play, does this mean that substantive imbalance alone will not be sufficient to find unfairness? And, conversely, can procedural irregularity alone suffice?[989]

With the closure of the OFT and 'the extension of enforcement powers beyond the Office of Fair Trading may not necessarily operate in the interests of consumers. Much will depend on the ability of these different qualifying bodies to forge a coherent and effective enforcement strategy'.[990] It is hoped that the new Competition & Markets Authority (CMA) will be able to do this and it also hoped that the CMA will begin to monitor the DTCGT industry and that it will be able to have similar success in eliminating unfair terms. It is also hoped that the ICO and the Human Tissue Authority will begin to investigate industry compliance with data protection law and the requirements of the HTA.

While there has been limited case law involving the OFT, the OFT frequently published bulletins and notices and had much success through direct negotiation with industry. Some of the most significant cases in this context are: *Director General of Fair Trading v First National Bank*[991]*; Office of Fair Trading v Abbey National plc*[992]*;* and more recently *Office of Fair Trading v Ashbourne Management Services Ltd*, which will be considered later in this chapter.

989 ibid n 985)178
990 McKendrick (n 932) 490
991 *Director General of Fair Trading v. First National Bank plc* UKHL
992 *Office of Fair Trading v Abbey National plc* [2009] UKSC 6, [2010] 1 AC 696

(b) The new Competition and Markets Authority (CMA)

The CMA was formed in 2014 and it has taken over some of the functions of the OFT and the Competition Commission. Under the Consumer Rights Act the CMA has authority to take enforcement actions against companies, which are using unfair terms or notices. It can apply to a court for an injunction against specific companies. However, it cannot take on individual cases on behalf of individual consumers, which means that in practice if consumers seek redress their options may be limited. It can be very difficult for individuals to sue such large companies.[993] It is hoped that the CMA will monitor DTCGT companies' practices where they offer services to UK based consumers. The consumer functions, which have been transferred to the CMA are as follows:

- using consumer enforcement powers to tackle market wide practices including the UTCCRs (for which the CMA has the lead but shares the power to enforce with TSS), CPRs and the Consumer Protection (Distance Selling) Regulations 2000 (DSRs) either directly or under Part 8 EA02
- carrying out business facing education in relation to the application of the UTCCRs or where a need for business education has been identified resulting from a market study, UTCCRs cases or similar in which the CMA has built significant expertise
- receiving notifications from enforcers who are in particular required to notify the CMA before they apply for an enforcement order under section 214 of the EA02, and taking steps to ensure coordination of enforcement under s.216, where appropriate, acting as the UK's Single Liaison Office and ensuring compliance under the EU Regulation on Consumer Protection Cooperation (CPC),12 and
- having an international role on consumer law and policy liaison13, for example representing the UK in the International Consumer Enforcement Protection Network (ICPEN) and the Organisation for Economic Cooperation and Development (OECD) Committee on Consumer Policy.[994]

---

993 Kim, *Wrap Contracts: Foundations and Ramifications* (n 227);

994 Competition & Markets Authority, *Consumer Protection: Guidance on the CMA's approach to use of its consumer powers* (Competition & Markets Authority, CMA7, March 2014) 7, para 2.5

(i.) ***Update on CMA's approach to unfair terms***

The CMA has recently released its findings report, *Consumer Law Compliance Review: Cloud Storage*.[995] This review was concerned with assessing whether cloud storage providers' terms and business practices complied with consumer protection law. It should be noted that the report has already had some degree of success with improving terms, as several cloud service providers have made commitments to improve their terms.[996] The report is very relevant to the present discussion, as it indicates the types of terms and business practices which the CMA is likely to view as problematic and potentially unfair. For each of the terms that the CMA finds problematic, it also makes recommendations on how terms and business practice might be improved. Some of these suggestions could usefully adapted to the DTCGT context. In paragraph 5.2 of the report, which summarizes the effect of Part 1 of the Consumer Rights Act, the CMA states that:

> in relation to contracts for the supply of goods, digital content and services (or any combination of these), in particular:
> - a service must be performed with reasonable skill and care;
> - anything said or written about the service by or on behalf of the trader and which is taken into account by the consumer, is to be treated as a term of the contract (subject to certain conditions);
> - pre-contractual information provided under the Consumer Contracts (Information, Cancellation and Additional Charges) Regulations 2013 is to be treated as a term of the contract;[997]

This could indicate that where website content on DTCGT websites describes services in a way that differs from the exclusion or limitation of scope of purpose clauses contained in a DTCGT contract, that website content might be taken to constitute part of the contract, which might have the effect of overriding such clauses, where there is a discrepancy between the two.

---

995 CMA, *Consumer Law Compliance Review* (n 224)

996 CMA, 'Cloud storage: consumer compliance review' homepage <https://www.gov.uk/cma-cases/cloud-storage-consumer-compliance-review> accessed 30 May 2016

997 CMA, *Consumer Law Compliance Review* (n 224) para 5.2

In relation to unilateral variation clauses, the report indicates that several examples of clauses of this type may cause consumer detriment[998] and that they view such clauses as unfair under the CRA.[999] Relevant here is that this includes terms that 'allow the provider to change the terms or the service in any way for any reason and at any time' or those that 'do not require providers to give consumers notice of changes' are of concern.[1000] In order to address its concerns relating to unilateral variation clauses the CMA recommends that cloud service providers should:

- They should only be able to make changes to the terms or the service for valid reasons that are clearly set out in the contract, so that consumers understand how the changes might affect their rights and obligations under the contract. This is particularly important for fixed-term contracts where the scope to make changes should be limited.
- They should ensure that consumers receive adequate notice of changes, so that they can consider their position and decide whether to accept the changes.
- They should ensure that consumers who do not wish to accept changes can cancel the contract, obtain a refund for any services not yet provided (including, where relevant, any additional services they have purchased) and retrieve their data.[1001]

If the CMA were to take a similar approach towards DTCGT companies it seems likely that many unilateral variation clauses would be deemed to be unfair and that it would be useful for DTCGT companies to apply a similar approach to that recommended for cloud computing providers.

In relation to choice of law clauses the CMA was concerned by clauses that:

- require consumers to bring legal proceedings in countries other than where they live;
- specify that the contract is only subject to the law of other countries; and

998 CMA, *Consumer Law Compliance Review* (n 224) para 5.24
999 ibid para 5.25
1000 ibid para 5.24
1001 ibid para 5.37

- include legal jargon that is likely to confuse consumers about which courts have jurisdiction and which laws will apply (eg 'without prejudice to mandatory law provisions').[1002]

In relation to these clauses, the CMA recommended that providers should:

- ensure consumers are able to bring legal proceedings in their local courts;
- ensure the contract is subject to the consumer's local law; and
- clearly explain that the consumer's local courts will have jurisdiction and their local law will apply.[1003]

This suggests that clauses in DTCGT contracts, which purport to apply the law of another jurisdiction may not be enforceable against UK consumers and are likely to be deemed unfair. Again, the CMA's recommendations here could be usefully adapted to apply to the DTCGT context.

In relation to exclusions of liability, in the context of cloud computing, the CMA indicated concern over terms, which:

> attempt to exclude or restrict a consumer's statutory rights and remedies under the CRA, for example, excluding liability where the provider has failed to use reasonable skill and care when providing the service;
> despite the potential for consumers to have large amounts of data saved or stored, place an unreasonably low cap on liability (outside of a consumer's statutory remedies);
> contain confusing or contradictory information, so that it is not possible for consumers to know what liability is or is not excluded in any particular situation; and
> include significant amounts of unnecessary 'legal jargon' (for example, 'mutatis mutandis', 'workmanlike effort' and 'implied warranties of merchantability'). Businesses should, of course, generally avoid using jargon at all in their terms. We had particular concerns about the amount and complexity of legal jargon in providers' liability terms.[1004]

They indicated that they viewed these as likely to be unfair under the CRA and that many exclusion clauses are also likely to be blacklisted under the Act and that 'Blacklisted terms are automatically unenforceable by a trader against a consumer'.[1005] In the context

1002 CMA, *Consumer Law Compliance Review* (n 224) para 5.67
1003 ibid para 5.72
1004 ibid para 5.59
1005 ibid para 5.59, para 5.60

of DTCGT, it would seem likely that several of the exclusion clauses mentioned in chapter five are likely to be deemed unfair. Those purporting to exclude liability for fitness for purpose or limiting the scope of purpose for health tests to non-medical purposes seem particularly likely to be deemed unfair. The CMA's recommended practices in relation to these clauses are as follows:

- They should not exclude or limit a consumer's statutory rights and remedies under the CRA. For example, terms should not seek to exclude or limit the provider's liability if it fails to provide the service with reasonable skill and care. They should not exclude or limit the provider's liability if the provider fails to provide the service in accordance with a statement or description given to the consumer by the provider. As noted above most terms that exclude or limit liability for breaches of consumers' rights under the CRA are also blacklisted.
- They should not otherwise unreasonably limit or exclude their liability for losses or harm to consumers, for example, where a provider's breach of contract is caused by events outside the provider's control. Concerns may arise, for example, where a contract places an unreasonably low cap on compensation which the consumer can claim.
- They should clearly set out the circumstances when liability will not be excluded as well as explaining any applicable limitations or restrictions.
- They should avoid unnecessary 'legal jargon'.[1006]

Again, it seems that similar recommendations could helpfully be applied to the DGCGT context.

Regarding transparency, the CMA expressed concern over clauses that:

- do not use plain and intelligible language;
- are structured in a manner that may make it difficult for the consumer to understand their rights and obligations under the contract;
- are not incorporated in the consumer's contract but in other documents.[1007]

The CMA's recommended practices in relation to transparency are:

- ensure they clearly and comprehensibly set out the consumer's rights and obligations under the contract, for example by:
  — drafting terms in plain English, using, as far as possible, ordinary words in their normal sense;
  — minimising the need for consumers to cross-refer to different terms or documents; and
  — ensuring that terms do not just name or allude to regulatory or legal provisions, but instead put consumers in a position of being able to

1006 CMA, *Consumer Law Compliance Review* (n 224) 5.64
1007 ibid para 5.74

understand the effects of those provisions;

- ensure that consumers can see how their obligations relate to each other, for example, by:

— organising terms in a clear and comprehensible way;
— using short sentences;
— breaking up the text of the contract with easily understood subheadings; and
— covering similar issues in the same section; and

- ensure that terms that could have a disadvantageous impact on the consumer are given appropriate prominence, for example by:

— highlighting them to the consumer by comparison with the majority of terms; and
— setting out clearly the obligations and the circumstances in which they arise.[1008]

Again, it seems that similar suggestions could be used to help improve DTCGT contracts, although in order to make DTCGT services sufficiently transparent, there may be a heightened need for further information to be provided, especially for providers of health tests.

(ii.) *The CMA's Guidance for Businesses and Draft Guidance on Unfair Terms*

The CMA has released several documents relating to unfair terms. Early in 2015, it released a short guide for businesses, entitled *Unfair contract terms explained*[1009] and draft guidance, entitled *Draft Guidance on unfair contract terms - Consultation document,*[1010] for which it conducted a public consultation. The final guidance document has only recently been released at the end of July 2015. The *Unfair Terms Explained* is primarily 'intended to provide businesses with a short overview of the types of terms and notices that the CMA considers are open to challenge under the Act' and it has been a helpful resource in conducting this research.[1011] The *Unfair Terms Explained* covers a variety of matters including:

1008 *Consumer Law Compliance Review* (n 224) para 5.80

1009 Competition & Markets Authority, *Unfair contract terms explained* (n 816)

1010 Competition & Markets Authority, *Draft guidance on unfair contract terms Consultation document* (Competition & Markets Authority, CMA37con, 26 January 2015)

1011 Competition & Markets Authority, *Unfair contract terms explained* (n 816) para 5

- when the fairness provisions will apply
- the test of fairness;
- the test of transparency;
- 'blacklisted' terms and notices;
- examples of types of working that the CMA might consider unfair;
- the possible consequences for your business of using unfair terms or notices; and
- references to some related consumer law.[1012]

According to the this document, terms which have the effect of hindering or preventing consumers from taking legal action are very likely to be construed as unfair. They may in fact be blacklisted under Part 1 of the Consumer Rights Act and specifically clauses compelling disputes to be resolved by arbitration for sums under £5,000 will always be deemed unfair.[1013]

In paragraphs 39 and 40 of *Unfair Terms Explained* the CMA makes suggestions for how companies might improve their terms and notices so that they are more transparent. These include: refraining from using jargon; avoiding ambiguity; making documents 'reader-friendly'; making terms 'comprehensible'; and providing the consumer with additional information to help them to understand the terms.[1014]

It is submitted that the majority of DTCGT contracts could benefit from these recommendations and it is likely that current practice by most DTCGT companies breaches transparency requirements under the new Consumer Rights Act. This includes the most prominent companies. In conducting the examination of company contracts, documents were often not in reader-friendly formats and sometimes files corrupted after being saved and difficulties were encountered in copying text between files. Many contracts were also jargon heavy and used complex legalese which an ordinary consumer might have difficulty understanding.

1012 Competition & Markets Authority, *Unfair contract terms explained* (n 816) para 5
1013 ibid paras 76-8
1014 ibid paras 39-40

(iii.) ***The CMA's Final Guidance – Unfair contract terms guidance (Final Guidance)***

The CMA's *Final Guidance* has been released very recently, but it seemed desirable to incorporate it into this discussion and it will be mentioned also in the next section on the Consumer Rights Act 2015. Significantly, the CMA notes that:

> 2.8 This guidance treats UK case law under the UTCCRs relating to the requirements of fairness and transparency as relevant to understanding the corresponding requirements in the Act. As explained above (part 1, 'the relevance of earlier unfair terms law'), the law on these issues has not substantially changed, but it is one of the purposes of reissuing this guidance, to draw attention to ways in which the law has been clarified in recent cases, particularly at European level.[1015]

Furthermore:

> 2.9 It is the CMA's view that the requirements of fairness as interpreted by the courts should be understood to apply in the same way, and to the same extent, to all terms and notices, irrespective of technical legal issues as to whether they fall within the scope of the minimum protection required by the Directive. Part 2 as a whole obviously needs to be given a consistent interpretation so far as possible. Such an interpretation is, in any case, required to the extent that the purpose underlying Part 2 of the Act as a whole remains the same as that of the Directive – to protect consumers who contract with a trader, so far as they are in a weaker position than the trader regarding their bargaining power and level of knowledge.[1016]

Regarding the test for fairness set by section 62 of the CRA, the *Final Guidance* specifies that:

> 2.12 **Significant imbalance** is concerned with the parties' rights and obligations under the contract. The requirement is met if a term is so weighted in favour of a business that it tilts the rights and obligations under the contract significantly in its favour, for instance by granting the trader undue discretion or imposing a disadvantageous burden on the consumer.17
>
> 2.13 A consumer contract may be considered balanced if both parties enjoy rights of equal extent and value in reality, particularly taking into

---

1015 Competition & Markets Authority, *Unfair contract terms guidance - Guidance on the unfair terms provisions in the Consumer Rights Act 2015* (n 815) 20, para 2.8

1016 ibid 20-1, para 2.9

> account the nature of the goods, services or digital content provided under the contract. The CMA considers that significant imbalance cannot be avoided just by ensuring a merely mechanical or formal equivalence in rights and obligations. For instance, the fact that the same financial sanction is imposed on both the consumer and the trader for cancelling the contract is unlikely to be acceptable, where (as is often the case) the trader has no interest in cancelling. In these circumstances, the sanction on the trader does not 'balance' fairly the imposition of the same sanction on the consumer for cancelling.18
>
> 2.16 A term is considered most likely to cause an unfair imbalance if it alters the balance in rights and obligations that the law would have struck if left to itself. The CJEU has indicated that an important part of the assessment of fairness of any term is to consider the extent to which it places the consumer in a legal position less favourable than that ordinarily provided for by the law.20

4 Current UK Legislation on Unfair Terms in Contracts

The legislation on unfair terms has recently been reformed and the provisions of the new Consumer Rights Act 2015 will be discussed before briefly looking at the previous legislation. However, drawing upon how previous legislation has been interpreted in this context, in general, 'there are three different contexts in which a challenge to the fairness of a contractual term may arise'.[1017] These are: pre-emptive challenge where the OFT (or now the CMA) negotiate directly with companies; through the OFT (or now the CMA) applying for an injunction in order to prevent companies from 'continuing to use unfair terms in contracts for general use'; or through 'judicial action in relation to an individual contract, an ex casu challenge'.[1018]

(a) The Consumer Rights Act 2015

The Consumer Rights Act 2015 came into force on the 1st of October 2015. The Act is of great significance in the context of discussing potentially unfair terms as it consolidates previous UK legislation governing unfair terms in business to consumer contracts as well

[1017] Bright 174
[1018] ibid 174

as implementing EU directives. Namely, it essentially replaces the Unfair Contract Terms Act 1977, the Unfair Terms in Consumer Contracts Regulations 1999 (UTCCR); and implements aspects of the Consumer Rights Directive and the Unfair Contract Terms Directive. The Act applies to both contract terms and notices. As this is the most current law this chapter takes the provisions of this Act as its central focus, but it will touch upon the previous Unfair Contract Terms Act and the Unfair Terms Regulations. Because it is intended to consolidate previous legislation and continue to implement the Unfair Terms Directive the new Act does resemble the UTCCR and the Directive.

(i.) Defining what constitutes an 'unfair' term

Section 62 of the Act requires terms and notices to be fair. It sets out how fairness is to be determined in subsections 4 and 5 thus:

> (4) A term is unfair if, contrary to the requirement of good faith, it causes a significant imbalance in the parties' rights and obligations under the contract to the detriment of the consumer.
>
> (5) Whether a term is fair is to be determined—
>
> – (a) taking into account the nature of the subject matter of the contract, and
>
> – (b) by reference to all the circumstances existing when the term was agreed and to all of the other terms of the contract or of any other contract on which it depends.

As assessing fairness requires consideration of the surrounding circumstances and the other terms agreed upon and the subject matter of the contract, it seems that in the context of assessing the fairness of particular terms in a DTCGT contract that a Court should consider the environment in which such contracts are made. Namely, that these are wrap contracts often entered into by the consumer in their home and they are for a service which has normally only been offered to people in a clinical setting. While much e-commerce is concerned with the sale of ordinary consumer products, DTCGT services are novel and represent disruptive innovation. Where companies provide tests for health

purposes the information they provide is of a complex nature and it may be that using wrap contracts to govern DTCGT services may not be providing sufficient protection for consumers. It is also likely that current practices for acquiring consent in this context may not be sufficient to meet the requirements of data protection law. It is also important here that consumers are given sufficient notice of the terms, so that they are in fact aware that they are entering into legal agreements. At present, it is possible that many consumers do not in fact understand the legal nature of the terms and conditions provided on DTCGT websites.

(ii.) The requirement for transparency

The Act also requires both contractual terms and notices to be transparent. Section 68 sets out the requirement for transparency as follows:

> (1) A trader must ensure that a written term of a consumer contract, or a consumer notice in writing, is transparent.
> (2) A consumer notice is transparent for the purposes of subsection (1) if it is expressed in plain and intelligible language and it is legible.

As many DTCGT contracts are particularly lengthy and use complex legalese it is quite likely that many terms would fail these requirements. For instance, many of the indemnity clauses mentioned in chapter five may fail the requirements of transparency, as according to the CMA's *Final Guidance* clauses that allow a company to:

> (…) claim its legal costs on an 'indemnity' basis, that is all costs, not just costs reasonably incurred. The words 'indemnity' and 'indemnify' are also objectionable as legal jargon (…)
>
> The fairness of any term is assessed having regard to the other terms of the contract, and even if not excessive when considered separately, may be unfair if it could operate together with another term or terms so as to lead to the trader being compensated twice for the same loss.[1019]

[1019] Competition & Markets Authority, *Unfair contract terms guidance - Guidance on the unfair terms provisions in the Consumer Rights Act 2015* (n 815) 87-8, para 5.14.3

Furthermore, the overall length of DTCGT contracts might weigh against a DTCGT company in the context of considering transparency.

(iii.) The definition of consumer under the Act

Section 2 (3) defines the term consumer as follows, 'Consumer means an individual acting for purposes that are wholly or mainly outside that individual's trade, business, craft or profession'. This definition easily covers the typical DTCGT consumer who will normally purchase these services online in their home. It is possible that DTCGT consumers could be treated as vulnerable consumers given the nature of the genetic disease risk test results as discussed previously. However, if the Act is relied upon in order to challenge the validity of certain terms included in DTCGT contracts, it is clear that a person purchasing a DTCGT test would meet the definition of consumer provided in the Act.

(iv.) The Black List

Part 1 of the Act also blacklists certain terms, meaning that terms of the type specified are automatically void. Importantly, section 65 of the Act has the effect of voiding terms, which purport to restrict a company's liability for personal injury or death caused by their negligence. The section provides:

> 65 – Bar on exclusion or restriction of negligence liability
>
> (1) A trader cannot by a term of a consumer contract or by a consumer notice exclude or restrict liability for death or personal injury resulting from negligence.
>
> (2) Where a term of a consumer contract, or a consumer notice, purports to exclude or restrict a trader's liability for negligence, a person is not to be taken to have voluntarily accepted any risk merely because the person agreed to or knew about the term or notice.
>
> (3) In this section "personal injury" includes any disease and any impairment of physical or mental condition.
>
> (4) In this section "negligence" means the breach of—

(a) any obligation to take reasonable care or exercise reasonable skill in the performance of a contract where the obligation arises from an express or implied term of the contract,

(b) a common law duty to take reasonable care or exercise reasonable skill, (…)

(5) It is immaterial for the purposes of subsection (4)—

(a) whether a breach of duty or obligation was inadvertent or intentional, or

(b) whether liability for it arises directly or vicariously.

(6) This section is subject to section 66 (which makes provision about the scope of this section).

Similarly, forum selection clauses that purport to apply the law of a non-EEA state and thus bind the consumer to resolving potential disputes in another jurisdiction are likely to be ineffective in accordance with section 32 of the Act. Section 32 provides that:

(1) If—

(a) the law of a country or territory other than an EEA State is chosen by the parties to be applicable to a sales contract, but

(b) the sales contract has a close connection with the United Kingdom, this Chapter, except the provisions in subsection (2), applies despite that choice.

(2) The exceptions are—

(a) sections 11(4) and (5) and 12;

(b) sections 28 and 29;

(c) section 31(1)(d), (j) and (k).

(3) For cases where those provisions apply, or where the law applicable has not been chosen or the law of an EEA State is chosen, see Regulation (EC) No. 593/2008 of the European Parliament and of the Council of 17 June 2008 on the law applicable to contractual obligations.

Part 1 also blacklists other terms that purport to opt out of the terms implied by the CRA into consumer contracts of different types, such as the requirements to carry out services with reasonable skill and care. This suggests that exclusion clauses commonly found in DTCGT contracts may also count as unfair terms and not be enforceable. This could mean that where a company attempts to limit liability either for their services being fit

for purpose or attempts to limit the scope of their services to non-medical, where the tests are offered for health purposes, they may not have the intended effect.

In the CMA's *Unfair contract terms explained*, it also suggested that variation clauses may be blacklisted in Part 1 of the CRA. The CMA suggests that:

> Variation clauses are likely to be unfair if they could be used to force the **consumer** to accept increased costs, new requirements or reduced benefits. For example in contracts where important elements of the contract – such as the price – have not been fully agreed at the time the contract is concluded, **terms** that give the **trader** the sole right to determine these matters are likely to be unfair. So too are terms that give the **business** the right to change, at its discretion, elements that have been agreed.[1020]

Furthermore, in its *Final Guidance* the CMA suggest that in determining whether a variation clause is unfair there are three matters, which should be considered. These are:

> (a) its breadth – the extent of the changes that it allows, and particularly changes that are exclusively in the interest of the trader;
> (b) its transparency – how far it can result in changes that are unexpected to and unforeseeable by the consumer; and
> (c) the vulnerability of the consumer – in particular, whether consumers can realistically escape the impact of the changes by cancelling the contract. [1021]

Clauses are 'more likely to be found fair if' they are narrow in effect.[1022] As demonstrated in chapter five, broad variation clauses are a common feature of DTCGT contracts and are a very common feature of wrap contracts more generally.[1023] Overall 72 % of DTCGT companies examined herein included such clauses. It is likely that many of these would be deemed to be void, as most are very broad in scope and only a small minority. 6 % will in fact notify consumers of changes by email. The 30% of companies that deem acceptance to altered terms through use of the website are also likely to fail the

---

1020 Competition & Markets Authority, *Unfair contract terms explained* (n 816) 14, para 66

1021 Competition & Markets Authority, *Unfair contract terms guidance - Guidance on the unfair terms provisions in the Consumer Rights Act 2015* (n 815) 98-9, para 5.21.2

1022 ibid 99, para 5.21.5

1023 Loos and Luzak (n 805)

requirement of transparency.[1024] Finally, Loos and Luzak in their study of Internet service provider clauses suggest that the CJEU's approach to interpreting unilateral price variation clauses might be extended to apply to clauses allowing for unilateral changes to other terms[1025] and as several of the terms they examined are actually less onerous than those found in DTCGT contracts it is possible that the CJEU would also deem these to be unfair.

(v.) The Grey List

Schedule 2 of the Consumer Rights Act provides a non-exhaustive and indicative list of terms that are likely to be deemed unfair. This list closely resembles the list provided in the Consumer Rights Directive.[1026] As this list is indicative only it is possible that some terms of a type specified in the Schedule will not in fact be deemed to be unfair and likewise, terms of a type not specified in the Schedule may be deemed to be unfair. For present purposes, the CMA's Draft Guidance is particularly helpful in considering what terms are likely to be deemed unfair.

In relation to exclusion clauses, the most relevant sections are sections 1 and 2 of the list:

> 1 A term which has the object or effect of excluding or limiting the trader's liability in the event of the death of or personal injury to the consumer resulting from an act or omission of the trader. This does not include a term which is of no effect by virtue of section 65 (exclusion for negligence liability).
>
> 2 A term which has the object or effect of inappropriately excluding or limiting the legal rights of the consumer in relation to the trader or another party in the event of total or partial non-performance or inadequate performance by the trader of any of the contractual obligations, including the option of offsetting a debt owed to the trader against any claim which the consumer may have against the trader.

1024 Competition & Markets Authority, *Unfair contract terms guidance - Guidance on the unfair terms provisions in the Consumer Rights Act 2015* (n 815) 99-100, para 5.21.6

1025 Loos and Luzak (n 805)

1026 93/13/EEC of 5 April 1993 on unfair terms in consumer contracts

In relation to variation clauses, the most relevant sections are sections 10 and 11, which provide as follows:

> 10 A term which has the object or effect of irrevocably binding the consumer to terms with which the consumer has had no real opportunity of becoming acquainted before the conclusion of the contract.
>
> 1 A term which has the object or effect of enabling the trader to alter the terms of the contract unilaterally without a valid reason which is specified in the contract. This is subject to paragraphs 22 (financial services), 23 (contracts which last indefinitely) and 24 (sale of securities, foreign currency etc).

As previously noted, it is also likely that variation clauses are blacklisted under Part 1 of the Act. This should have the consequence that many variation clauses included in DTCGT contracts would be deemed to be unfair and unenforceable. This is reinforced by the CMA's recent findings report for its review of cloud storage providers[1027] as it states at paragraph 5.25 that it believes terms of this type are 'unfair under the CRA'.[1028]

In relation to choice of law and international jurisdiction clauses, section 20 of Schedule 2 provides:

> A term which has the object or effect of excluding or hindering the consumer's right to take legal action or exercise any other legal remedy, in particular by—
>
> (a) requiring the consumer to take disputes exclusively to arbitration not covered by legal provisions,
>
> (b) unduly restricting the evidence available to the consumer, or
>
> (c) imposing on the consumer a burden of proof which, according to the applicable law, should lie with another party to the contract.

It is possible that many of the choice of law and jurisdiction clauses used by DTCGT companies might be unenforceable where they conflict with section 20.

1027 CMA, *Consumer Law Compliance Review* (n 224) para 5.24-38

1028 ibid para 5.25

(b) The CRA's provisions relating to different categories of consumer contract

(i.) Mixed Contracts

The Act divides business to consumer contracts into three categories, which are: contracts for the sale of goods; contracts for the supply of digital content; and contracts for the supply of services. However, the Act also applies to business to consumer contracts that do not fit into the specific categories identified. These contracts are referred to as 'mixed contracts' in section (1)(4). Given the nature of DTCGT services, it is likely that DTCGT contracts would be considered to be mixed contracts and consequently the respective provisions of the Act relating to the three categories of consumer contracts would be applicable to DTCGT contracts.

(ii.) The requirements for contracts for the sale of goods

The Act implies certain terms into consumer contracts for the supply of goods. The most significant implied terms for present purposes are set out in sections 9 to 11. These specify that goods are to be of satisfactory quality, fit for purpose, and also to be as described. Section 31 then includes these on a list of matters that traders are not permitted to exclude liability for. The relevant provisions in section 31 are as follows:

> (1) A term of a contract to supply goods is not binding on the consumer to the extent that it would exclude or restrict the trader's liability arising under any of these provisions—
>
> (a) section 9 (goods to be of satisfactory quality);
>
> (b) section 10 (goods to be fit for particular purpose);
>
> (c) section 11 (goods to be as described);
>
> (d) section 12 (other pre-contract information included in contract);

These sections are relevant to the DTCGT context because DTCGT companies while not engaged in the sale of goods in a more traditional sense are in fact providing a good in

the form of their test kits. Consequently, in accordance with the Act the kits need to be of satisfactory quality, fit for purpose and in accordance with their description.

(iii.) The requirements for contracts for the supply of digital content

The Act implies similar terms into consumer contracts for digital content in sections 34 to 36. It defines 'digital content' in section 2, as 'data which are produced and supplied in digital form'. Digital content is 'a new category of product distinct from goods and services'[1029] and it is likely that DTCGT tests results would be included in this category. The Act requires that where 'digital content has been paid for',[1030] it is to be of satisfactory quality (section 34), fit for particular purpose (section 35), and the content must also be in accordance with its description (section 36). The implied terms of the Act are particularly important in the DTCGT context, as the main entity that a consumer is in fact purchasing is a sequencing service that will lead to the consumer receiving test results in digital form, ie digital content. Consequently, these implied terms could be relied upon as requiring DTCGT test results to in fact be fit for purpose and of satisfactory quality. This is an interesting matter, as it is quite common (as previously noted) for DTCGT companies to also limit the scope of their services with 51% of companies examined including a term specifying that their services are provided for informational, educational, or recreational purposes and 44% specify that their services are provided on an 'as is' basis. These terms are actually blacklisted[1031] under section 47 of the CRA, which provides that:

> (1) A term of a contract to supply digital content is not binding on the consumer to the extent that it would exclude or restrict the trader's liability arising under any of these provisions—
> (a) section 34 (digital content to be of satisfactory quality),

---

1029 Competition & Markets Authority, *Unfair contract terms guidance - Guidance on the unfair terms provisions in the Consumer Rights Act 2015* (n 815) 54, para 4.16

1030 ibid (n 815) 54, para 4.17

1031 ibid (n 815) 54, para 4.17

(b) section 35 (digital content to be fit for particular purpose),
(c) section 36 (digital content to be as described),
(d) section 37 (other pre-contract information included in contract)
(…)

Thus, it is likely that many DTCGT companies' terms aimed at limiting the scope of purpose of their services or specifying that services are provided on 'as is' basis are likely to be unenforceable under UK law. It is also likely that where testing services are described on websites in a particular way and test results do not match this description that companies' terms will also be deemed to be unfair and unenforceable, as tests results supplied as digital content ought to be of satisfactory quality, fit for purpose, and as described.

(iv.) The requirements for contracts for the supply of services

Similarly, the Act implies terms into contracts for the supply of services. These include the requirement that services are to be performed with reasonable care and skill (section 49). As the sequencing service element is at the heart of what DTCGT companies are selling requiring services to be carried out with reasonable care and skill seems desirable. The CMA notes in its *Final Guidance* that:

> Consumers enjoy additional protection where they are given information about the trader and/or the service. If it is taken into account by the consumer, it is likely to be treated as a term of the contract. This goes further than rights under previous legislation. It means that if a business makes statements about itself and its services, which the consumer is likely to see, it is likely to find itself legally bound actually to supply, for instance, something that meets any description applied to it in those statements. In these circumstances, the service provider's liability is similar to that of a supplier of goods or digital content – it is not accountable, for example, only for statements that could be considered misleading.[1032]

This might have the result that in future the information provided on DTCGT websites regarding their services could be deemed to be contractual information, and if so this

[1032] ibid (n 815) 56, para 4.26

might have implications for the enforceability of other terms included in DTCGT contracts.

In relation to contracts for the provision of services, the CRA also blacklists terms, which attempt to 'exclude the trader's liability for failing to carry out the service with reason-able care and skill, or for failing to act in compliance with information about the trader or service which is binding on the trader under the Act'.[1033] As was noted in chapter five, exclusion clauses are also very common in DTCGT contracts with 80% of companies examined including some form of exclusion clause. Accordingly, it is likely that many exclusion clauses included in DTCGT contracts would be unenforceable.

(c) The Consumer Contracts (Information, Cancellation and Additional Charges) Regulations 2013

These Regulations replace previous Regulations on distance selling. They came into force on the 13th of June 2014.They apply to contracts between consumers and traders and provide consumers certain rights and require traders to provide pre-contract information. A distance contract is defined in Regulation 5, as:

> a contract concluded between a trader and a consumer under an organised distance sales or service-provision scheme without the simultaneous physical presence of the trader and the consumer, with the exclusive use or one or more means of distance communication up to and including the time at which the contract is concluded

Although '"organised distance sales" and "service-provision scheme" are not defined in the regulations (…) they are likely to refer to services like mail order, online sales and telesales'.[1034] Regulation 4 defines consumer and trader for the purposes of the Regulations. Consumer in this context 'means an individual acting for the purposes

1033 ibid (n 815) 57, para 4.27

1034 The Law Society, *Consumer Contracts Regulations 2013* (The Law Society, Practice Note, last updated 18 September 2014)

which are wholly or mainly outside that individual's trade, business, craft or profession' and trader 'means a person acting for purposes relating to that person's trade, business, craft or profession, whether acting personally or through another person acting in the trader's name or on the trader's behalf'. The Regulations require traders to provide certain information to consumers. Part 2 of the Regulations set out the information requirements. It should be noted that if DTCGT services are not regulated as consumer service and were instead regulated by medical devices legislation, then it is possible that these Regulations would not apply, as they may be exempted under regulation 7, which provides in 7(2) that:

> This Part does not apply to contracts to the extent that they are—
> (a) for the supply of a medicinal product by administration by a prescriber, or under a prescription or directions given by a prescriber;
> (b) for the supply of a product by a health care professional or a person included in a relevant list, under arrangements for the supply of services as part of the health service, where the product is one that, at least in some circumstances is available under such arrangements free or on prescription.

However, while these are framed as consumers services it is likely that the Regulations would be applicable to DTCGT and so the pre-contractual information requirements set out in regulation 13 would be applicable, meaning that companies would need to provide consumers with the information set out in schedule 2 of the Regulations before a consumer would be bound by the contract. The information requirements set out in schedule 2 require traders to provide information regarding a large number of matters. The most relevant provisions for DTCGT contracts include: (a)'the main characteristics of the goods or services, to the extent appropriate to the medium of communication and to the goods or services'; (c) – (e) the trader's geographical address; (f) – (i) several matters pertaining to prices and payment; (l) 'where a right to cancel exists, the conditions, time limit and procedures for exercising that right in accordance with regulations 27 to 38'; (m) – (o) matters relating to

cancellation; (v) ‘where applicable, the functionality, including applicable technical protection measures, of digital content’; and (x) ‘where applicable, the possibility of having recourse to an out-of-court complaint and redress mechanism, to which the trader is subject, and the methods for having access to it’. Schedule 3 then provides model instructions for cancellation, which companies can use as a template for composing cancellation forms.

Regulation 14 sets out the requirements for distance contracts concluded by electronic means, which should be applicable to DTCGT contracts. The Regulations provide that:

> 14.—
> (1) This regulation applies where a distance contract is concluded by electronic means.
> (2) If the contract places the consumer under an obligation to pay, the trader must make the consumer aware in a clear and prominent manner, and directly before the consumer places the order, of the information listed in paragraphs (a), (f), (g), (h), (s) and (t) of Schedule 2.
> (3) The trader must ensure that the consumer, when placing the order, explicitly acknowledges that the order implies an obligation to pay.
> (4) If placing an order entails activating a button or a similar function, the trader must ensure that the button or similar function is labelled in an easily legible manner only with the words ‘order with obligation to pay’ or a corresponding unambiguous formulation indicating that placing the order entails an obligation to pay the trader.
> (5) If the trader has not complied with paragraphs (3) and (4), the consumer is not bound by the contract or order.
> (6) The trader must ensure that any trading website through which the contract is concluded indicates clearly and legibly, at the latest at the beginning of the ordering process, whether any delivery restrictions apply and which means of payment are accepted.

Regulation 16 then has requirements for confirmation of distance contracts. These provide that:

> 16.—(1) In the case of a distance contract the trader must give the consumer confirmation of the contract on a durable medium.
> (2) The confirmation must include all the information referred to in Schedule 2 unless the trader has already provided that information to the

> consumer on a durable medium prior to the conclusion of the distance contract.
> (3) If the contract is for the supply of digital content not on a tangible medium and the consumer has given the consent and acknowledgment referred to in regulation 37(1)(a) and (b), the confirmation must include confirmation of the consent and acknowledgement.
> (4) The confirmation must be provided within a reasonable time after the conclusion of the contract, but in any event—
>
> (a) not later than the time of delivery of any goods supplied under the contract, and
> (b) before performance begins of any service supplied under the contract.
>
> (5) For the purposes of paragraph (4), the confirmation is treated as provided as soon as the trader has sent it or done what is necessary to make it available to the consumer.

If applicable this would mean that DTCGT companies would need to provide more detailed confirmation that many are currently. Part 3 of the Regulations set out matters relating to cancellation rights in detail. The most relevant provision is regulation 37, which deals with the supply of digital content. Regulation 37 provides:

> (1) Under a contract for the supply of digital content not on a tangible medium, the trader must not begin supply of the digital content before the end of the cancellation period provided for in regulation 30(1), unless—
>
> (a) the consumer has given express consent, and
> (b) the consumer has acknowledged that the right to cancel the contract under regulation 29(1) will be lost.

If these Regulations were applicable to DTCGT, they might help to improve consent mechanisms. Overall, these Regulations if applicable to DTCGT could be drawn upon to improve matters for consumers, as compliance by companies should improve transparency, although as they are mainly concerned with cancellation rights and financial matters they should only be viewed as one tool to improve regulation of the industry.

5 Relevant Case Law

While there is case law on unfair terms, there is a lack of case law in the UK specifically addressing the unfairness of provisions in wrap contracts or their validity or enforceability. It does seem likely that in terms of their interpretation of what constitutes unfairness Courts will take a similar approach to wrap contracts as they have to other types of standard form contract. However, it is important to acknowledge the lack of case law specifically addressing wrap contracts and it does seem possible that Courts may look to cases from other jurisdictions. In fact, the jurisdiction with the most significant body of case law on wrap contracts to date is the USA. Consequently, it should have been useful to include a substantive comparative component herein with US law, but due to restrictions of time and words this has not been possible. However, future research will address the American case law. In the meantime there are two cases in the UK, which are directly relevant. These are *Beta Computers v Adobe Systems*[1035] and *Spreadex v Cochrane*[1036]. However, this section will also consider some of the other most relevant cases on unfair terms and will also mention the very recent case of *Arnold v Britton*.

(a) Significant cases

(i.) Spreadex v Cochrane[1037]

Spreadex is the only UK case to date specifically dealing with a wrap contract. Briefly, the case concerned an online betting account. Cochrane had joined Spreadex's online betting platform, but while he was away from home his girlfriend's five year old son used his account to place bets and accrued a £50,000 debt which the company wanted Cochrane to repay. The main clause that was in dispute was clause 10(3), which was

1035 *Beta Computers (Europe) Ltd v Adobe Systems (Europe) Ltd* [1996] SLT 604
1036 *Spreadex Ltd v Cochrane*
1037 ibid

included in Spreadex's 49 page Customer Agreement. The clause purported to make the customer responsible for all transactions made with their account. The clause read as follows, '(…) You will be deemed to have authorised all trading under your account number'.[1038]

Donaldson J questioned whether there was in fact valid consideration provided in the circumstances, due to the fact that *Spreadex* was merely providing a platform and although Cochrane had created an account the service was not activated in essence until he had in fact placed a bet. According to the Court:

> The provision of an on-line interactive platform is in effect simply a more modern equivalent of the expressed readiness of a potential contracting party (also covered in the Consumer Agreement) to enter into contracts by receiving and responding orally to telephone calls.[1039]

The Court then went on to hold that clause 10(3) did result in 'not only a significant imbalance in the parties' rights and obligations but one which viewed overall is unfair within the meaning of the UTCCR'.[1040] The Judge went on to state that:

> It would have come close to a miracle if he had read the second sentence of Clause 10(3), let alone appreciated its purport or implications, and it would have been quite irrational for the claimant to assume that he had.[1041]

As *Spreadex* is only a High Court case it is not strong authority, but if courts were to take a similar approach to other wrap contracts this could be beneficial for consumers and might mean that several terms commonly included in DTCGT contracts could be deemed unfair by the courts. Although the facts of this case do not resemble the situation where a dispute might potentially arise between a DTCGT company and consumer, the Court's approach here is relevant to this discussion. Significantly, the length of the contract in *Spreadex* was treated as weighing against the company and in line with the

---

1038 *Spreadex* [8].
1039 *Spreadex Ltd v Cochrane* [15]
1040 ibid [20]
1041 ibid [21]

CMA's guidance it is likely that particularly lengthy contracts may be treated as failing transparency requirements. If companies bury unexpected terms in very long contracts, it seems more likely that they might be viewed as unfair and unenforceable.

(ii.) Beta Computers v Adobe Systems[1042]

Prior to *Spreadex, Beta* was the only case specifically to consider the 'legality of shrink-wrap, click-wrap, or browse-wraps agreements in UK law'.[1043] This is a Scottish case concerning the validity of shrink-wrap licences and has been problematic for English commentators as:

> in deciding that shrinkwrap licences were enforceable in Scotland, Lord Penrose utilised a unique property of Scottish contract law, namely jus quastium tertio. Strictly there is no equivalent in English law but the Contracts (Rights of Third Parties) Act 1999 creates a close statutory approximation. It may be assumed therefore that the authority of *Beta* suggests 'wrap' licences are legal in all parts of the UK.[1044]

Briefly, Adobe purchased software from Beta. The software packaging contained a shrink-wrap licence specifying that opening the packaging constituted acceptance of the terms and conditions. Adobe did not open the package and returned the software unopened. Beta refused to take the software back and sued for the purchase price. Adobe argued that 'acceptance of the licence conditions was an implied condition suspensive of their agreement with' Beta.[1045] The ruling in this case has been criticised[1046] and as Cameron writes the main:

1042 *Beta*

1043 Andrew Murray, *Information technology law: the law and society* (Oxford University Press 2013) 240

1044 ibid 240

1045 John N Adams, 'Snark was a Boojum, You See: Beta Computers (Europe) Ltd v Adobe Systems (Europe) Ltd; St Albans City and District Council v International Computers Ltd, The' (1996) 1 Edinburgh L Rev 386

1046 Struan JA Robertson, 'The Validity of Shrink-Wrap Licences in Scots Law Beta Computers (Europe) Ltd v. Adobe Systems (Europe) Ltd' The Journal of Information, Law and Technology <http://www2.warwick.ac.uk/fac/soc/law/elj/jilt/1998_2/robertson/> accessed 13 August 2015

> issue in the case seems to have occurred 'the wrong way round'. One would imagine that the normal situation would be that the supplier or the copyright owner would be argueing for the validity of the conditions against a claim by the customer that the terms were not binding upon him. Yet here it is the customer who elaborately argues that the conditions are potentially binding upon it if he were to open the package. The reason is that the purchaser wished to argue that it was entitled to reject the software at any time prior to it being given the opportunity to accept the terms by opening the package. By contrast the suppliers simply argued that the contract was complete at the time of supply and that the obligation to pay had thus arisen. The purchaser would find it more difficult to resist this argument if the conditions were of no effect. But if they were potentially binding, then it could be argued that it would be unreasonable, at the policy level at least, that the purchaser should be regarded as bound before having the opportunity to consider the terms. What this means is that we did not have the 'natural' defendant arguing for the invalidity of the conditions as a whole or in part. [1047]

This decision was largely decided on pragmatic grounds with Lord Penrose stressing the need to address industry interests.[1048]

While it may be desirable to challenge the validity of clickwrap and browsewrap contracts, it seems possible that *Beta Computers* might be relied upon and extended to support the validity of clickwrap and browsewrap agreements. Hedley notes that, 'there is now a considerable bulk of US cases (…) holding clickwrap contracts prima facie valid, and there seems little doubt that they are valid in Irish and UK law as well'.[1049] However, it should be noted that *Beta* concerned the validity of a shrink-wrap licence and is also a Scottish case, which was decided on the basis of Scottish law and so it is possible that it might not be followed widely in the UK. Although as noted the enactment of the Contracts (Rights of Third Parties) Act makes it much more likely that the case will be followed. However, the more recent *Spreadex* case might signify a different approach to wrap contracts in the UK.

1047 Euan Cameron, 'Major cases the scrutinity of computer contracts: At last. International Review Of Law' (1996) 10 Computers & Technology [serial online] 331

1048 ibid

1049 Hedley (n 820) 248

(iii.) Arnold v Britton & Ors[1050]

This very recent case highlights the general reluctance of UK courts to rewrite contracts even where the result seems undesirable. Again, the facts of this case do not seem especially relevant to disputes likely to arise between DTCGT companies and their consumers, but the case needs to be mentioned because it does highlight the Court's reluctance to intervene. However, I submit that given the nature of DTCGT services and the guidance produced by the CMA and the previous successes of the OFT, it is more likely that a Court might be more ready to intervene in this context. The case involved the tenants of twenty-five leases of chalets in a leisure park. The leases were each 'for a period of 99 years'.[1051] Twenty-one of the twenty-five leases were granted between 1977 and 1991.[1052] At issue was the interpretation of a covenant included in the lease requiring tenants to pay service charges. The Respondent (landlord) argued that:

> the service charge provision in clause 3(2) requires the lessee to pay an initial annual service charge of £90, which increases at a compound rate of 10% for the first 70 chalets to be let, every three years, but for the last 21 chalets to be let, every year. The service charge provisions in four of the 70 leases were subsequently varied so that the increases were yearly rather than every three years.

The issue on appeal was whether the Respondent's interpretation was correct. In the leading judgment Lord Neuberger held that:

> When interpreting a written contract, the court is concerned to identify the intention of the parties by reference to "what a reasonable person having all the background knowledge which would have been available to the parties would have understood them to be using the language in the contract to mean", to quote Lord Hoffmann in Chartbrook Ltd v Persimmon Homes Ltd [2009] UKHL 38, [2009] 1 AC 1101, para 14. And it does so by focussing on the meaning of the relevant words, in this

---

1050 *Arnold v Britton & Ors* [2015] UKSC 36

1051 The Supreme Court, 'Arnold (Respondent) v Britton and others (Appellants) [2015] UKSC 36 - Press Summary' (*The Supreme Court*) <supremecourt.uk/cases/docs/uksc-2013-0193-press-summary.pdf> accessed 29 July 2015 1

1052 *Arnold v Britton & Ors* [6] (Lord Neuberger)

> case clause 3(2) of each of the 25 leases, in their documentary, factual and commercial context. That meaning has to be assessed in the light of (i) the natural and ordinary meaning of the clause, (ii) any other relevant provisions of the lease, (iii) the overall purpose of the clause and the lease, (iv) the facts and circumstances known or assumed by the parties at the time that the document was executed, and (v) commercial common sense, but (vi) disregarding subjective evidence of any party's intentions. In this connection, see Prenn at pp 1384-1386 and Reardon Smith Line Ltd v Yngvar Hansen-Tangen (trading as HE Hansen-Tangen) [1976] 1 WLR 989, 995-997 per Lord Wilberforce, Bank of Credit and Commerce International SA (in liquidation) v Ali [2002] 1 AC 251, para 8, per Lord Bingham, and the survey of more recent authorities in Rainy Sky, per Lord Clarke at paras 21-30.[1053]

The Court ruled in favour of the respondent despite the fact that approving the Respondent's interpretation of the clause had the effect that the service charges tenants were obliged to pay would increase to over £550,000 per annum by 2072.[1054] Due to the time at which the leases were entered into the case falls outside the legislation on unfair terms,[1055] but it is worthy of mention because it confirms the approach of English courts in refusing to rewrite bargains even where the result is detrimental to the parties involved. This might indicate that Courts will be reluctant not to uphold the validity of wrap contracts and thus reinforces the need to challenge specific terms on the basis of their potential unfairness.

(b) Unfair terms case law

Prior to consideration of whether a term ought to be construed as unfair is the matter of whether the term has in fact been validly incorporated into the contract.[1056] However, in the DTGCT context generally if the wrap contracts employed are held to be valid contracts then the question of incorporation is not as significant and that is why the discussion herein is focussed more on whether or not particular terms might be construed as unfair, rather than in questioning whether they have been validly incorporated.

1053 ibid [15] (Lord Neuberger)
1054 ibid [30] (Lord Neuberger)
1055 ibid [93] (Lord Neuberger)
1056 Lawson 3.

Furthermore, in relation to challenging unfair terms in standard form contracts the work of the OFT has been focussed more on negotiations with companies, rather than pursuing litigation. It seems that the CMA is following a similar approach to the OFT in tending to avoid litigation and trying to negotiate directly with industry. Its recent compliance review of cloud storage providers had already secured commitments from a number of cloud storage providers to improve their terms. The lack of case law in the UK specifically addressing validity of wrap contracts does mean though that it might be possible for courts to follow a different path than the American courts have done.

(i.) *Director General of Fair Trading v First National Bank*[1057]

This is one of most significant cases dealing with the UTCCR and while it 'actually concerned the interpretation of the 1994 rather than the 1999 Regulations (…) the differences between the two sets of Regulations are immaterial for the purposes of the case'.[1058] The case involved the application by the Director General of Fair Trading:

> for an injunction to restrain First National Bank from using or relying upon a sentence in their standard terms of business on the ground that it was an 'unfair term' within the meaning of regulation 4(1) of the Unfair Terms in Consumer Contracts Regulations 1994.[1059]

The case involved two main issues. 'The first was whether the Regulations were applicable to the term or not. The second was, if they were, whether or not the term was unfair'.[1060] Briefly, First National Bank was 'licensed to carry on consumer credit business' and the provision that was at issue was a sentence included in condition 8 of the Bank's standard terms. The clause stated that 'should the customer default on reepayments to it, it was to be entitled to recover from the customer the whole of the

---

1057 *Director General of Fair Trading v First National Bank* [2001] UKHL 52 [2001] 3 WLR 1297
1058 McKendrick (n 932) 479-80
1059 ibid (n 932) 480
1060 ibid (n 932) 484

balance on the customer's loan account together with outstanding interests and the costs of seeking judgement'.[1061] The clause's effect:

> was to extend the liability of customers to First National Bank in the case where they paid off an outstanding loan pursuant to an instalment scheme that had been approved by a court. In such a case payment pursuant to the instalment scheme did not necessarily have the effect of discharging the debt because interest continued to accrue on the unpaid balance of the debt by virtue of clause 8.[1062]

The House of Lords held that the term was not unfair, but the case is important for present purposes because it provides guidance on the interpretation of unfairness. Lord Bingham noted that:

> 17. The test laid down by regulation 4(1), deriving as it does from article 3(1) of the directive, has understandably attracted much discussion in academic and professional circles and helpful submissions were made to the House on it. It is plain from the recitals to the directive that one of its objectives was partially to harmonise the law in this important field among all member states of the European Union. The member states have no common concept of fairness or good faith, and the directive does not purport to state the law of any single member state. It lays down a test to be applied, whatever their pre-existing law, by all member states. If the meaning of the test were doubtful, or vulnerable to the possibility of differing interpretations in differing member states, it might be desirable or necessary to seek a ruling from the European Court of Justice on its interpretation. But the language used in expressing the test, so far as applicable in this case, is in my opinion clear and not reasonably capable of differing interpretations. A term falling within the scope of the regulations is unfair if it causes a significant imbalance in the parties' rights and obligations under the contract to the detriment of the consumer in a manner or to an extent which is contrary to the requirement of good faith. The requirement of significant imbalance is met if a term is so weighted in favour of the supplier as to tilt the parties' rights and obligations under the contract significantly in his favour.[1063]

Unfortunately, the case was decided in favour of the bank and to some extent represents a failed effort by the OFT, although the more recent case of *Ashbourne*, which is discussed below shows that it is possible for regulators to take successful action against industry. However, it appears that several terms commonly included in DTCGT contracts would

---

1061 ibid (n 932) 480.
1062 ibid (n 932) 480.
1063 *Director General of Fair Trading v First National Bank* [17] (Lord Bingham)

meet the test for unfairness set out in this case. Specifically, terms that allow for unilateral variation, compel the consumer to resolve disputes in another jurisdiction or limit liability in a variety of ways, do seem likely to meet this test in that they are likely to create a real imbalance in the parties' rights weighted too much in favour of the company. Terms allowing for unilateral variation have particular significance in the context of DTCGT, as they could allow a company to make very serious changes to its policies on the storage, sharing, use, or sale of consumers' data. Given the variety of uses to which stored genetic data may be put and the ways it can be linked to other types of personal data, it seems likely that unilateral variation clauses are especially likely to be deemed to be unfair in this context.

(ii.) *Office of Fair Trading v Abbey National plc*[1064]

This case is important for present purposes, because it considers issues relating to the meaning of the phrase 'plain intelligible language' requirement set out in regulation 6(2) of the UTCCR[1065] and thus is pertinent to discussion of how Courts might interpret the CRA's requirement for transparency. Andrew Smith J considered a number of issues in this context, but several points are relevant for present purposes. Firstly, 'the question whether terms are in plain intelligible language is to be considered from the point of view of the typical consumer or the average consumer'.[1066] Furthermore, '[a] term which is 'obscure and difficult to understand at all' may not be in plain intelligible language even if it can bear only one meaning 'for anyone who managed to fathom what it is saying'.[1067] However, the 'requirement does not require that the consumer be put in a position to be able to make a 'fully informed choice about whether to enter into a

1064 *Office of Fair Trading v Abbey National plc* EWHC 875 (Comm), [2008] 2 All ER (Comm)
1065 McKendrick (n 932) 468
1066 ibid (n 932) 468 citing *Office of Fair Trading v Abbey National plc* [89]
1067 McKendrick (n 932) 468 citing *Office of Fair Trading v Abbey National plc* [87]

contract on the standard terms of the seller or supplier'.[1068] Also, there is no requirement under the UTCCR that companies provide 'all the information that' the consumer 'needs in order to make an informed decision whether to enter into the contract'.[1069] Although the 'requirement demands not only that the actual wording is comprehensible to the consumer 'but that the typical consumer can understand how the terms affect the rights and obligations the he and the seller or supplier have under the contract'.[1070]It should be noted that this standard is significantly different from the requirements for valid consent to treatment in a medical context. However, it is submitted that several terms commonly included in DTCGT contracts would fail to meet the Court's standards. Again, this includes: terms allowing for unilateral alteration of terms; certain exclusion clauses, such as those limiting liability for fitness for purpose; choice of law clauses; and certain consent or assent clauses.

(iii.) *Office of Fair Trading v Ashbourne Management Services Ltd and others*[1071]

This is one of the most significant recent cases considering unfair terms legislation in the UK.[1072] Briefly the facts were as follows. Ashbourne 'carries on the business of recruiting members for gym and health and fitness clubs (collectively "gym clubs"), providing standard form agreements for their use and collecting payments from members under those agreements'.[1073] At issue were terms, which imposed minimum membership periods. The OFT made a number of contentions, which stemmed from complaints it had received. Briefly it argued that these terms were unfair because:

1068 McKendrick (n 932) 468 citing *Office of Fair Trading v Abbey National plc* [99]

1069 McKendrick (n 932) 468 citing *Office of Fair Trading v Abbey National plc* [100]

1070 McKendrick (n 932) 468 citing *Office of Fair Trading v Abbey National plc* [103]

1071 *Office of Fair Trading v Ashbourne Management Services Ltd and others* [2011] EWHC 1237 (Ch)

1072 Lee Mason, 'Protecting Consumers from Unfair Terms in Standard Form Contracts: The UK Approach' (2015) 26 European Business Law Review 335

1073 *Office of Fair Trading v Ashbourne Management Services Ltd and others* [2]

> consumers tend to overestimate the use they will make of their gym club memberships, that unforeseen circumstances often make it impractical for members to use the gym facilities, and that often a monthly payment that may have been affordable at the beginning of the agreement ceases to be affordable before the end of the minimum membership period. Mr Jason Freeman has exhibited to his witness statements many such complaints. They also reveal that consumers often do not appreciate that they have entered into an agreement which requires them to remain a member for a minimum period until they seek to bring it to an end. Indeed statements have sometimes been made to them which have positively misled them into believing that they have a right to terminate under their agreements when in truth they do not.[1074]

There were three issues considered by the Court. These were:

> first, whether the terms imposing a minimum membership period fell within the scope of regulation 6(2)(a), thereby precluding an assessment of its fairness; secondly, whether the terms were written in plain intelligible language; and thirdly, whether the terms were fair.[1075]

Kitchin J relying on *First National Bank*, 'identified three key elements which are required to establish unfairness' for the purposes of regulation 5(1)[1076] and these were:

> (1) a significant imbalance in the parties' rights and obligations,
> (2) to the detriment of the consumer, and
> (3) in a manner, or to an extent, which is contrary to good faith.[1077]

Kitchin J then again referred to Lord Bingham's judgement in *First National Bank* regarding the 'meaning of "significant imbalance" and "good faith"' and held that this meant the test for fairness must involve consideration of the 'typical parties and the effects of typical relationships between them'.[1078] His Lordship described the typical consumer as follows:

> The concept of a typical or average consumer is a familiar one in European consumer law extending also into the law of registered trade marks. Such a person is generally assumed to be reasonably well informed and reasonably observant and circumspect, and to read the relevant documents and to seek to understand what is being read. The standard is a variable one and must, I believe, take colour from the context. For example, consumers who are financially sophisticated may be expected to

---

1074 ibid [133]

1075 Mason, 'Protecting Consumers from Unfair Terms in Standard Form Contracts: The UK Approach' 339 citing UTCCR regs 6(2) and 5(1) respectively.

1076 ibid 340 citing *Ashbourne*

1077 ibid 340 citing *Ashbourne* [123]

1078 ibid 340 citing *Ashbourne* [128]

> bring to bear a greater understanding of the meaning and implications of the terms of a contract than consumers who are vulnerable as a result of their naivety or credulity. As will be seen, this typical consumer is relevant not only to the assessment of fairness but also the consideration of whether a particular term is expressed in clear intelligible language.[1079]

In relation to the first issue before the Court, his Lordship held that:

> If reg 6(2)(b) only precludes the assessment of the fairness of a term by reference to the adequacy of the price or remuneration as against the goods or services supplied then, in my judgment, it follows that reg 6(2)(a) only precludes the assessment of the fairness of a term by reference to the definition of the main subject matter of the contract. This is not only the natural meaning of the words used in reg 6(2) but also gives effect to the purpose of its two paragraphs as explained by Lord Walker JSC. Moreover, as the House of Lords explained in the First National Bank case, this regulation should be given no wider an interpretation than necessary. This is a matter to which I must return in addressing the third issue, namely fairness.[1080]

In relation to the issue of whether the term was expressed in plain intelligible language Kitchin J held that this was to be assessed 'from the perspective of an "average consumer"', and he considered that in this instance that meant 'a member of the public interested in using a gym club' and on this basis he resolved that the term 'was plain and intelligible'.[1081]

Finally, in relation to whether the terms were in fact fair, Kitchin J held that the terms were unfair. In deciding this, his Lordship noted that:

> In all these circumstances I believe that the Defendants' business model is designed and calculated to take advantage of the naivety and inexperience of the average consumer using gym clubs at the lower end of the market. As the many complaints received by the OFT show, the Defendants' standard form agreements contain a trap into which the average consumer is likely to fall.[1082]

It was held that:

> those contracts which provided no qualification allowing for early termination (…) were so weighted as to cause a significant imbalance in

---

1079 *Office of Fair Trading v Ashbourne Management Services Ltd and others* [128]

1080 ibid [153]

1081 Mason, 'Protecting Consumers from Unfair Terms in Standard Form Contracts: The UK Approach'

1082 *Office of Fair Trading v Ashbourne Management Services Ltd and others* [173]

> the rights and obligations of the parties in such a way as was contrary to good faith.[1083]

Although:

> those contracts which did provide qualifications (allowing members to terminate their membership period early) only created a significant imbalance in the parties' rights and obligations in a such a way that was contrary to good faith insofar as they required a minimum membership period exceeding 12 months.[1084]

This decision has had far reaching impact as consequently the OFT:

> put all UK gym clubs on notice that they should ensure that their membership contracts are compliant with the court's ruling. Since then, in September 2013, the OFT reported that it has now secured agreements from various major gym clubs across the UK, with a collective membership of millions of customers, to make the appropriate *Ashbourne*-compliant improvements to their membership contracts.[1085]

In its Press Release, the OFT noted that:

> Health and fitness club operators LA Fitness and Dave Whelan Sports ('DWS'), which together have nearly half a million members, and Harlands Group, a gym management company which manages over 900,000 customer contracts, have agreed to give consumers better cancellation rights and make their contract terms more transparent following an OFT investigation.
> This follows agreement earlier this year by Bannatyne Fitness Limited, David Lloyd Leisure Limited and Fitness First Clubs Limited to change their contract terms.
> The OFT is also today writing to 20 other health and fitness operators, highlighting contract terms and commercial practices which may be considered unfair and advising them to review their contract terms.[1086]

This is an example of a resounding success by the OFT and it is hoped that something similar might be possible were the CMA to work with the DTCGT industry to improve contract terms, although this is only one option in improving regulation for the industry and specific legal regulation in legislative form is desirable. The CMA's recent compliance review of cloud computing providers suggests it may be open to reviewing

---

1083 Mason, 'Protecting Consumers from Unfair Terms in Standard Form Contracts: The UK Approach' 344, citing *Ashbourne* [174]

1084 ibid 344, citing *Ashbourne* [174]

1085 ibid 344, citing Office of Fair Trading, *OFT secures further improvements to gyms contracts* (Office of Fair Trading, Press Relase, 2013)

1086 Office of Fair Trading

the DTCGT industry and other web-based industries as well.

6 Previous Legislation on unfair terms

(a) Unfair Terms in Consumer Contracts Regulations 1999 (UTCCR)

The UTCCR were created in order to give effect to the EC Directive on unfair Terms in Consumer Contracts.[1087] These Regulations provided the courts and the Director-General of the Office of Fair Trading (OFT) 'broad powers to regulate unfair terms in stand form consumer contracts' and 'the reach of the Regulations is much broader than the Unfair Contract Terms Act 1977'.[1088] The 1999 Regulations replaced and revoked the previous Unfair Terms in Consumer Contracts Regulations 1994 (SI No 1999/2083).[1089] Overall, as the Regulations followed a 'copy-out approach' the text of the Regulations is very similar to the language used in the Directive itself.[1090] There is also much similarity with the CRA 2015 and Schedule 2 provides an indicative non-exhaustive list of terms, which may be deemed unfair (also dubbed the Grey List),[1091] which closely resembles the CRA's Grey List.

Regulation 5(1) sets out the requirements for unfairness. It is very similar to the new CRA. It provides as follows:

> 5—(1) A contractual term which has not been individually negotiated shall be regarded as unfair if, contrary to the requirement of good faith, it causes a significant imbalance in the parties' rights and obligations arising under the contract, to the detriment of the consumer.
> (2) A term shall always be regarded as not having been individually negotiated where it has been drafted in advance and the consumer has therefore not been able to influence the substance of the term.
> (3) Notwithstanding that a specific term or certain aspects of it in a contract has been individually negotiated, these Regulations shall apply to

1087 McKendrick (n 932) 460
1088 McKendrick (n 932) 460
1089 ibid (n 932) 461
1090 ibid (n 932) 460
1091 ibid (n 932) 475-9

> the rest of a contract if an overall assessment of it indicates that it is a pre-formulated standard contract.
> (4) It shall be for any seller or supplier who claims that a term was individually negotiated to show that it was.
> (5) Schedule 2 to these Regulations contains an indicative and non-exhaustive list of the terms which may be regarded as unfair.

The provisions in Regulation 5 closely resemble the provisions of article 3 of the Unfair Terms Directive.

Regulation 6(1) lists matters that should be taken into consideration when assessing unfairness.[1092] It proves that:

> 6—(1) Without prejudice to regulation 12, the unfairness of a contractual term shall be assessed, taking into account the nature of the goods or services for which the contract was concluded and by referring, at the time of conclusion of the contract, to all the circumstances attending the conclusion of the contract and to all the other terms of the contract or of another contract on which it is dependent.

Regulation 7(1) introduces the requirement for terms to be in plain and intelligible language thus, 'A seller or supplier shall ensure that any written term of a contract is expressed in plain, intelligible language'.

Regulation 8 deals with the consequences of a finding that a term is unfair:

> 8—(1) An unfair term in a contract concluded with a consumer by a seller or supplier shall not be binding on the consumer. (2) The contract shall continue to bind the parties if it is capable of continuing in existence without the unfair term.

Regulation 9 deals with choice of law clauses:

> These Regulations shall apply notwithstanding any contract term which applies or purports to apply the law of a non-Member State, if the contract has a close connection with the territory of the Member States.

In the context of the consideration of DTCGT contracts, the most important provisions listed in Schedule 2 are:

> (1) Terms which have the object or effect of–
> (a) excluding or limiting the legal liability of a seller or supplier in the event of the death of a consumer or personal injury to the latter resulting

[1092] McKendrick (n 932) 467

from an act or omission of that seller or supplier;
(b) inappropriately excluding or limiting the legal rights of the consumer vis-à-vis the seller or supplier or another party in the event of total or partial non-performance or inadequate performance by the seller or supplier of any of the contractual obligations, including the option of offsetting a debt owed to the seller or supplier against any claim which the consumer may have against him;
(c) making an agreement binding on the consumer whereas provision of services by the seller or supplier is subject to a condition whose realisation depends on his own will alone;
(i) irrevocably binding the consumer to terms with which he had no real opportunity of becoming acquainted before the conclusion of the contract;
(j) enabling the seller or supplier to alter the terms of the contract unilaterally without a valid reason which is specified in the contract;
(k) enabling the seller or supplier to alter unilaterally without a valid reason any characteristics of the product or service to be provided;
(l) providing for the price of goods to be determined at the time of delivery or allowing a seller of goods or supplier of services to increase their price without in both cases giving the consumer the corresponding right to cancel the contract if the final price is too high in relation to the price agreed when the contract was concluded;
(m) giving the seller or supplier the right to determine whether the goods or services supplied are in conformity with the contract, or giving him the exclusive right to interpret any term of the contract;
(o) obliging the consumer to fulfil all his obligations where the seller or supplier does not perform his;
(p) giving the seller or supplier the possibility of transferring his rights and obligations under the contract, where this may serve to reduce the guarantees for the consumer, without the latter's agreement;
(q) excluding or hindering the consumer's right to take legal action or exercise any other legal remedy, particularly by requiring the consumer to take disputes exclusively to arbitration not covered by legal provisions, unduly restricting the evidence available to him or imposing on him a burden of proof which, according to the applicable law, should lie with another party to the contract.

As there is much similarity between the UTCCR and the new CRA, and as indicated by the CMA in its recent guidance the interpretation of provisions of the UTCCR will likely influence interpretation of the new CRA.

(b) Unfair Contract Terms Act 1977

While the Consumer Rights Act replaces the previous 1977 Act in relation to business to consumer contracts, it is still important to consider the provisions of the old Act and the

manner in which Courts have applied it in assessing unfairness, as they will have an influence on how Courts and the CMA decide on unfair terms in the future. Whereas, the UTCCR apply to business to consumer contracts and are concerned primarily with the provisions of standard form contracts the terms of which have not been individually negotiated, the 1977 Act had a broader focus. The Act did apply to contracts between businesses, whereas the new Act and the UTCCR's definitions of consumer are restricted to natural persons.[1093] The Act also could only be applied once it had 'been demonstrated that the defendant was in some way liable to the claimant' meaning that it regulated 'liability in respect of recognized causes of action' and it was 'vital to first identify the basis upon which the defendant is liable to the claimant'.[1094] Different sections of the Act would then apply depending on whether the liability was based in negligence or breach of contract.

Section 25 defines consumer in its definition of consumer contract:

> "consumer contract" means a contract (not being a contract of sale by auction or competitive tender) in which-
>
> (a) one party to the contract deals, and the other party to the contract (" the consumer") does not deal or hold himself out as dealing, in the course of a business, and
>
> (b) in the case of a contract such as is mentioned in section 15(2)(a) of this Act, the goods are of a type ordinarily supplied for private use or consumption; and for the purposes of this Part of this Act the onus of proving that a contract is not to be regarded as a consumer contract shall lie on the party so contend-ing

The Act provides a definition of negligence for the purposes of the Act in section (1). For present purposes the most relevant provisions are:

> 1-(1) (…) 'negligence' means the breach –

1093 McKendrick (n 932) 463
1094 ibid (n 932) 421-2

(a) of any obligation, arising from the express or implied terms of a contract, to take reasonable care or exercise reasonable skill in the performance of the contract;
(b) of any common law duty to take reasonable care or exercise reasonable skill (but not any stricter duty);

Section 2 of the Act then prohibits terms avoiding liability for negligence as follows:

(1) A person cannot by reference to any contract term or to a notice given to persons generally or to particular persons exclude or restrict his liability for death or personal injury resulting from negligence.

(2) In the case of other loss or damage, a person cannot so exclude or restrict his liability for negligence except in so far as the term or notice satisfies the requirement of reasonableness.

(3) Where a contract term or notice purports to exclude or restrict liability for negligence a person's agreement to or awareness of it is not of itself to be taken as indicating his voluntary acceptance of any risk.

The Act prohibited indemnity clauses in section 4:

(1) A person dealing as consumer cannot by reference to any contract term be made to indemnify another person (whether a party to the contract or not) in respect of liability that may be incurred by the other for negligence or breach of contract, except in so far as the contract term satisfies the requirement of reasonableness.

(2) This section applies whether the liability in question-
(a) is directly that of the person to be indemnified or is incurred by him vicariously;
(b) is to the person dealing as consumer or to someone else.

As was shown in chapter five, indemnity clauses are very common in DTCGT contracts with 44% of the companies examined including such a clause.

7 Way forward for DTCGT contracts

The present chapter has set out the special features of wrap contracts that differentiate them from other standard form contracts. Given the nature of DTCGT services, particularly those for health purposes, the use of these contracts to govern all matters ranging from test purchase to participating in research, may not be optimal, it has argued

that it might be possible to challenge certain types of terms (such as those allowing for unilateral variation; exclusion clauses; choice of law clauses; and consent clauses) commonly included in DTCGT contracts on the grounds of their potential unfairness. It has also argued that overall many DTCGT contracts are likely to fail transparency requirements and it is desirable that the CMA takes action to discourage the use of these terms. There may also be a potential role for other regulators, such as the ICO, the Human Tissue Authority, and the MHRA, but especially given the CMA's recent work with the cloud computing industry, a compliance review by the CMA seems an attractive first step in improving regulation of the DTCGT industry for UK consumers.

As chapter five has shown there is much similarity in the content of DTCGT contracts. This in turn results in limitations on consumer choice, as it is unlikely that consumers can access the same services on more favourable terms elsewhere. While it is desirable that specific legislation be developed to regulate the industry, it is suggested here that in the short-term it is desirable that DTCGT contracts are improved. While it is hoped that the CMA will play an active role in this there are also other possibilities. Kim has suggested that one way to improve wrap contracts would be to introduce a model of specific assent and this seems an attractive idea.[1095] Kim also suggests introducing a duty on companies to draft reasonably and this could be very helpful in the DTCGT context. Her suggestion is that:

> The standard of reasonable drafting would require that businesses take certain measures to make their contracts noticeable. There are several aspects to this duty to draft reasonably. The first is visibility. The terms should be presented to attract the attention of the nondrafting party. This is the aspect that courts currently require, but often they fail to sufficiently consider the effect of inattentional blindness. Christopher Chabris and Daniel Simons define inattentional blindness as an "error of perception" and explain that when "people devote their attention to a particular area or aspect of their visual world, they tend not to notice unexpected objects,

[1095] Kim, *Wrap Contracts: Foundations and Ramifications* 192-200

> even when those unexpected objects are salient, potentially important, and appear right where they are looking."35 It is inattentional blindness which makes someone who is preoccupied with counting shirt colors during a basketball game overlook a gorilla pounding its chest in the middle of the court. It is also inattentional blindness which makes website visitors, caught up in the flow of the transaction, ignore hyperlinks and click "I agree" without realizing what they are doing.
>
> The second aspect of reasonable drafting is that the drafting party should make reasonable efforts to present the terms in a way that makes it likely that the other party will read them, not simply see them. In the Target.com example, the terms might be presented as soon as the visitor clicks on a product category. Thus, a duty to draft reasonably would consider the "look and feel" of the website.
>
> Reasonable drafting also considers word choice. Most websites use the demure wording of "Terms of Use" or "Conditions of Use" or simply "Terms," to provide notice of their online agreements. This language may seem benign to most nonlawyers. Companies should start using language that their users understand, such as "The Contract Between You and [Company]" or "Your Legal Obligations" instead of the more innocuous-sounding "Terms."[1096]

Consent and authorisation models discussed in the academic literature in relation to biobanks, such as Hofmann et al's suggestions for conditional authorization drawing upon Greely and Arnason's work,[1097] or HeLEX's dynamic consent model,[1098] may provide useful guidance here. The use of short summary notices, or in this context, perhaps short summary contracts drawing upon the work of Good et al[1099] might also be beneficial for consumers. In the short term though, it is desirable that the CMA works with the DTCGT industry to improve their contracts.

8 Conclusion

This chapter has sought to demonstrate how particular types of terms commonly included in DTCGT contracts might be challenged on the grounds of their unfairness. Specifically,

---

1096 ibid 187

1097 Bjørn Hofmann, Jan Helge Solbakk and Søren Holm, 'Consent to Biobank Research: One Size Fits All?' in Jan Helge Solbakk, Sore Holm and Bjorn Hoffman (eds), *The ethics of research biobanking* (Springer 2009) 17-20

1098 Kaye et al, 'Dynamic consent: a patient interface for twenty-first century research networks' (n 321)

1099 Good et al (n 978)

it has argued that the following types of terms are likely to be deemed unfair and consequently unenforceable: clauses allowing for unilateral variation of the contract; clauses disclaiming liability for fitness for purpose or for personal injury caused by the company's negligence; clauses limiting scope of purpose; clauses purporting to bind the consumer to resolve any disputes in another jurisdiction; and consent clauses. It has done this with reference to legislation on unfair terms, focussing more on the CRA than previous legislation in the interest of keeping abreast of current law and also, the recent work of the CMA. It is hoped that the discussion has shown that the terms mentioned above, which are commonly included in DTCGT contracts are open to challenge on the grounds of unfairness and that it is desirable that the CMA attempts to work with the industry to discontinue the use of such terms. I should recommend that the CMA undertake a compliance review of the DTCGT industry similar to its cloud storage provider compliance review.

This chapter has also argued that the use of wrap contracts in this context can be viewed as a form of private legislation and industry self-regulation, which is skewed heavily in the favour of companies and overall seems likely to be detrimental to consumers' rights. Drawing upon Kim's work, it is argued that this imbalance needs correcting. The use of wrap contracts in the DTCGT context is problematic given the complex and ambiguous nature of genetic test results and the variety of uses to which genetic information can be put.[1100]

However, although it may be possible also for individual consumers to challenge the validity of DTCGT contracts in some circumstances, it is likely that prima facie many DTCGT contracts would be held to be valid contracts.[1101] Furthermore, even where the validity of such contracts could be successfully challenged it is always going to be

[1100] Kim, *Wrap Contracts: Foundations and Ramifications* (n 227)
[1101] Hedley (n 820) 248

difficult for individuals to sue large companies. Overall it seems that in order to protect consumers it this context, it is advisable that contracts are improved in cooperation with the CMA, rather than waiting for individual consumers to take DTCGT companies to court.

CHAPTER SEVEN – CONCLUSION – THE WAY FORWARD FOR DTCGT REGULATION

This thesis has presented an analysis of current regulation of the DTCGT industry, focussing on use of wrap contracts by DTCGT companies. A major component has consisted of a document review of the contracts of DTCGT companies and considered how specific terms might be challenged under existing contract and consumer protection law. It has argued that in light of the lack of specific legal regulation of the industry, the use of wrap contracts is the main means of industry governance at present. This situation means that contract law is the current mechanism that consumers are most likely to draw upon in seeking redress, but it may not be the best suited to protection of their interests in this context. (The class actions against 23andMe in the USA have centred on its contract). It suggests that in the short-term one possible strategy to enhancing consumer protection in this context is for the CMA to undertake a compliance review of the DCTGT industry, similar to its recent review of cloud storage providers. Especially, in the area of genetic tests for health purposes, I do suggest that the MHRA and ICO in the UK have a greater role to play in regulating the industry. However, due to on-going reform of data protection and medical devices law, it is important to consider current industry practice and how matters might be improved for consumers and companies based on current business practice. Given the legislation on unfair terms and the previous work of the Office of Fair Trading the best way forward in the short-term is for the new CMA to take on the role of primary regulator of this industry in the UK and to work with the industry to discontinue the use of certain terms and increase transparency.

I have not argued strongly for one solution, as given the nature of DTCGT services and the variety of areas of law which might be drawn upon to regulate the

industry, it seems that there is not one obvious solution that is more compelling than all others. Consequently, this chapter discuss various options for reform. I should note though that the reluctance of regulators to take action in this context is something that does need to change in the near future as this industry and other similar innovations grow. While the law often struggles to keep up with technology, with the wide range of new technologies coming to market, which have the potential to change the way we live and affect our lives in significant ways, regulators, legislators, lawyers, researchers, technology companies, and the public need to come together and engage in open discussion so that laws can be created that can respond to the specific issues raised by particular technologies and regulate them appropriately. The public also needs to have access to balanced information about new technologies in general so that individuals can make informed choices about whether to engage with particular services and products.[1102] There are numerous historical examples of why it might not be beneficial for consumers or companies to leave sole responsibility for regulating up to the industry itself.

DTCGT services for health purposes are representative of a broader paradigm shift from patient to consumer in the field of personalised medicine. These services as they are offered via the Internet internationally do challenge existing governance mechanisms, especially those based nationally. They raise similar issues to wearable health monitoring devices, such as Fitbit, Jawbone, and Garmin or innovations in the field of biometrics. In an increasingly globalised world where legal regulation is no

1102 Andelka Phillips, I.S. Mian, and J. Charbonneau, 'Living in a Panopticon City: the Biological-Geographic-Economic-Social-Behavioural-Physical complex -- people and places under dynamic surveillance' – paper presented for Surveillance: Power, Performance & Trust (7th Biannual Surveillance and Society Conference) (April 2016)- this has been submitted to the Surveillance and Society Journal.

longer restricted to national laws, DTCGT highlights some of the problems associated more generally with regulation of Internet based industries.

For health related testing relying on medical device regulation does seem one of the most attractive options, although this still leaves many other types of DTCGT largely unregulated. If the IVD Regulation is enacted it would still be beneficial to have regulation in the USA as well. With the FDA's decision to release guidance regulating LDTs it did seem as though this was going to happen. However, the FDA's statement in footnote 4 of the Anticipated Guidance that it was not going to regulate DTCGT as LDTs because it already regulated DTCGT is surprising and extremely unhelpful and inaccurate in terms of the FDA's history regarding DTCGT.

Companies are also often selling products that may not in fact be fit for the purpose and may also not live up to the marketing claims made on DTCGT websites. Lack of regulation here also makes it difficult to regulate advertising of such tests, as it 'makes it difficult to determine what is false advertising as opposed to innovative new use'.[1103] While it was not possible to address this matter herein, it is hoped that future research will be able to explore the manner in which DTCGT tests are advertised in detail. In this context, it is possible that the ordinary consumer, even were she to be reasonably observant and circumspect assuming she is neither a geneticist nor legally trained, would have difficulty in understanding her test results and the implications that they have, and also she will likely have difficulty with understanding the terms of the wrap contract. It is also very likely that she has not provided valid consent to undergo a genetic test. It is also likely that in accordance with Kim's work, she has also not provided valid assent to the contract. While contract law does protect autonomy, there should be some degree of mutuality and a person should be aware that she has entered

[1103] Myers (n 338)

into a contract. DTCGT contracts as they are currently framed attempt to bind the consumer in a manner that is not transparent and it is possible that many terms included in these contracts are open to challenge on the grounds of unfairness.

In line with the views of Hudson and Javitt and also, the Association for Molecular Pathology's Revised Position Statement, ensuring that DTCGT tests are of high quality is vital.[1104] It is also desirable that there is greater protection provided for consumers in this context, especially in relation to the protection of consumers' privacy in their genomic sequence data and also in other types of personal data, which DTCGT companies may collect. As previously noted, there is a need to both strengthen and harmonise the standards used by different DTCGT companies and at a minimum it is desirable that the tests offered by DTCGT companies providing tests for health purposes are 'fit for purpose'.

Where consumers participate in research focussed on serious psychiatric diseases, addiction susceptibility, or late-onset diseases, which may be untreatable, different standards, may need to be developed and adhered to.[1105] While web-based interfaces can be beneficial for consumers, they need to be used carefully. It might be advisable for DTCGT companies to look to web-based models used in the research context such as HeLEX's dynamic consent model.[1106] It might be particularly helpful if online genetic counselling services were made available to consumers.

As corporations change their business models by offering new types of testing, merging or partnering with others, and the lines between different types of testing are

---

1104 Javitt and Hudson, 'Federal Neglect: Regulation of Genetic Testing-Government needs to ensure that genetic tests provide useful medical information and that the test results are reliable'

1105 R Mathews, W Hall, and A Carter, 'Direct-to-Consumer Genetic Testing For Addiction Susceptibility: A Premature Commercialisation of Doubtful Validity and Value (Dec 2012) 107(12) Addiction 2069-74; Pirzadeh-Miller et al (n 299) 293-302

1106 Kaye et al, 'Dynamic consent: a patient interface for twenty-first century research networks' (n 321)

increasingly blurred, it seems that it would be difficult to contemplate regulating different categories of tests differently. Ultimately, in the short term the best approach to regulation of DTCGT for health purposes appears to be that of relying on existing regulation for medical devices as well as hopefully, the new IVD Regulation once it is passed, although this still leaves other types of DTCGT tests for the most part unregulated. As it seems unlikely that there will be industry specific regulation at present, it is desirable that the industry does engage in self-regulation to some extent ideally with the development of a code of conduct.

It is important to recognise that DTCGT as an Internet based industry does pose challenges for regulation if the focus of regulation is solely on national regulatory systems. The majority of DTCGT companies that provide health related testing are based in the USA and UK based consumers who purchase tests from companies, such as 23andMe will have their biological samples sent overseas and their genetic information and other types of personal information will in fact be processed, stored and shared in other countries. This data flow is borderless and it may be naïve to focus too much on regulating at a national level, even though specific regulation at a national level is desirable. It does seem that the ideal regulatory response is to be found in international law. For instance, part of the Data Protection Directive's success has been due to its extra-jurisdictional reach.[1107] And here the proposed IVD Regulation might be useful as it would significantly restrict DTCGT for health purposes in the EU, prohibiting direct-to-consumer advertising and requiring a prescription in order to purchase a genetic test for health purposes. Although, as noted in chapter three this approach still does have flaws, partly because it allows manufacturers to limit the ostensible purposes of their

[1107] Cunningham 122.

testing.[1108] It is also questionable what counts as advertising, for instance, does website content constitute advertising or the mere provision of information regarding tests? Also, restricting advertising may increase advertising to physicians, which may result in impartiality.[1109] It should be noted as well that the IVD Regulation will not catch recreational DTCGT.

Some types of DTCGT services may not in fact offer any real benefit to consumers. This is primarily due to the fact that some tests currently offered lack clinical utility and may also lack clinical validity and consumers are often not well equipped to understand the genetic test results they receive from DTCGT companies. The ideal 'average consumer' contemplated in English and EU case law may be 'well informed, reasonably observant and circumspect', but as has been noted this ideal often does not reflect reality.[1110] Moreover, in the context of the provision of services that are complex in nature, it may be even less likely that an ordinary consumer would really meet these standards. On-going work of a colleague, Jan Charbonneau, highlights the problems ordinary consumers may encounter when presented with genetic risk information.[1111]

Currently the industry is using wrap contracts to govern several matters including; the sale of tests; participation in research activities; use, sharing and storage of genetic and other types of personal information; and use of their websites. As the industry is at present largely unregulated, the use of these contracts allows the industry to effectively engage in private legislation, which has the consequence of causing an imbalance in the respective rights of the parties –consumer and company– which is heavily skewed in favour of companies and is likely to be detrimental to the rights of consumers.

1108 Kalokairinou, Howard and Borry, 'Changes on the horizon for consumer genomics in the EU' (n 654)

1109 ibid (n 654) 298

1110 Benöhr (n 275) 17; Waddington (n 275) 5-6

1111 Charbonneau (n 292)

In analysing DTCGT contracts much commonality was found in the terms included and the language used. At present, the majority are skewed heavily in the company's favour. A variety of terms commonly included in these contracts seem likely to be deemed unfair and consequently unenforceable under UK law. These include: terms allowing for unilateral variation; exclusion clauses; indemnity clauses; choice of law clauses; and consent and assent clauses. It is therefore desirable that companies do reform their contracts and omit some of these terms. Overall, contracts also do not represent a fair balance between the respective parties' interests and due to the nature of genetic information it is desirable that companies engage in better practice. They could look to governance mechanisms developed in the medical research context.

The pattern observed amongst DTCGT contracts fits in with broader trends in online contracting more generally, where consent or assent to a website's terms are often deemed through use of the website. It might be argued that a consumer purchasing a shirt on Amazon accepts certain potential risks and accepts the possibility that there may be certain additional contractual clauses that they might not necessarily want, they accept all this in exchange for ease of purchase and lower prices. It seems though that even in this situation the paradigm is one that needs to change, while companies are entitled to minimise their own level of risk, online contracts ought to be written in clear, concise, and comprehensible language, displayed in readable formats with any unexpected clauses highlighted, so that a consumer can actually enter into the bargain knowingly. Currently, many consumers do not expect that anything surprising would be included in the contract, but often this is not the case.

Ideally, an industry specific regulatory authority should be created either with an international mandate or at the national level. An analogy can be made here to the financial services sector, which has its own specific industry regulator in several

countries including the UK. Here, there has been recognition that the nature of financial services means that consumers may require specific additional protection and such regulation is not necessarily viewed as overly paternalistic.

Companies could also work with the CMA to improve their contracts. As many companies do want to conduct medical research based upon data they have collected from consumers then it is a two way street and sharing of information will benefit all parties in the long-term. Regulatory reform is also needed, but improving contracts and privacy policies would be a cost effective and useful strategy in the short term. Contracts could be developed so that they were shorter and more interactive with attention being drawn to key clauses, by using bold font or other visual aids. Companies could also develop something akin to Kim's suggested of specific assent. Contracts could allow more opportunities for customers to opt out of particular services, and provide more information about use, storage, and disclosure of data. Also, the ability to save documents in a printer friendly, easily readable form is very important, as at the moment it is quite difficult to save or print most DTCGT contracts and privacy policies.

Educational videos about genetics more generally, understanding test results, and the risks of learning unwanted information could also be provided. There have been some successful efforts in the field of genetic counselling which utilise such videos.

Concern has been also been expressed regarding governments retaining identifiable DNA profiles and consequently it seems justifiable that where private companies are collecting and retaining DNA they are subject to greater scrutiny of their activities. While some tests currently offered by DTCGT companies may have little predictive value, stored sequenced data may allow individuals to be identified and may also enable people to learn much about the individuals, which they may not want shared. With continuing advances in biometrics, it is possible that hackers may target DNA

databases. There is potential here for the ICO to also take on a role in regulating DTCGT as well given the privacy concerns raised by the nature of DTCGT services.

In an age where a range of technology companies are acquiring vast amounts of personal data, the activities of companies providing DNA test and combining them with other sources of personal data do need to be monitored. The public needs enough information about the industry to be able to make an informed choice about whether or not to engage with it. At present, there is a real need for companies not only to improve their contracts, but also to be more transparent about the nature of the services they provide and the uses to which consumer data may be put.

BIBLIOGRAPHY

23andMe, 'Carrier Status' <http://www.23andme.com/health/carrier/> accessed 3 January 2013

—— 'Health' <23andme.com/en-gb/health/reports/> accessed 19 July 2015

—— 'Journey Through Your DNA' <23andme.com/fyr/> 10 December 2012

—— 'Understand the Story of Your Past' <https://http://www.23andme.com/ancestry/> 3 January 2013

23andMe (UK), 'Health' <23andme.com/en-gb/health/reports/> accessed 2 July 2015

1000 Genomes Project, <http://www.1000genomes.org/about> 3 January 2013

CMA, *Draft Guidance on unfair contract terms - Consultation document* (CMA, 2015)

Adams JN, 'Snark was a Boojum, You See: Beta Computers (Europe) Ltd v Adobe Systems (Europe) Ltd; St Albans City and District Council v International Computers Ltd, The' (1996) 1 Edinburgh L Rev 386

Adams SD, Evans JP and Aylsworth AS, 'Direct-to-consumer genomic testing offers little clinical utility but appears to cause minimal harm' (2013) 74 N C Med J 494

Adeoye S and Bozic KJ, 'Direct to consumer advertising in healthcare: history, benefits, and concerns' (2007) 457 Clinical orthopaedics and related research 96

Adeyemo A and Rotimi C, 'Genetic variants associated with complex human diseases show wide variation across multiple populations' (2010) 13 Public Health Genomics 72

Adjin-Tettey E, 'Potential for Genetic Discrimination in Access to Insurance: Is There a Dark Side to Increased Availability of Genetic Information?' (2013) 50 Alberta L Rev 577

ALDA, 'Why I won't give a sample of my DNA to Decode Genetics' *The Iceland Weather Report* <http://icelandweatherreport.com/why-i-wont-give-a-sample-of-my-dna-to-decode-genetics/> accessed 7 June 2014

All About Truth DNA Services, <allabouttruthdna.com/other-testing-services/infidelity-dna-testing/> accessed 28 April 2014

Allyse M, '23 and Me, We, and You: direct-to-consumer genetics, intellectual property, and informed consent' (2013) 31 Trends in biotechnology 68

AMP, *Association for Molecular Pathology Position Statement: Direct Access Genetic Testing (Direct to Consumer Genetic Testing)* (Association for Molecular Pathology, 2015)

Ancker JS et al, 'Consumer experience with and attitudes toward health information technology: a nationwide survey' (2013) 20 Journal of the American Medical Informatics Association 152

Angrist M, *Here Is a Human Being* (Harper Perennial 2011)

Annes JP, Giovanni MA and Murray MF, 'Risks of presymptomatic direct-to-consumer genetic testing' (2010) 363 New England Journal of Medicine 1100

Article 29 Data Protection Working Party, Opinion 05/2012 on Cloud Computing, European Commission 27 (1 July 2012) <http://ec.europa.eu/justice/data-protection/article-29/documentation/opinion-recommendation/files/2012/wp196_en.pdf> accessed 15 May 2016

Article 29 Data Protection Working Party, Opinion 03/2012 on developments in biometric technologies (27th April 2012) <http://ec.europa.eu/justice/data-protection/article-29/documentation/opinion-recommendation/files/2012/wp193_en.pdf> accessed 29 May 2016

Asper Biotech, 'Athletic Gene Test' <http://www.asperbio.com/asper-biotech-varia/athletic-gene-test> accessed 9 April 2014

Association for Molecular Pathology, *Association for Molecular Pathology Position Statement: on Direct Access Genetic Testing (Direct to Consumer Genetic Testing)* (Association for Molecular Pathology, 2007)

Association of British Insurers, *Concordat and Moratorium on Genetics and Insurance* (Department of Health 2011)

Athleticode, <http://athleticode.com> accessed 10 August 2013. [Checked again 22 January 2014 and still operating]. [Checked again 9 April 2014].

Atlas Sports Genetics, <atlasgene.com> accessed 28 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 9 April 2014]

Ayday Erman et al, 'Whole Genome Sequencing: Revolutionary Medicine or Privacy Nightmare?' (2015) 2 Computer 58

Ayres I and Schwartz A, 'The No-Reading Problem in Consumer Contract Law' (2014) 66 Stan L Rev 545

—— 'No-Reading Problem in Consumer Contract Law, The' (2014) 66 Stan L Rev 545

Bamshad MJ et al, 'Exome sequencing as a tool for Mendelian disease gene discovery' (2011) 12 Nature Reviews Genetics 745

Barnhizer DD, 'Escaping Toxic Contracts: How We Have Lost the War on Assent in Wrap Contracts' (2014) 44 Sw L Rev 215

Barry P, 'Seeking Genetic Fate Personal genomics Companies Offer Forecasts of Disease Risk, but the Science behind the Packaging Is Still Evolving' (2009) 176 Science News,

—— ‘Seeking Genetic Fate Personal genomics Companies Offer Forecasts of Disease Risk, but the Science behind the Packaging Is Still Evolving’ (2009) 176(1) Science News 16

Beaudet A, ‘Assign Regulation Appropriate to the Level of Risk’ (2010) Nature - Opinion 817

Behesti B, ‘Cross-Jurisdictional Variation in Internet Contract Regulation’ (2013)

Belton P, ‘In your irises: The new rise of biometric banking’ *BBC News* (20 March 2015) Business <bbc.co.uk/news/business-31968642>

Benöhr I, *EU Consumer Law and Human Rights* (OUP 2013)

Bhatia G, ‘FDA Fears Hacking Risks In Medical Devices; Says Hospira Pump Should Not Be Used’ *International Business Times* (5 August 2015) Technology <ibtimes.com/fda-fears-hacking-risks-medical-devices-says-hospira-pump-should-not-be-used-2039898> accessed 11 August 2015

Bieber FR, Brenner CH and Lazer D, ‘Finding criminals through DNA of their relatives’ (2006) 5778 SCIENCE-NEW YORK THEN WASHINGTON- 1315

Bloss C, Schork N and Topol E, ‘Effect of direct-to-consumer genomewide profiling to assess disease risk’ (2011) 364 N Engl J Med 524

Bloss CS, Schork NJ and Topol EJ, ‘Direct-to-consumer pharmacogenomic testing is associated with increased physician utilisation’ (2014) 51 Journal of Medical Genetics 83

Boddington P, ‘The ethics and regulation of direct-to-consumer genetic testing’ (2009) 1 Genome Medicine 71

Bollinger JM, Green RC and Kaufman D, ‘Attitudes about regulation among direct-to-consumer genetic testing customers’ (2013) 17 Genetic testing and molecular biomarkers 424

Borry P, Cornel M and Howard H, ‘Where are you going, where have you been: a recent history of the direct-to-consumer genetic testing market’ (2010) 1 J Community Genet 101

Borry P and Henneman L, ‘Debating the clinical utility of direct-to-consumer genetic testing for addiction susceptibility’ (2012) 107 Addiction 2076

Borry P et al, ‘Preconceptional genetic carrier testing and the commercial offer directly-to-consumers’ (2011) 26 Hum Reprod 972

Borry P et al, ‘Legislation on direct-to-consumer genetic testing in seven European countries’ (2012) 20 Eur J Hum Genet 715

Botkin JR et al, ‘Points to Consider: Ethical, Legal, and Psychosocial Implications of Genetic Testing in Children and Adolescents’ (2015) 97 The American Journal of Human Genetics 6

Brady W and Glazer E, ‘Cybersecurity in Hospitals: Protecting Electronic Patient Devices from the Risk of Hacking’ *MD News* (7 August 2015) Legal Technology <mdnews.com/news/2015_08/cybersecurity-in-hospitals-protecting-electronic-patient-devices-from-.aspx> accessed 11 August 2015

Brandie H, Emily E and Charis E, ‘Prospective Comparison Of Family Medical History With Personal Genome Screening For Risk Assessment Of Common Cancers’ (2012) 20 EJHG

Brett GR et al, ‘An Exploration Of Genetic Health Professionals' Experience With Direct-To-Consumer Genetic Testing In Their Clinical Practice’ (2012) 20 EJHG 825

Bright S, ‘Unfairness and the Consumer Contract Regulations’ in Burrows A and Peel E (eds), *Contract Terms* (Hart 2007)

Bryn W-J, ‘‘Be ready against cancer, now’: direct-to-consumer advertising for genetic testing’ (2006) 25 New Genetics and Society

Bunnik EM, Janssens A and Schermer MH, ‘Informed Consent in Direct-to-Consumer Personal Genome Testing: The Outline of A Model between Specific and Generic Consent’ (2014) 28 Bioethics 343

Burrows A, *A Casebook on Contract* (4th edn, Hart Publishing 2013)

Callaway E, ‘Ancestry Testing Goes For Pinpoint Accuracy’ (2012) 486 Nature 17

Cameron E, ‘Major cases the scrutinity of computer contracts: At last. International Review Of Law’ (1996) 10 Computers & Technology [serial online] 331

Cammack R et al (eds), *Oxford Dictionary of Biochemistry and Molecular Biology* (Oxford University Press)

Camporesi S, ‘Bend it like Beckham! The ethics of genetically testing children for athletic potential’ (2013) 7 Sport, Ethics and Philosophy 175

Caplan A and Matloff E, ‘Direct to Confusion: Lessons Learned from Marketing BRCA Testing ’ (2008) 8(6) The American Journal of Bioethics 5

Castle D and Ries NM, ‘Ethical, legal and social issues in nutrigenomics: the challenges of regulating service delivery and building health professional capacity’ (2007) 622 Mutation Research/Fundamental and Molecular Mechanisms of Mutagenesis 138

Caulfield T, ‘Direct-to-consumer testing: if consumers are not anxious, why are policymakers?’ (2011) 130 Human Genetics 23

—— ‘DTC genetic testing: pendulum swings and policy paradoxes’ (2012) 81 Clinical genetics 4

—— ‘Predictive or Preposterous? The marketing of DTC Genetic Testing’ (2011) 10 JCOM 3

Caulfield T and McGuire A, ‘Direct-to-consumer genetic testing: perceptions, problems, and policy responses’ (2012) 63 Annu Rev Med 23

Caulfield T et al, 'Direct-to-consumer genetic testing: good, bad or benign?' (2010) 77 Clinical Genetics 101

Center for Jewish Genetics, 'Jewish Genetic Disorders' <http://www.jewishgenetics.org/?q=content/jewish-genetic-disorders> accessed 3 January 2013.

Charbonneau J, 'Straight from the lab to the market: General Public Engagement with Direct-to-Consumer Genetic Testing (conference slides)' (DTC genetics – consumers, contracts and complexities, King's College London, 19th June 2015)

Chua E and Kennedy M, 'Current state and future prospects of direct-to-consumer pharmacogenetics' (2012) 3 Frontiers in Pharmacology

Clarke R, 'Introduction to Dataveillance and Information Privacy, and Definitions of Terms' <rogerclarke.com/DV/Intro.html#Intro> accessed 31 August 2015

Cohn B and Surofchy D, 'Fighting for the Right to Know: OBR-Bay Debates FDA regulation of DTC Genetic Testing' (*Oxbridge Biotech Roundtable*, 2014) <http://www.oxbridgebiotech.com/review/featured/23andme-debate/> accessed 27 May 2014

Collier R, 'Genetic tests for athletic ability: Science or snake oil?' (2012) 184 Canadian Medical Association Journal E43

Competition & Markets Authority, *Consumer Protection: Guidance on the CMA's approach to use of its consumer powers* (Competition & Markets Authority, CMA7, March 2014)

—— *Draft guidance on unfair contract terms Consultation document* (Competition & Markets Authority, CMA37con, 26 January 2015)

—— *Unfair contract terms explained* (Competition & Markets Authority, CMA37(a), 31 July 2015)

—— *Unfair contract terms guidance - Guidance on the unfair terms provisions in the Consumer Rights Act 2015* (Competition & Markets Authority, CMA37, 31 July 2015)

—— *Update on cloud storage consumer compliance review* (CMA, 1st April 2016) <https://assets.digital.cabinet-office.gov.uk/media/56fe3227ed915d117d000037/Investigation_update-1_April_2016.pdf> accessed 29 May 2016

—— *Consumer Law Compliance Review: Cloud Storage* (CMA, Findings Report, 2016) <https://assets.digital.cabinet-office.gov.uk/media/57472953e5274a037500000d/cloud-storage-findings-report.pdf> accessed 29 May 2016

Contributor E, 'Genetic Exceptionalism and the Precautionary Principle' Genomics Law Report <genomicslawreport.com/index.php/2009/10/06/genetic-exceptionalism-and-the-precautionary-principle/> accessed 10 December 2012

Cornel MC, van El CG and Borry P, 'The Challenge Of Implementing Genetic Tests With Clinical Utility While Avoiding Unsound Applications' (2014) 5 J Community Genet 7

Counsyl, <http://www.counsyl.com> accessed 29 May 2014

Cunningham M, 'Next Generation Privacy: The Internet of Things, Data Exhaust, and Reforming Regulation by Risk of Harm' (2015) 2 Groningen Journal of International Law

Curnutte M and Testa G, 'Consuming genomes: scientific and social innovation in direct-to-consumer genetic testing' (2012) 31 New Genetics and Society 159

Curren L and Kaye J, 'Revoking consent: A 'blind spot'in data protection law?' (2010) 26 Computer Law & Security Review 273

Cussins J, 'Direct-to-consumer genetic tests should come with a health warning' The Pharmaceutical Journal <pharmaceutical-journal.com/opinion/comment/direct-to-consumer-genetic-tests-should-come-with-a-health-warning/20067564.article> accessed 3rd August 2015

Daley L et al, 'Personal DNA testing in college classrooms: perspectives of students and professors' (2013) 17 Genetic testing and molecular biomarkers 446

David G and Yael B-E, 'Personal genomics services: whose genomes?' (2009) 17 Eur J Hum Genet 883

Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine

DeCODEme, 'Conditions Covered' decodeme.com/conditions-covered 19 October 2012

Dickenson D, *Me Medicine vs. We Medicine: Reclaiming Biotechnology for the Common Good* (Columbia UP 2013)

93/13/EEC of 5 April 1993 on unfair terms in consumer contracts

DNA DTC, 'Products' <dnadtc.com/products.aspx> accessed 11 December 2012

DNAFit, <dnafit.com> accessed 20 July 2015.

—— 'Fitness' <dnafit.com/fitness/> accessed 20 July 2015.

Dohany L et al, 'Psychological Distress With Direct-To-Consumer Genetic Testing: a Case Report of an Unexpected BRCA Positive Test Result' (2012) 21 Journal of genetic counseling 399

Downes L and Nunes P, 'Regulating 23andMe Won't Stop the New Age of Genetic Testing' *Wired* (1 January 2014) <wired.com/2014/01/the-fda-may-win-the-battle-this-holiday-season-but-23andme-will-win-the-war/> accessed 25 August 2015

Dreyfuss J, ‘How Accurate Can Genetic Predictions Be?’ (2012) 13 BMC genomics 340

Duhaime-Ross A, ‘23andMe plans to move beyond genetic testing to making drugs’ <theverge.com/2015/3/12/8199303/23andme-drug-development-testing>

Dvoskin R and Kaufman D, ‘Tables of direct-to-consumer genetic testing companies and conditions tested–August 2011’ (2011) <dnapolicy.org/images/reportpdfs/NewMethodsForDTCTable_updated_Jan2012.pdf >

EASAC and FEAM, ‘Direct-To-Consumer Genetic Testing For Health-Related Purposes In The European Union’ EASAC Policy Report 18 <http://www.easac.eu/home/reports-and-statements/detail-view/article/direct-to-co.html> accessed 10 December 2012

easyDNA, 'DNA Testing for Ancestry - Find Your Origins Here!' <http://www.easydna.co.uk/dna-ancestry-test.html> accessed 3 January 2013.

Edwards K et al, ‘Genetics researchers' and IRB professionals' attitudes toward genetic research review: a comparative analysis’ (2012) 14 Genet Med 236

Emerging Science and Bioethics Advisory Committee, 'Emerging Science and Bioethics Advisory Committee (closed)' <gov.uk/government/groups/emerging-science-and-bioethics-advisory-committee> accessed 5 August 2015

Erlich Y and Narayanan A, ‘Routes for breaching and protecting genetic privacy’ (2014) 15 Nature Reviews Genetics 409

European Academies Science Advisory Council (EASAC) and the Federation of European Academies of Medicine (FEAM), *Direct-to-Consumer Genetic Testing-Summary Document* (EASAC-FEAM Project on Direct-to-Consumer Genetic Testing, October 2012)

European Society of Human Genetics, ‘Statement of the ESHG on direct-to-consumer genetic testing for health-related purposes’ (2010) 18 Eur J Hum Genet 1271

——‘Direct-To-Consumer Genetic Tests Neither Accurate in Their Predictions nor Beneficial to Individuals, Study Suggests’ (2011) <http://www.sciencedaily.com/releases/2011/05/110530190344.htm> accessed 3 November 2011

Evans HM, ‘Do patients have duties?’ (2007) 33 Journal of Medical Ethics 689

Evans JP and Burke W, ‘Genetic exceptionalism. Too much of a good thing?’ (2008) 10 Genetics in Medicine 500

Evans JP, Burke W and Khoury M, ‘The rules remain the same for genomic medicine: the case against “reverse genetic exceptionalism”’ (2010) 12 Genetics in Medicine 342

Evans JP and Green RC, ‘Direct to consumer genetic testing: avoiding a culture war’ (2009) 11 Genetics in Medicine 568

Family Tree DNA, <http://www.familytreedna.com> accessed 3 January 2013

——, 'Surname & Geographical Projects' <familytreedna.com/projects.aspx> accessed 3rd August 2015

FCA, *Consumer Vulnerability* (FCA, Occasional Paper No 8, 2015)

FDA, *Cybersecurity Vulnerabilities of Hospira Symbiq Infusion System* (FDA Safety Communication, 31 July 2015)

Fears R, ter Meulen V and and for the EASAC-FEAM Working Group, ‘The perspective from EASAC and FEAM on direct-to-consumer genetic testing for health-related purposes’ (2012) 21 Eur J Hum Genet 1

Feero W and Guttmacher A, ‘Genomic Medicine — An Updated Primer’ (2010) 362 N Engl J Med 2001

Field Dawn and Davies Neil, *Biocode The New Age of Genomics* (OUP 2015)

Finlay T, ‘UK Users’ and Genetics Clinicians’ Experiences of Direct-to-Consumer Genetic Testing’ (PhD thesis, Cardiff University 2015)

Fletcher AL, ‘Field of genes: the politics of science and identity in the Estonian genome project’ (2004) 23 New Genetics and Society 3

Food and Administration D, ‘Anticipated details of the draft guidance for industry’ (2014) Food and Drug Administration staff, and clinical laboratories: framework for regulatory oversight of laboratory developed tests (LDTs)

Foster A, ‘Critical Dilemmas in Genetic Testing: Why Regulations to Protect the Confidentiality of Genetic Information Should Be Expanded’ (2010) Baylor L Rev

Frazzetto G, ‘The drugs don't work for everyone. Doubts about the efficacy of antidepressants renew debates over the medicalization of common distress’ (2008) 9 EMBO Reports 605

Frebourg T, ‘Direct-to-consumer genetic testing services: what are the medical benefits?’ (2012) 20 Eur J Hum Genet 483

Frueh FW et al, ‘The future of direct-to-consumer clinical genetic tests’ (2011) 12 Nature Reviews Genetics 511

Frumkin A et al, ‘"The Most Important Test You'll Ever Take"?: attitudes toward confidential carrier matching and open individual testing among modern-religious Jews in Israel’ (2011) 73 Soc Sci Med 1741

Gabel J, ‘Redeeming the Genetic Groupon: Efficacy, Ethics, and Exploitation in Marketing DNA to the Masses’ (2012) 81 Mississippi Law Journal

Gabel JD, ‘Redeeming the Genetic Groupon: Efficacy, Ethics, and Exploitation in Marketing DNA to the Masses’ (2012) 81 Mississippi Law Journal

Gardner E, ‘Gene Swipe: With More DNA Labs, Few Know Whether Those Chromosomes are Yours-Or You Stole Them from Someone Else’ (2011) 97 ABAJ 50

Gene By Gene, <genebygene.com/pages/company> accessed 21 July 2015

—— ‘Whole Genome Sequencing’ <genebygene.com/pages/dnadtc> accessed 1 October 2014. As of 25 August 2015 the price has actually increased to $10,395.00(US).

GenePlanet, 'NutriFit' <http://www.geneplanet.com/nutrifit-en.html> accessed 3 January 2013

Genetic Center Company Limited,

——, 'Disease Susceptibility Gene Test' <genetic-center.com/index_moduleId-114_pageName-content_pId-31.html> accessed 13 August 2013

Genetic Healthcare Group, 'Inborn Talent & Behavioural (DNA Test)' <genetic-healthcare.com/gh_services.html> accessed 30 April 2014

Genetic Profiles, <geneticprofiles.com> accessed 27 January 2014. [Checked again 28 January 2014 and still operating]

Geneticists CCoM, ‘CCMG Statement on Direct-to-Consumer Genetic Testing’ (2012) 81 Clin Genet 1

Genetics & Public Policy Center, ‘Survey of Direct-to-Consumer Testing Statutes and Regulations’ (2007) <dnapolicy.org/news.release.php?action=detail&pressrelease_id=81> accessed 10 October 2012 - checked again 15 June 2014

—— *Table of Direct-to-Consumer Genetic Testing Companies listed alphabetically* (Gentics & Public Policy Center, 2011)

GenomeWeb Staff Reporter, ‘Study Finds Clinical Worries over DTC Tests in Europe’ *GenomeWeb Daily News* (31 May 2011) <genomeweb.com/dxpgx/study-finds-clinical-worries-over-dtc-tests-europe> accessed 10 December 2012

Gensys, 'Do you need a legal or in-home paternity test?' <paternity-answers.com/paternity-test.html> accessed 12 August 2013. [Checked again 14 April 2014]

Geransar R and Einsiedel E, ‘Evaluating online direct-to-consumer marketing of genetic tests: informed choices or buyers beware?’ (2008) 12 Genetic testing 13

Geransar R and Einsiedel E, ‘Evaluating online direct-to-consumer marketing of genetic tests: informed choices or buyers beware?’ (2008) 12 Genet Test 13

Giannella E, ‘Morality and the Idea of Progress in Silicon Valley’ Berkeley Journal of Sociology <http://berkeleyjournal.org/2015/01/morality-and-the-idea-of-progress-in-silicon-valley/> accessed 12 April 2015

Gibbs S, ‘DNA-screening test 23andMe launches in UK after US ban’ *The Guadian* (2 December 2014) <theguardian.com/technology/2014/dec/02/google-genetic-testing-23andme-uk-launch> accessed 4 December 2014

—— ‘DNA-screening test 23andMe launches in UK after US ban’ *The Guardian* (2 December 2014) <theguardian.com/technology/2014/dec/02/google-genetic-testing-23andme-uk-launch> accessed 30 August 2015

Gillis N and Innocenti F, ‘Evidence required to demonstrate clinical utility of pharmacogenetic testing: the debate continues’ (2014) 96 Clinical Pharmacology & Therapeutics 655

Ginsburg D, ‘Genetics and Genomics to The Clinic: a Long Road Ahead’ (2011) 147 Cell 17

Ginsburg GS and Willard HF, ‘Genomic and personalized medicine: foundations and applications’ (2009) 154 Translational Research 277

Goddard K, et al, ‘Health-Related Direct-to-Consumer Genetic Tests: A Public Health Assessment and Analysis of Practices Related to Internet-Based Tests for Risk of Thrombosis’ (2009) 12 Public Health Genomics

Goh AM et al, ‘Perception, experience, and response to genetic discrimination in Huntington's disease: the Australian results of The International RESPOND-HD study’ (2013) 17 Genetic testing and molecular biomarkers 115

Goldman E, ‘23andMe’s Browsewrap Fails, But Its Post-Purchase Clickthrough Works Anyway–Tompkins v. 23andMe’ (2014) <http://blog.ericgoldman.org/archives/2014/07/23andmes-browsewrap-fails-but-its-post-purchase-clickthrough-works-anyway-tompkins-v-23andme> accessed 3 July 2014

Goldsmith L et al, ‘Direct-to-consumer genomic testing: systematic review of the literature on user perspectives’ (2012) 20 Eur J Hum Genet 811

Good NS et al, *Noticing notice: a large-scale experiment on the timing of software license agreements* (ACM 2007)

Graceful Earth, ‘Alzheimer's Genome Test’ <gracefulearth.com/alzheimerstest.aspx> accessed 10 August 2013

Gray S et al, ‘The impact of risk information exposure on women’s beliefs about direct-to-consumer genetic testing for BRCA mutations’ (2012) 81 Clin Genet 29

Greenbaum D and Gerstein M, ‘The Role of Cloud Computing in Managing the Deluge of Potentially Private Genetic Data’ (2011) 11 The American journal of bioethics : AJOB 39

Griffiths A, et al, *Introduction to Genetic Analysis* (10th edn, GH Freeman and Company 2012)

Gustafson D, ‘Expanding on the role of patient as consumer’ (1991) 17 QRB Quality review bulletin 324

Gymrek M et al, ‘Identifying personal genomes by surname inference’ (2013) 339 Science 321

Haga SB et al, ‘Public knowledge of and attitudes toward genetics and genetic testing’ (2013) 17 Genetic testing and molecular biomarkers 327

Haga SB and Burke W, ‘Pharmacogenetic testing: not as simple as it seems’ (2008) 10 Genetics in Medicine 391

Hall M, ‘False DNA test led father to reject daughter’ *The Telegraph* (11 February 2001) <telegraph.co.uk/news/uknews/1322077/False-DNA-test-led-father-to-reject-daughter.html> accessed 11 February 2015

Hall TO et al, ‘Risk Prediction for Complex Diseases: Application to Parkinson Disease’ (2012) 15 Genetics in Medicine 361

Halo Health, halohealth.com/item/home-4/ accessed 14 August 2013. [Checked again 29 January 2014 and still operating]. [Checked again 15 April 2014].

Hamburg MA and Collins FS, ‘The path to personalized medicine’ (2010) 363 New England Journal of Medicine 301

Harris A, Wyatt S and Kelly SE, ‘The Gift of Spit (And the Obligation to Return it) How consumers of online genetic testing services participate in research’ (2013) 16 Information, Communication & Society 236

Harvard PGP, 'Sharing Personal Genomes' <personalgenomes.org/harvard> accessed 3rd August 2015

Hastings R et al, ‘The changing landscape of genetic testing and its impact on clinical and laboratory services and research in Europe’ (2012) 20 Eur J Hum Genet 911

Hayden EC, ‘The $1,000 genome’ (2014) 507 Nature 294

—— ‘Technology: The $1,000 genome’ (2014) 507 Nature

Haynes AW, ‘Online privacy policies: Contracting away control over personal information’ (2006) 111 Penn St L Rev 587

Health Law Institute, *Analysis of Privacy Policies and Practices of Direct-to-Consumer Genetic Testing Companies: Private Sector Databanks and Privacy Protection Norms* (Report funded by the Office of the Privacy Commissioner of Canada, 2010)

Hedley S, *The Law of Electronic Commerce and the Internet in the UK and Ireland* (2nd edn, Cavendish Publishing Limited 2006)

Hernandez D, ‘Ancestry.Com Is Quietly Transforming Itself Into A Medical Research Juggernaut’ *The World Post* (6 April 2015) <http://www.huffingtonpost.com/2015/04/06/ancestrycom-medical-research-juggernaut_n_7008446.html> accessed 6 April 2015

Herring J, *Medical Law and Ethics* (4th edn, OUP 2012)

Hofmann B, Solbakk JH and Holm S, 'Consent to Biobank Research: One Size Fits All?' in Solbakk JH, Holm S and Hoffman B (eds), *The ethics of research biobanking* (Springer 2009)

Hogarth S, Javitt G and Melzer D, 'The current landscape for direct-to-consumer genetic testing: legal, ethical, and policy issues' (2008) 9 Annu Rev Genomics Hum Genet 161

Hogarth S, Melzer D and Zimmern R, 'The regulation of commercial genetic testing services in the UK' (2005) A briefing for the Human Genetics Commission Cambridge

Holtzman NA and Watson MS, 'Promoting safe and effective genetic testing in the United States: final report of the Task Force on Genetic Testing' (1997)

Howard H, Avard D and Borry P, 'Are the kids really all right? Direct-to-consumer genetic testing in children: are company policies clashing with professional norms?' (2011) 19 EJHG 1122

Howard H and Borry P, 'Is there a doctor in the house? : The presence of physicians in the direct-to-consumer genetic testing context' (2012) 3 J Community Genet 105

Howard H and Borry P, 'Survey of European clinical geneticists on awareness, experiences and attitudes towards direct-to-consumer genetic testing' (2013) 5 Genome Med 45

Howard H, Knoppers B and Borry P, 'Blurring lines. The research activities of direct-to-consumer genetic testing companies raise questions about consumers as research subjects' (2010) 11 EMBO Reports 579

Howard HC and Borry P, 'Direct-to-consumer genetic testing: more questions than benefits?' (2008) 5 Personalised Medicine 317

——, 'Personal genome testing: do you know what you are buying?' (2009) 9 The American Journal of Bioethics 11

Huang, Hsiao-Ying and Bashir Masooda, 'Direct-to-consumer genetic testing: contextual privacy predicament' Proceedings of the 78th ASIS&T Annual Meeting: Information Science with Impact: Research in and for the Community (2015) American Society for Information Science 50

Hudson K et al, 'ASHG Statement* on direct-to-consumer genetic testing in the United States' (2007) 81 American Journal of Human Genetics 635

Hughes JT, 'Consent and Forgetting: What Privacy Pros Can Learn From One Family's Unexpected Experience' (2014) <https://privacyassociation.org/news/a/consent-and-forgetting-what-privacy-pros-can-learn-from-one-familys-unexpected-experience/> accessed 14 September 2014

Human Genetics Commission, *Genes Direct: Ensuring The Effective Oversight Of Genetic Tests Supplied Directly To The Public* (Department of Health, 2003)

—— *More Genes Direct* (Department of Health, 2007)

—— *A Common Framework of Principles for direct-to-consumer genetic testing services* (Department of Health, 2010)

——*Human Genetics Commission Final Report* (Department of Health, 2012)

Human Genome Project, 'History of the Human Genome Project' <ornl.gov/sci/techresources/Human_Genome/project/hgp.shtml> accessed 2nd April 2012

Hustinx Peter, Opinion of the European Data Protection Supervisor on the Commission's Communication on "Unleashing the Potential of Cloud Computing in Europe" Eur Data Protection Supervisor (16 November, 2012) <https://secure.edps.europa.eu/EDPSWEB/webdav/site/mySite/shared/Documents/Consultation/Opinions/2012/12-11-16_Cloud_Computing_EN.pdf> accessed 12 May 2016.

Information NCfB, 'Genetic Testing Registry' (2012) <ncbi.nlm.nih.gov/gtr/> accessed accessed 23rd October 2012

Inherent Health, <inherenthealth.com/our-tests.aspx> accessed 13 August 2013. [Checked again 29 January 2014 and still operating]. [Checked again 15 April 2014]

International Biosciences, 'DNA Testing Services and Prices' <ibdna.com/regions/UK/EN/?page=services#PM_Paternity> accessed 2 February 2013. [Checked again 16 April 2014]

International Society of Genetic Genealogy, 'Welcome to ISOGG!' <isogg.org> 3rd August 2015

Irick M, 'Age of an Information Revolution: The Direct-to-Consumer Genetic Testing Industry and the Need for a Holistic Regulatory Approach' (2012) 49 San Diego L Rev 279

Jackson L, Goldsmith L and Skirton H, 'Guidance for patients considering direct-to-consumer genetic testing and health professionals involved in their care: development of a practical decision tool' (2014) Family practice

Janssens A and Deverka P, 'Useless until proven effective: the clinical utility of preemptive pharmacogenetic testing' (2014) 96 Clinical Pharmacology & Therapeutics 652

Javitt G, 'Which Way for Genetic Test Regulation'

Javitt GH and Hudson K, 'Federal Neglect: Regulation of Genetic Testing-Government needs to ensure that genetic tests provide useful medical information and that the test results are reliable' (2006) 22 Issues in Science and Technology 59

Joh EE, ‘DNA Theft: Recognizing The Crime of Nonconsensual Genetic Collection and Testing’ (2011) 91 B U L Rev 665

Joly Y, Ngueng Feze I and Simard J, ‘Genetic discrimination and life insurance: a systematic review of the evidence’ (2013) 11 BMC Med 25

Jostins L and Barrett JC, ‘Genetic Risk Prediction in Complex Disease’ (2011) 20 Human Molecular Genetics R182

Kacen JJ, Hess JD and Kevin Chiang W-Y, ‘Bricks or clicks? Consumer attitudes toward traditional stores and online stores’ (2013) 18 Global Economics and Management Review 12

Kalf R et al, ‘Variations in predicted risks in personal genome testing for common complex diseases’ (2014) 16 Genet Med 85

Kalokairinou L and Carmen H, ‘INSIGHTS’ (2014)

Kalokairinou L, Howard HC and Borry P, ‘Changes on the horizon for consumer genomics in the EU’ (2014) 346 Science 296

Katz J, ‘Informed Consent-A Fairy Tale-Law's Vision’ (1977) 39 U Pitt L Rev 137

Kaufman DJ et al, ‘Risky business: risk perception and the use of medical services among customers of DTC personal genetic testing’ (2012) 21 Journal of genetic counseling 413

Kaye J, ‘The Regulation of Direct-to-Consumer Genetic Tests’ (2008) 17 Hum Mol Genet R180

Kaye J et al, ‘Dynamic consent: a patient interface for twenty-first century research networks’ (2015) 23 Eur J Hum Genet 141

Kaye J, Bell Jessica, Briceno Linda, and Mitchell Colin, ‘Biobank Report: United Kingdom’ (2016) 44(1) The Journal of Law, Medicine & Ethics 96-105

Kazemian L, Pease K and Farrington DP, ‘DNA retention policies: The potential contribution of criminal career research’ (2011) 8 European Journal of Criminology 48

Kendall M, ‘Koh Appoints Lead Counsel in Scrum Over 23andMe Suits’ (*The American Lawyer*, 2014) <americanlawyer.com/id=1202655508972/Koh-Appoints-Lead-Counsel-in-Scrum-Over-23andMe-Suits?slreturn=20140516142508> accessed 15 May 2014

——‘SF Judge Sides With 23andMe on Class Claims’ *The Recorder* (10 June 2015) <therecorder.com/id=1202729012905?keywords=Marisa+Kendall>

Khanna S and Tosh PK, *A clinician's primer on the role of the microbiome in human health and disease* (Elsevier 2014)

Khoury M, Rogowski W and Grosse S, ‘Challenges of Translating Genetic Tests into Clinical and Public Health Practice’ (2009) 10 Nat Rev Genet 489

Kim NS, ‘Contract's Adaptation and the Online Bargain’ (2010) 79 U Chi L Rev 1327

——‘Exploitation by Wrap Contracts-Click’ (2014) 39 California Bar IP Journal, New Matter 10

—— *Wrap Contracts: Foundations and Ramifications* (OUP 2014)

King RC, Mulligan P and Stansfield W (eds), *A Dictionary of Genetics* (8th edn, OUP 2013)

Kishore D, ‘Test at Your Own Risk: Your Genetic Report Card and the Direct-to-Consumer Duty to Secure Informed Consent’ (2009) Emory LJ

Klass G, Letsas G and Saprai P (eds), *Philosophical Foundations of Contract Law* (OUP 2014)

Knoppers B, ‘Consent to ‘personal’ genomics and privacy. Direct-to-consumer genetic tests and population genome research challenge traditional notions of privacy and consent’ (2010) 11 EMBO Rep 416

Koch V, ‘PGTandMe: social networking-based genetic testing and the evolving research model’ (2012) 22 Health Matrix Clevel 33

Kraft P and Hunter DJ, ‘Genetic risk prediction: Are We There Yet?’ (2009) 360 N ENGL J Med 1701

Kraft P et al, ‘Beyond odds ratios—communicating disease risk based on genetic profiles’ (2009) 10 Nature Reviews Genetics 264

Kramer P and Bressan P, ‘Humans as Superorganisms How Microbes, Viruses, Imprinted Genes, and Other Selfish Entities Shape Our Behavior’ (2015) 10 Perspectives on Psychological Science 464

Krol A, ‘23andMe Pursues Health Research in the Shadow of the FDA’ *Bio IT World* (24 March 2014) <bio-itworld.com/BioIT_Article.aspx?id=136445>

—— ‘Open Humans Aims to Be the Social Network for Science Volunteerism’ *Bio IT World* (9th April 2015) <bio-itworld.com/2015/4/9/open-humans-aims-social-network-science-volunteerism.html>

—— ‘What Comes New for Direct-to-Consumer Genetics?’ (*Bio IT World*, 2015) <bio-itworld.com/2015/7/16/what-comes-next-direct-consumer-genetics.html> accessed 18 July 2015

Kuehn B, ‘Inconsistent results, inaccurate claims plague direct-to-consumer gene tests’ (2010) 304 JAMA : the journal of the American Medical Association 1313

Kurzweil, ‘23andMe granted authorization by FDA to market first direct-to-consumer genetic test’ (*KurzweilAI*) <kurzweilai.net/23andme-granted-authorization-by-fda-to-market-first-direct-to-consumer-genetic-test> accessed 23 February 2015

Kutz G, *Direct-to-Consumer Genetic Tests: Misleading Test Results are Further Complicated by Deceptive Marketing and Other Questionable Practices: Congressional Testimony* (DIANE Publishing 2010)

Lachance CR et al, 'Informational content, literacy demands, and usability of websites offering health-related genetic tests directly to consumers' (2010) 12 Genetics in Medicine 304

Lagorio-Chafkin C, '23andMe Exec: You Ain't Seen Nothing Yet' *Inc* (7 January 2015) <http://www.inc.com/christine-lagorio/23andMe-new-partnerships.html> accessed accessed 9 March 2015

Lanktree MB et al, 'Positive perception of pharmacogenetic testing for psychotropic medications' (2014) 29 Human Psychopharmacology: Clinical and Experimental 287

Laurie G, *Genetic Privacy : A Challenge To Medico-Legal Norms* (reprint edn, Cambridge University Press 2002)

Lawson R, *Exclusion Clauses and Unfair Contract Terms* (11th edn, Thomson Reuters (Professional) UK Limited 2014)

Leachman SA et al, 'Direct-to-consumer genetic testing: personalized medicine in evolution'

Lee S and Crawley L, 'Research 2.0: social networking and direct-to-consumer (DTC) genomics' (2009) 9 The American journal of bioethics : AJOB 35

Lee SS-J et al, 'Attitudes towards Social Networking and Sharing Behaviors among Consumers of Direct-to-Consumer Personal Genomics' (2013) 3 Journal of Personalized Medicine 275

Lewis NP et al, 'DTC genetic testing companies fail transparency prescriptions' (2011) 30 New Genetics and Society 291

Limited GCC, 'Genetic Center Company Limited' <genetic-center.com/index_moduleId-114_pageName-content_pId-30.html> accessed 13 August 2013. [Checked again 28 January 2014 and still operating]. [Checked again 14 April 2014]

Lindblom A and Robinson P, 'Bioinformatics for Human Genetics: Promises and Challenges' (2011) 32 Hum Mutat 495

Liu Y and Pearson YE, 'Direct-to-consumer marketing of predictive medical genetic tests: assessment of current practices and policy recommendations' (2008) 27 Journal of Public Policy & Marketing 131

Loos M and Luzak J, 'Wanted: A Bigger Stick. On Unfair Terms in Consumer Contracts with Online Service Providers' (2015) On Unfair Terms in Consumer Contracts with Online Service Providers (January 8, 2015) Centre for the Study of European Contract Law Working Paper Series

Lynch J and al e, ‘Media Coverage of Direct-to-Consumer Genetic Testing ’ (2011) 20 J Genet Counsel 486

MacLeod R et al, ‘Experiences of predictive testing in young people at risk of Huntington’s disease, familial cardiomyopathy or hereditary breast and ovarian cancer’ (2014) 22 EJHG 396

Mahon S, ‘Impact of Direct-to-Consumer Genetic Testing’ (2012) 8 J Oncol Pract 260

Mangen A, Walgermo BR and Brønnick K, ‘Reading linear texts on paper versus computer screen: Effects on reading comprehension’ (2013) 58 International Journal of Educational Research 61

Manwaring K, ‘Enforceability of Clickwrap and Browsewrap Terms in Australia: Lessons from the US and the UK’ (2011) 5 Studies in Ethics, Law, and Technology

Map My Gene, 'About' <mapmygene.com> accessed 14 August 2013

——, 'Disease Susceptibility Test' <mapmygene.com/disease-susceptibility-gene-test.html> accessed 19 July 2015

—— ‘Inborn Talent Genetic Test’ <mapmygene.com/inborn-talent-genetic-test.html> accessed 20 July 2015

Marchione M, ‘Study reveals shortcomings in gene testing; results on estimating disease risk often conflict’ *The Associated Press* (27 May 2015)

Marietta C and McGuire AL, ‘Direct-to-consumer genetic testing: Is it the practice of medicine?’ (2009) 37 The Journal of Law, Medicine & Ethics 369

Mason J and Laurie G, *Mason and McCall Smith's Law and Medical Ethics* (8th edn, OUP 2011)

Mason L, ‘Protecting Consumers from Unfair Terms in Standard Form Contracts: The UK Approach’ (2015) 26 European Business Law Review 335

Mathews R, Hall W and Carter A, ‘Direct-To-Consumer Genetic Testing For Addiction Susceptibility: A Premature Commercialisation Of Doubtful Validity And Value’ (2012) 107 Addiction 2069

McDonald AM and Cranor LF, ‘The Cost of reading privacy policies’ (2008) 4 I/S A Journal of Law and Policy For the Information Society

McGillivray Kevin, ‘Conflicts in the Cloud: Contracts and Compliance with Data Protection Law in the EU’ (2014) 17 Tul J Tech & Intell Prop 217

McGinn S and Gut IG, ‘DNA sequencing–spanning the generations’ (2013) 30 New Biotechnology 366

McGuire A and Burke W, ‘Health System Implications of Direct-to-Consumer Personal Genome Testing’ (2011) 14 Public Health Genomics

McGuire A et al, ‘Social networkers’ attitudes toward direct-to-consumer personal genome testing’ (2009) 9 The American Journal Of Bioethics : AJOB 3

McKendrick E, *Contract law: text, cases, and materials* (5th edn, OUP 2012)

McLaughlin H, ‘What’s in a name: ‘client’, ‘patient’, ‘customer’, ‘consumer’, ‘expert by experience’, ‘service user’—what's next?’ (2009) 39 British Journal of Social Work 1101

McPherson E, ‘Genetic diagnosis and testing in clinical practice’ (2006) 4 Clinical Medicine & Research 123

Meikle J, ‘Superdrug criticised by doctors for stocking genetic self-testing kits’ *The Guardian* (31 March 2015) Genetics <theguardian.com/science/2015/mar/31/superdrug-criticised-doctors-genetic-self-testing-kits>

Mello M and Wolf L, ‘The Havasupai Indian Tribe Case — Lessons for Research Involving Stored Biologic Samples’ (2010) 363 N Engl J Med 204

Meyer MJ, ‘Patients' duties’ (1992) 17 Journal of Medicine and Philosophy 541

Meyer U, ‘Personalized medicine: a personal view’ (2012) 91 Clinical Pharmacology & Therapeutics 373

MHRA, 'New Legislation on Medical Devices' <http://www.mhra.gov.uk/Howweregulate/Devices/Legislation/NewLegislationonMedicalDevices/index.htm> 30 May 2014

Moringiello JM, ‘Notice, Assent, and Form in a 140 Character World’ (2014) Southwestern Law Review, Forthcoming 14

Morrison A, ‘A Research Revolution: Genetic Testing Consumers Become Research (And Privacy) Guinea Pigs’ (2011) 9 J on Telecomm & High Tech L 573

Motoc IV, ‘The International Law of Genetic Discrimination’ in Murphy T (ed), *New Technologies and Human Rights* (Oxford Scholarship Online 2009)

Murray A, *Information technology law: the law and society* (Oxford University Press 2013)

My Gene Diet, <http://www.my-gene-diet.com/products.php> accessed 13 August 2013. [Checked again 29 January 2014 and still operating]. [Checked again 23 April 2014]

Myers MF, ‘Health Care Providers And Direct-To-Consumer Access And Advertising Of Genetic Testing In The United States’ (2011) 3 Genome Medicine 81

National Human Genome Research Institute, 'Genome-Wide Association Studies' <genome.gov/20019523> accessed 9 December 2012

Naveed M et al, ‘Privacy and Security in the Genomic Era’ (2014) arXiv preprint arXiv:14051891

Navigenics, <navigenics.com/visitor/what_we_offer/how_it_works/international_orders/> accessed 2 April 2012

—— 'Find a Physician' <navigenics.com/visitor/about_us/find_a_physician/> accessed 5 April 2012

—— 'How It Works' <navigenics.com/visitor/what_we_offer/how_it_works/international_orders/> accessed 2 April 2012

—— 'Our Acquisition by Life Technologies' <navigenics.com> accessed 10 December 2012

NHS Choices, 'Consent to treatment' (*NHS Choices*) <nhs.uk/Conditions/Consent-to-treatment/Pages/Introduction.aspx> accessed 31 July 2015

Nimble Diagnostics, 'Ancestry DNA Testing' <http://www.nimblediagnostics.com/home/anc.html> 3 January 2013

Nordgren A, 'Neither as harmful as feared by critics nor as empowering as promised by providers: risk information offered direct to consumer by personal genomics companies' (2014) 5 J Community Genet 59

—— 'Neither as harmful as feared by critics nor as empowering as promised by providers: risk information offered direct to consumer by personal genomics companies' (2014) 5(1) J Community Genet 59

Novy MC, 'Privacy at a price: direct-to-consumer genetic testing & the need for regulation' (2010) U Ill JL Tech & Pol'y 157

Nuffield Council on Bioethics, *The collection, linking and use of data in biomedical research and health care: ethical issues* (Nuffield Council on Bioethics, February 2015)

O'Huallachain M et al, 'Extensive genetic variation in somatic human tissues' (2012) 109 PNAS 18018

Office of Fair Trading, *OFT secures further improvements to gyms contracts* (Office of Fair Trading, Press Relase, 2013)

Office of the Privacy Commissioner (OPC), *Statement on the use of genetic test results by life and health insurance companies* (OPC, 2014)

Offit K, 'Genomic profiles for disease risk: predictive or premature?' (2008) 299 JAMA : the journal of the American Medical Association 1353

Online O, '"patient, adj. and n."' in *Oxford English Dictionary* (Web edn, Oxford University Press 2014) <http://www.oed.com/view/Entry/138820?rskey=BIE58d&result=1&isAdvanced=false> accessed 15 June 2014

Ornstein C, ‘Tracking Your Own Health Data Too Closely Can Make You Sick’ (*NPR*, 2015) <npr.org/sections/health-shots/2015/04/06/397848621/tracking-your-own-health-data-too-closely-can-make-you-sick> accessed 7 April 2015

Otlowski M, Taylor S and Bombard Y, ‘Genetic discrimination: international perspectives’ (2012) 13 Annu Rev Genomics Hum Genet 433

Pagliery J, ‘MasterCard will approve purchases by scanning your face’ *CNN Money* (1 July 2015) Cyber-Safe <money.cnn.com/2015/07/01/technology/mastercard-facial-scan/>

Parvizi N and Woods K, ‘Regulation of medicines and medical devices: contrasts and similarities’ (2014) 14 Clinical Medicine 6

Patenaude AF, ‘Commentary: Save the Children: Direct-to-Consumer Testing of Children is Premature, Even for Research’ (2011) 36 J Pediatr Psychol 1122

Pathway Genomics, <pathway.com> accessed 21 July 2015

—— ‘Drug Response (Medication) Insight’ <http://www.pathway.com/dna-reports/medication-response> 3 January 2013

—— “Pathway Fit” <pathway.com/about-us/management> accessed 3 February 2014.

Patsner B, ‘New "Home Brew" Predictive Genetic Tests Present Significant Regulatory Problems’ (2009) Hous J Health L & Pol'y 237

Perton M, ‘Read Fine Print Or GameStation May Own Your Soul’ Consumerist <http://consumerist.com/2010/04/16/read-fine-print-or-gamestation-may-own-your-soul/> accessed 8 September 2014

Petersen C and DeMuro P, ‘Legal and Regulatory Considerations Associated with Use of Patient-Generated Health Data from Social Media and Mobile Health (mHealth) Devices’ (2015) 6 Appl Clin Inform 16

Petrone J, ‘Ancestry Sees AncestryHealth Offering as First Step in New Health-Focused Strategy’ *GenomeWeb* (17 July 2015)

—— ‘AncestryDNA Aims to Have 1.3M Genotyped by Year End’ *GenomeWeb* (28 April 2015) <genomeweb.com/microarrays-multiplexing/ancestrydna-aims-have-13m-genotyped-year-end>

Phillips Andelka M, ‘Only a click away—DTC genetics for ancestry, health, love… and more: A view of the business and regulatory landscape’ (2016) 8 Applied & Translational Genomics 16-22

—— ‘Think Before You Click Ordering A Genetic Test Online’ (2015) 11 Scitech Lawyer 8

—— ‘Genomic Privacy and Direct-to-Consumer Genetics Big Consumer Genetic Data – What’s in that Contract?’ (2015 IEEE CS Security and Privacy Workshops)

Phillips, Andelka M and Finlay T, '"DNA a click away" -Workshop on 'agreements' in DTCGT' (Translation in Healthcare – Exploring the Impact of Emerging Technologies, Oxford, 23-25 June 2015)

Phillips, Andelka M, Mian IS, and Charbonneau J, 'Living in a Panopticon City: the Biological-Geographic-Economic-Social-Behavioural-Physical complex -- people and places under dynamic surveillance' – paper presented for Surveillance: Power, Performance & Trust (7th Biannual Surveillance and Society Conference) (April 2016)- this has been submitted to the Surveillance and Society Journal.

Pines WL, 'History and Perspective on Direct-to-Consumer Promotion, A' (1999) 54 Food & Drug LJ 489

Pirzadeh-Miller S et al, 'Direct-to-consumer genetic testing: helpful, harmful, or pure entertainment?' (2011) 8 Community Oncology 263

Plaut VC and Bartlett III RP, 'Blind consent? A social psychological investigation of non-readership of click-through agreements' (2012) 36 Law and human behavior 293

Pollack A, 'DNA Sequencing Caught in Deluge of Data' *The New York Times* (New York, 30 June 2011) <beacon-center.org/wp-content/uploads/2010/10/NYT113011_DNASeqDelugeData.pdf>

Popovsky M, 'Exaggerated Benefits and Underestimated Harms: The Direct-to-Market Consumer Genetic Test Market and How to Manage It Going Forward' (2010) 8 Dartmouth LJ 65

Powell KP et al, 'Educational Needs Of Primary Care Physicians Regarding Direct-To-Consumer Genetic Testing' (2012) 21 Journal of Genetic Counseling 469

Powell KP et al, 'Primary Care Physicians' Awareness, Experience And Opinions Of Direct-To-Consumer Genetic Testing' (2012) 21 Journal of genetic counseling 113

Proffitt A, 'Deals center on self-reported patient data services' (2012) 30 Nature biotechnology 1016

Prophase Genetics, <prophase-genetics.com/home_legal_paternity2.html> accessed 13 August 2013. [Checked again 24 April 2014]

Prudente S et al, 'Genetic Prediction Of Common Diseases. Still No Help For The Clinical Diabetologist!' (2012) 22 Nutrition, Metabolism and Cardiovascular Diseases 929

Radin MJ, *Boilerplate* (Princeton Press 2013)

Raj A, 'Soon, It Will Cost Less To Sequence A Genome Than To Flush A Toilet — And That Will Change Medicine Forever' (*Business Insider*, 2014) <businessinsider.com/super-cheap-genome-sequencing-by-2020-2014-10?IR=T> accessed 31 July 2015

Ray T, '23andMe Gets CE Mark, Launches PGS Offering in UK for £125' *GenomeWeb* (1 December 2014) <genomeweb.com/microarrays-

multiplexing/23andme-gets-ce-mark-launches-pgs-offering-uk-125> accessed 20 August 2015

—— 'GAO Stands By Its 2010 Report on DTC Genomics Firms; Lead Investigator Assigned to New Position' *GenomeWeb* (16th March 2011)

Ray T, 'Will Other States Follow NY, Calif., in Taking On DTC Genetic-Testing Firms' <http://www.genomeweb.com/dxpgx/will-other-states-follow-ny-calif-taking-dtc-genetic-testing-firms-0>

—— 'With Decode Purchase, Amgen Gains Genetics Expertise, Consumers Lose DTC Testing Option' *GenomeWeb* (12 December 2012) <genomeweb.com//node/1163376?hq_e=el&hq_m=1432031&hq_l=1&hq_v=654c94516e> accessed 12 December 2012

Rehm HL et al, 'ClinGen — The Clinical Genome Resource' (2015) 372 N Engl J Med 2235

Reporter GS, 'AncestryDNA, Calico to Collaborate on Genetics of Human Longevity' *GenomeWeb* (21 July 2015)

Rew L, et al,, 'Systematic Review Of Psychosocial Benefits And Harms Of Genetic Testing' (2010) 31 Issues in Mental Health Nursing 631

Ries NM and Castle D, 'Nutrigenomics and ethics interface: direct-to-consumer services and commercial aspects' (2008) 12 OMICS A Journal of Integrative Biology 245

Roberts JS and Ostergren J, 'Direct-to-Consumer Genetic Testing and Personal Genomics Services: A Review of Recent Empirical Studies' (2013) 1 Current Genetic Medicine Reports 182

Roberts NJ et al, 'The predictive capacity of personal genome sequencing' (2012) 4 Science translational medicine 133ra58

Robertson SJ, 'The Validity of Shrink-Wrap Licences in Scots Law Beta Computers (Europe) Ltd v. Adobe Systems (Europe) Ltd' The Journal of Information, Law and Technology <http://www2.warwick.ac.uk/fac/soc/law/elj/jilt/1998_2/robertson/> accessed 13 August 2015

Robson M et al, 'American Society of Clinical Oncology Policy Statement Update: Genetic and Genomic Testing for Cancer Susceptibility ' (2010) 28 Journal of Clinical Oncology 893

Rothstein Mark A, 'Epigenetic Exceptionalism' (2013) 41 The Journal of Law Medicine & Ethics 733

Rubinstein W et al, 'The NIH genetic testing registry: a new, centralized database of genetic tests to enable access to comprehensive information and improve transparency' (2013) 41 Nucleic acids research D925

Sampson TR and Mazmanian SK, 'Control of Brain Development, Function, and Behavior by the Microbiome' (2015) 17 Cell host & microbe 565

Samuel G, Jordens C and Kerridge I, 'Direct-to-Consumer Personal Genome Testing: Ethical and Regulatory Issues That Arise From Wanting to 'Know' Your DNA' (2010) 40 Internal Medicine Journal 220

Saukko P, 'State of play in direct-to-consumer genetic testing for lifestyle-related diseases: market, marketing content, user experiences and regulation' (2013) 72 The Proceedings of the Nutrition Society 53

Saukko P et al, 'Negotiating the boundary between medicine and consumer culture: Online marketing of nutrigenetic tests' (2010) 70 Soc Sci Med 744

Saunders R and Ashcroft RE, 'Consumer Genetics And Addiction Susceptibility Testing—Just What The Consumer Ordered' (2012) 107 Addiction 2075

Sboner A et al, 'The real cost of sequencing: higher than you think!' (2011) 12 Genome biology 125

Scherr AE, 'Genetic Privacy & the Fourth Amendment: Unregulated Surreptitious DNA Harvesting' (2012) 47 Ga L Rev 445

—— 'Genetic Privacy & the Fourth Amendment: Unregulated Surreptitious DNA Harvesting' (2012) 47 Ga L Rev 445

Schlanger S, 'Filling in the Cracks: Improving the Regulation of Direct-to-Consumer Genetic Tests' (2011) 14 J Health Care L & Pol'y S1

Schneider G and Dekker C, 'DNA sequencing with nanopores' (2012) 30 Nature biotechnology 326

Sequeiros J, 'Regulating genetic testing: the relevance of appropriate definitions' in Kristoffersson U, Schmidtke J and Cassiman J (eds), *Quality Issues in Clinical Genetic Services* (Springer 2010)

Sequeiros J et al, 'The wide variation of definitions of genetic testing in international recommendations, guidelines and reports' (2012) 3 J Community Genet 113

Shanks P, 'Genomic Controversy in Iceland: Déja Vu All Over Again' (*Center for Genetics and Society*, 2014) <http://www.biopoliticaltimes.org/article.php?id=7778> accessed 30 May 2014

Shaywitz D, 'Does 23andMe Deal Mean Medical Centers Are Sitting On Data Worth Millions?' *Forbes* (8th January 2015) Pharma & Healthcare <forbes.com/sites/davidshaywitz/2015/01/08/does-23andme-deal-mean-medical-centers-are-sitting-on-data-worth-millions/>

She Cheated, <shecheated.net> accessed 2 February 2013. [Checked again 24 April 2014]

Sigmundsdóttir A, 'Privacy on Ice This company wants to collect DNA from one-third of Iceland's population.' (*Future Tense*, 2014)

<http://www.slate.com/articles/technology/future_tense/2014/05/decode_genetics_wants_to_collect_dna_from_one_third_of_icelanders.html> accessed 9 June 2014

Simoncelli T, 'Dangerous excursions: the case against expanding forensic DNA databases to innocent persons' (2006) 34 The Journal of Law, Medicine & Ethics 390

Slaughter L, 'Genetic Information Non-Discrimination Act' (2013) 50 Harvard Journal on Legislation 41

Smart DNA, <smartdna.net.au/howitworks.html> accessed 13 August 2013. [Checked again 29 January 2014 and still operating]. [Checked again 24 April 2014]

So H-C et al, 'Risk prediction of complex diseases from family history and known susceptibility loci, with applications for cancer screening' (2011) 88 The American Journal of Human Genetics 548

Sorenson Molecular Geneology Foundation, <smgf.org> 22nd July 2015

Spector-Bagdady K and Pike ER, 'Consuming Genomics: Regulating Direct-to-Consumer Genetic and Genomic Information' (2014) 92 Neb L Rev 677

Ståhl PL and Lundeberg J, 'Toward the single-hour high-quality genome' (2012) 81 Annual review of biochemistry 359

Storm D, 'MEDJACK: Hackers hijacking medical devices to create backdoors in hospital networks' *Computerworld* (8 June 2015) <computerworld.com/article/2932371/cybercrime-hacking/medjack-hackers-hijacking-medical-devices-to-create-backdoors-in-hospital-networks.html> accessed 11 August 2015

Stynen D, 'Revision of Europe's IVD Directive 98/79/EC Lessons and results from the Public Consultation document' (*IVD Technology*, 2011) <ivdtechnology.com/article/revision-europe's-ivd-directive-9879ec> accessed accessed 22 October 2012

Su P, 'Direct-to-Consumer Genetic Testing: A Comprehensive View' (2013) 86 The Yale Journal of Biology and Medicine 359

Sullivan M, '23andMe has signed 12 other genetic data partnerships beyond Pfizer and Genentech' *VentureBeat* (14 January 2015) <venturebeat.com/2015/01/14/23andme-has-signed-12-other-genetic-data-partnerships-beyond-pfizer-and-genentech/> accessed 20 August 2015

Sunderman SF, 'The Need For Regulation Of Direct-To-Consumer genetic Testing In The United States: Assessing And Applying The German Policy Model' (2013) 12 Wash U Global Stud L Rev 357

Swan M, 'Emerging patient-driven health care models: an examination of health social networks, consumer personalized medicine and quantified self-tracking' (2009) 6 International journal of environmental research and public health 492

Tabor HK and Kelley M, ‘Challenges in the use of direct-to-consumer personal genome testing in children’ (2009) 9 The American Journal of Bioethics 32

TallBear K, ‘The Emergence, Politics, and Marketplace of Native American DNA1’ (2014) Routledge Handbook of Science, Technology and Science 21

Tamir S, ‘Direct-to-consumer genetic testing: ethical-legal perspectives and practical considerations’ (2010) 18 Med Law Rev 213

Taylor M, *Genetic data and the law: a critical perspective on privacy protection*, vol 16 (CUP 2012)

Taylor M, ‘Problems of practice and principle if centring law reform on the concept of genetic discrimination’ (2004) 11 European Journal of Health Law 365

ter Meulen V et al, *Direct-to-consumer genetic testing for health-related purposes in the European Union* (EASAC Policy Report, 2012)

Test Country, ‘Paternity DNA Testing’ <testcountry.com/categories.html?cat=152&left> accessed 10 August 2013. [Checked again 24 April 2014].

Test Infidelity, <testinfidelity.com> accessed 20 January 2014. [Checked again 24 April 2014]

The Associated Press, ‘Pfizer, 23andMe team up to study bowel disease’ *Associated Press* (12 August 2014) <medicalxpress.com/news/2014-08-pfizer-23andme-team-bowel-disease.html 10 September 2014> accessed 10 September 2014

The Law Society, *Consumer Contracts Regulations 2013* (The Law Society, Practice Note, last updated 18 September 2014)

The Makings of Me, 'My Child’s DNA Insights Kit' <themakingsofme.com/dna-test-kit-for-kids.html> accessed 20 July 2015.

——, 'Speed vs Endurance' <themakingsofme.com/dna-test-running.html> accessed 20 July 2015.

The Supreme Court, ‘Arnold (Respondent) v Britton and others (Appellants) [2015] UKSC 36 - Press Summary’ (*The Supreme Court*) <supremecourt.uk/cases/docs/uksc-2013-0193-press-summary.pdf> accessed 29 July 2015

Thomas KH et al, ‘Reporting of drug induced depression and fatal and non-fatal suicidal behaviour in the UK from 1998 to 2011’ (2014) 15 BMC Pharmacology and Toxicology 54

Thompson D, ‘I Agreed to What-A Call for Enforcement of Clarity in the Presentation of Privacy Policies’ (2012)

Timp Gea, ‘Third Generation DNA Sequencing With A Nanopore’ in Iqbal S and Bashir R (eds), *Nanopores: Sensing and Fundamental Biological Interactions* (Springer 2011)

Trading OoF, *Vulnerable consumer groups: quantification and analysis* (Office of Fair Trading, Research Paper 15 1998, 1998)

Trinidad SB et al, 'Genomic research and wide data sharing: views of prospective participants' (2010) 12 Genet Med 486

Trinidad SB et al, 'Genomic research and wide data sharing: views of prospective participants' (2010) 12 Genetics in Medicine 486

UNESCO, 'International Declaration on Human Genetic Data' <portal.unesco.org/en/ev.php-URL_ID=17720&URL_DO=DO_TOPIC&URL_SECTION=201.html> accessed 6 January 2013.

US Food and Drug Administration, 'Warning letter of November 22, 2013' <http://www.fda.gov/iceci/enforcementactions/warningletters/2013/ucm376296.htm> 23 May 2014

US Government Accountability Office, *Direct-To-Consumer Genetic Tests: Misleading Test Results Are Further Complicated by Deceptive Marketing and Other Questionable Practice* (GAO-10-847T, 2010)

van den Hoven J et al, 'Privacy and Information Technology' in Zalta EN (ed), *The Stanford Encyclopedia of Philosophy* (Winter edn, 2014) <plato.stanford.edu/archives/win2014/entries/it-privacy/> accessed 10 June 2015

Varga O et al, 'Definitions of genetic testing in European legal documents' (2012) 3 J Community Genet 125

Vermeulen E et al, 'Public attitudes towards preventive genomics and personal interest in genetic testing to prevent disease: a survey study' (2013) The European Journal of Public Health ckt143

Visscher P, McEvoy B and Yang J, 'From Galton to GWAS: Quantitative Genetics of Human Height' (2010) 92 Genet Res (Camb) 371

Vorhaus D, 'DNA DTC: The Return of Direct to Consumer Whole Genome Sequencing' *Genomics Law Report* (29 November 2012) <genomicslawreport.com/index.php/2012/11/29/dna-dtc-the-return-of-direct-to-consumer-whole-genome-sequencing/> accessed 11 December 2012

—— 'Implications of Amgen/deCODE Deal for Genetic Testing Consumers' (2012) <http://www.genomicslawreport.com/index.php/2012/12/10/implications-of-amgendecode-deal-for-genetic-testing-consumers/> accessed 10 December 2012

—— 'The Past, Present and Future of DTC Genetic Testing Regulation' <genomicslawreport.com/index.php/2010/08/05/the-past-present-and-future-of-dtc-genetic-testing-regulation/>

Vorhaus D and Contributor G, 'DTC Genetic Testing and the FDA: is there an end in sight to the regulatory uncertainty?' (16th June 2011)

Waddington L, ‘Reflections on the Protection of ‘Vulnerable’ Consumers Under EU Law’ (2013) 2 Maastricht Faculty of Law Working Paper 1

Wagner J et al, ‘Tilting at windmills no longer: a data-driven discussion of DTC DNA ancestry tests’ (2012) 14 Genet Med 586

Wagner JK and Weiss KM, ‘Attitudes on DNA ancestry tests’ (2012) 131 Hum Genet 41

Wallace H, ‘GeneWatch UK PR: Shoppers warned not to buy gene tests from Superdrug’ (*GeneWatch UK*, 2015) <genewatch.org/article.shtml?als%5Bcid%5D=406259&als%5Bitemid%5D=575612> accessed 5 April 2015

Wallace H, ‘The UK national DNA database’ (2006) 7 EMBO Reports S26

Wang R et al, *Learning your identity and disease from research papers: information leaks in genome wide association study* (ACM 2009)

Ward A, ‘Google-backed genetic testing company hires veteran scientist’ *The Financial Times* (12 March 2015) <ft.com/cms/s/0/ead07e84-c8d8-11e4-bc64-00144feab7de.html> accessed 20 August 2015

Watson L, ‘Father who didn't want to pay child maintenance sent another man in his place to give DNA for paternity test’ *Mail Online* (5 June 2013) <dailymail.co.uk/news/article-2336469/Father-didnt-want-pay-child-maintenance-sent-man-place-DNA-paternity-test.html> accessed 25 August 2015

Who’z the Daddy?, ‘Court Approved DNA Tests’ <whozthedaddy.com/regions/UK/EN/courtApprovedDNAtests.asp> accessed 5 January 2013. [Checked again 24 April 2014]

——, ‘Peace of Mind DNA Tests’ <whozthedaddy.com/regions/UK/EN/peaceOfMindDNAtests.asp> accessed 5 January 2013. [Checked again 24 April 2014].

Wigley + Company Solicitors, ‘To read or not to read… Online Ts and Cs. Or Hamlet’ (*Wigley + Company Solicitors*, 2015) <wigleylaw.com/assets/Uploads/To-read-or-not-to-read.pdf> accessed 7 July 2015

Wilde A et al, ‘Public interest in predictive genetic testing, including direct-to-consumer testing, for susceptibility to major depression: preliminary findings’ (2010) 18 Eur J Hum Genet 47

Wilde A et al, ‘Implications Of The Use Of Genetic Tests In Psychiatry, With A Focus On Major Depressive Disorder: A Review’ (2013) 30 Depression and Anxiety 267

William-Jones B, ‘'Be ready against cancer, now': direct-to-consumer advertising for genetic testing’ (2006) 25 New Genetics and Society 89

Williams-Jones B, ‘Where there's a web, there's a way: commercial genetic testing and the Internet’ (2003) 6 Community genetics 46

Wojcicki A, ‘Power of One Million’ (*23andMeBlog*, 2015) <blog.23andme.com/news/one-in-a-million/> accessed 18 June 2015

Womack CA, ‘Ethical and epistemic issues in direct-to-consumer drug advertising: where is patient agency?’ (2013) 16 Medicine, Health Care and Philosophy 275

Woodage T, ‘Relative Futility: Limits to Genetic Privacy Protection Because of the Inability to Prevent Disclosure of Genetic Information by Relatives’ (2010) 95 Minnesota Law Review

Yeap N, ‘Your finger is about to replace your bank password’ *CCN Money* (9 June 2015) <money.cnn.com/2015/06/05/technology/bank-fingerprint-reader/index.html?iid=EL>

Zawati MnH, Borry P and Howard HC, ‘Closure of Population Biobanks and Direct-To-Consumer Genetic Testing Companies’ (2011) 130 Human Genetics 425

Zettler P, Sherkow J and Greely H, ‘23andMe, the Food and Drug Administration, and the future of genetic testing’ (2014) 174 JAMA Intern Med 493

Zimmer C, ‘DNA Double Take’ *The New York Times* (New York, 16 September 2013)

Zimmern R, ‘Issues Concerning the Evaluation and Regulation of Predictive Genetic Testing’ (2012) 5 J Community Genet 49