Disruption and the Political Economy of Biosensor Data

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Science and Technology Studies has long held that the frames and definitions designers give to new tools matter enormously for how those tools are initially received, and ultimately modified, by users (Fischer, 1994; Kline and Pinch 1996). Discourses are powerful forces in technology design, shaping, for instance, how gender and racial inequalities get designed into technologies (Suchman 2002). The startups working in biosensing and self-tracking present a case to examine the role that power plays in the discursive process of framing new technologies. One frame often used for defining new data tools and services include their abilities for "disruption," or the perceived ability of technologies to upend the *status quo* of power within established industries or social institutions. In this chapter we present findings on our research in the start-up environment in the consumer wellness field which is relatively less regulated and the more closely regulated field of mobile medical applications. We use two cases of health data innovation to present possibilities for scholars and practitioners to think about both the processes and discourses of disruption, and how these discourses might affect how people design and use new technologies. Our goal here is not to make normative or evaluative judgements about the roles that disruption discourses play in society. We hope to show that disruption discourses

limit, in part, the possibilities for people to imagine technologies bridging existing social contexts and categories. Disruption limits such vision by overlooking the distinct roles for and relationships around data across contexts. Data can have different expectations to different people within and across different social institutions (Fiore-Gartland and Neff, forthcoming). Social institutions produce the tools and methods for making data even sensible or intelligible. However, as a concept for thinking about technology disruption helps to reproduce existing discourses of institutional power, even as people using disruption to describe what they are doing purport to change, replace, or disrupt those same power arrangements.

This chapter examines how two popularly held expectations for disruption, democratizing power and democratizing access, function to replace one set of existing ideas about power with another. Our argument shows how the disruption label masks the underlying friction and fuzziness of contested imaginations for social institutions. It also shows that the discursive work of the label "disruptive innovation" marshals support for the technology development process. These imaginations matter because they can cut off possibilities for some markets, while attempting to remake the existing world in an image that dismisses a new set of power relations. Disruption as a discourse is a form of negotiating power—a form that often privileges one mode (for example, of access to data or markets or expertise) over another. In their most extreme form, disruption discourses use the concepts of democracy and democratization as ways to describe technological change, and in doing so ascribe social power to technological change in a teleological, deterministic way: if we say a technology disrupts power by bringing democratic access to data or power, then the technology will be democratic.

What we focus on here are the disruption discourses in healthcare innovation, which use contradictory notions of the process of social change that new technologies initiate. Disruption

discourses suggest that hardware and software can or should stand in or substitute for social power. These disruption discourses present an imagined process in which all the details managed by government, policies, and citizens--the social actors in existing institutional power--would be fully accounted for, and still wholly dismissed or wholly encompassed by the disruptive change. In this way, disruption functions as an ideology that imagines that new technology can displace this kind of institutional power, and yet forecasts a new world that relies on new social arrangements for power, arrangements that do not exist or are not yet specified. The disruption discourse embodies a friction between different notions of democratization which has implications for how technology is designed in relation to institutions. Disruption discourses shape how technologies are encoded with values about existing laws, regulations, norms, and social practices.

We examine two startups confronting the U.S. Food and Drug Administration (FDA), 23andMe, makers of a direct-to-consumer genetics test, and Biosense, makers of a mobile urinalyses app, Uchek. First, we look at the common disruption discourses around new kinds of data. Then we examine how the FDA ruled against these two companies that used disruption labels to market biosensing technologies and services. While neither case is settled at the time of this writing, we argue that thinking through how disruption is used show the multiple and conflicting roles data plays within social institutions and the process that intermediaries--mediators we call them--use to make data sensible in different social settings. Both the roles for data and the processes for mediators trouble a simplistic disruption ideology and suggest a complexity in how data is framed, what it is used for, and how it is regulated by norms, expectations, laws, and social arrangements. Finally, we suggest what our research implies for

technology designers, health innovation advocates, and scholars, and what it contributes to the critiques of disruption that are emerging.

DISRUPTION AS A DISCOURSE

Disruption is used to explain the trajectory of what has occurred and predict what will happen in the future. The concept has roots in Clayton Christensen's much-popularized theory of disruptive innovation (Christensen 1997; 2003). Disruptive innovation describes a process by which a new product or service that is worse than the status quo along some valued dimensions eventually displaces the industry incumbents. The idea is that industry incumbents are so busy focusing on their "sustaining technology" and meeting the needs of their mainstream customer base that they do not see the disruptive innovation coming (Christensen 1997). Christensen (2003) distinguishes between "low-end disruption" and "new market disruption," describing how disruptive innovation can take root either within the bottom of the market for customers that don't want or need the full performance valued by other customers, or within entirely new markets that are not serviced by incumbents. A disruptive innovation in an established field does not so much improve on incumbents' products as it offers simplicity, affordability, and accessibility.

Disruption has evolved into an ideology of the technology industry. Conferences such as "TechCrunch Disrupt" present a model of change defined around a clear choice: "Disrupt or be disrupted." Within the ideology of disruption, new technology is thought to generate a whole new plane of competition for market incumbents. The disruptive innovation label is widely applied to many new technologies, causing even Christensen to express skepticism to its ubiquity (Bennett 2014).

Critics point out that while disruption may function as a theory of why businesses fail, it does not help explain why and how industries change (Lepore 2014). Critics of Christensen and the ubiquitous use of disruption to describe how industries change also suggest that disruption may not apply outside of technology and manufacturing. Christensen himself advocated for disruption to describe what he sees as necessary changes for healthcare and education. However, large government actors who wield regulatory power are among the incumbents. Mehta (in this volume) provides an example of disruption can be used to understand the trajectory of Apple's QuickTake digital camera--a significantly more affordable and lower quality new product--in which Apple positioned itself as a disruptive innovator because camera industry incumbents ignored new markets. Mehta argues that the healthcare industry, distinct from the camera industry, doesn't just ignore the newcomers to the market, they try to regulate and stake their claim to emerging markets, even when they aren't actually providing services in those markets. Disruption discourses rely on the assumption of free markets, but in actuality, civic and public stakeholders and social factors shape how all businesses and industries work. However, disruption discourses suggest futures that are at least partly outside of social institutions such as governments and industries, even as these discourses are strongly invested with idea of changing those same social institutions from the outside. Take as an example the prediction that healthcare's "outmoded institutions" will be "replaced, soon enough, with new institutions whose business models are appropriate to the new technologies and markets" (Christensen, Bohmer, and Kenagy 2000). Here, too, healthcare institutions are framed as singular coherent systems instead of syncretic, plural, and hybrid entities that we know them to be as demonstrated by a wide range of scholarship. While Christensen presents disruption as predictive, we would argue that this logic of disruption is less a prediction about what will happen with the

introduction of new sets of technologies and data, than an attempt to define the space of innovation and the terms and timelines of institutional change. In other words, we argue that when people use the word disruption, they seek to be proscriptive in suggesting how society should adapt to innovation than predictive of how it will change. It is not a far stretch in that case to see how disruption discourses then shape the priorities of technology design and innovation in terms recognizable with the disruption ideology. In other words, the thrust of the remainder of our chapter is to ask how disruption literally changes the terms of debate for technology development in ways that frame social problems and market failures as having possible solutions only outside of social institutions.

INNOVATION & DISRUPTION IN HEALTH CARE

Our field research was at the intersection of healthcare and technology, two industries in the throes of infatuation with disruption discourses. Disruption advocates argued that the U.S. healthcare system is an incumbent industry that can be simultaneously displaced and transformed through market-driven and technology-enabled innovation. "Will Disruptive Innovations Cure Health Care?" This provocatively titled article co-authored by Christensen argues

> disruptive innovations, small and large, could end the crisis—but only if the entrenched powers get out of the way and let market forces play out. If the natural process of disruption is allowed to proceed, we'll be able to build a new system that's characterized by lower costs, higher quality, and greater convenience than could ever be achieved under the old system. (Christensen, Bohmer, and Kenagy 2000).

Healthcare is often noted as one of the last industries to be disrupted by the digital revolution (Vaitheeswaran 2010). Christensen and his coauthors use disruption to frame the U.S. healthcare system as inefficient and ineffective, fundamentally broken, unsustainable, and "the most

entrenched, change-averse industry in the U.S." (Christensen, Bohmer, and Kenagy 2000). Christensen suggests that disrupting healthcare institutions will make healthcare both cheaper and *better* (Christensen, Bohmer, and Kenagy 2000). This, of course is in contrast to a path of cheaper and worse that the ideology of disruption predicts for other industries.

One way advocates predicted disruption would happen in healthcare was by people having direct access to cheaper, consumer-grade technologies and data. The model of social change presented in technology demonstrations, advertisements and founders' talks presented technologies as capable of transforming how doctors in clinics and hospitals provide care and expanding where care is provided. Communities of entrepreneurs, designers of data and technologies, and users within the start-up environment of consumer health and wellness claimed that a wide range of digital health technologies could enable pervasive, ubiquitous sensing of our bodies, our minds, and our behaviors, driving a revolution in how people know and care for themselves. These data-intensive technologies developed outside of conventional healthcare institutions and followed a market-driven, consumer-oriented logic. Many were wrapped in "disruptive innovation" as part of their marketing. At the conferences we attended such as TEDMed, MedX, and Health 2.0 people referred to Christensen's language of healthcare disruption and Topol's (2012) "creative destruction of medicine" to say such technologies will disrupt conventional institutional arrangements in healthcare by undercutting the status quo with affordability and accessibility; by creating new ecosystems for clinical care, personal health, and wellness; and by democratizing consumers' access to data and diagnostic potential. Disruption was thus described as a desirable goal, an end, even, of the work of technology implementation.

Yet in these presentations and discussions no one mentioned that disruption says disruptors provide current customers with a worse product compared to that of incumbents.

Entrepreneurs may have presented disrupting healthcare as a goal, but rarely did they include details on what new kinds of power or what new middlemen would emerge from the ruins of disrupted industries. Nor did they include timelines for how disrupted socio-technological arrangements would reconfigure. The majority of these so-called "disruptive innovations" are not focused on the work of negotiating changes to social power—key, we would argue, to any institutional transformation. Nor do they account for how institutions learn, adapt, and evolve. In the disruption ideology, it is a quick and complete process, not one with intermediate steps, involving players and stakeholders from within and outside of social institutions.

Christensen's disruption framework sees newcomers as those who "sneak in from below" to displace incumbents (Christensen, Bohmer, and Kenagy 2000).. Healthcare disruption, however, is often talked about as contradictory institutional processes. By this we mean improving or streamlining the services of incumbents' (hospitals, clinics, regulators) *while simultaneously* displacing or making redundant those services such as diagnoses, expertise, or clinical visits. This begs the question of who exactly is the incumbent to be disrupted and whether disruption best characterizes the changes that innovators are working toward.

These tensions around the definitions of disruption and ends of innovation are evident at the line between health and wellness data. The number of health technology companies and the number of health and fitness apps and devices are booming. Big data and personal analytics are increasingly popular venture capital investments. Rock Health, a digital health accelerator, reported that in 2014 digital health funding exceeded $4 billion, and for the first time the digital health industry surpassed total medical device venture funding (Rock Health, 2015). However, there are few effective ways to aggregate, integrate, and use the abundance of personal data being collected and little work to date on creating models to help bring that data into health care

settings. While data is seen as the disruptive force, there have been relatively few examples of how data-driven business models apply to health care service provision.

Most of the health technology start-up community envisions disruptive innovation emerging through the convergence of what might be termed classically medical instruments for diagnosis and therapy on one side and consumer-oriented ICTs on the other. Disruption discourses position doctors, clinics and hospitals as inefficient and sometimes unnecessary intermediaries between patients and their data. Analogous to how Day and Lury (this volume) describe discourses around data as reassembling of the fiction we tell ourselves about the dividing line between the individual and the social, the disruption discourse reinscribes distinctions between social institutions and individuals. Another part of the disruption discourse is that a host of disruptive innovations enable self-monitoring and self-diagnostics, liberating healthcare from the confines of the clinic, while recreating, in effect, a data ecology of information, expertise, and analysis. Health and wellness management in this technological imagination becomes an *always-on* activity that exists everywhere the consumer is (Price Waterhouse Cooper 2012), blurring spaces of health and wellness in everyday life.

Our point is not to judge whether disruption is a reliable way to predict the effects of innovation in healthcare, but rather critique the important discursive work disruption does for healthcare technology design. What is at stake is a socio-technical negotiation process that represents and reproduces technologies along with the scripts and contexts for their appropriate use. This matters for two reasons. First, these configurations and scripts continually reshape boundaries between categories of medical and non-medical, health and wellness, patient and consumer, and device and data. Second, these shifting distinctions have important implications

for how health functions in practice within existing social institutions. How this is accomplished discursively is what we turn to in the next section.

DISRUPTION AS THE DEMOCRATIZATION OF POWER & ACCESS

One of the discourses of disruption concerns the effect that disruption will have on an industry. For healthcare, disruption is said to bring about the democratization of power and access: individuals' access to information and tools empowers them to act for themselves, challenge expert knowledge and shift power relations between doctors and patients (Eysenbach 2008; Hardey 2001; Topol 2012). In disruption discourses *democratization* is used in different ways with different implications for existing social institutions. Democratization of power refers to the empowering of laypeople through their data and technology to shift the power of medical expertise and entrenched actors in the healthcare system. Democratization of access refers to the increased access to healthcare by putting medical information, data, and technology in the hands of laypeople, not healthcare workers, often with the goal of providing care to underserved populations through decentralized means.

"Patient engagement" and "patient empowerment" are often tied to the process of providing new digital technologies and data to directly to individuals (Barello, Graffigna, and Vegni 2012; Eysenbach 2008; Swan 2012a). There is an idealization of data's democratic potential to put patients and consumers "at the center of action-taking in relation to health and healthcare" (Swan 2012a, 97). Such an empowered patient is the result of the shifting of trust and power away from social institutions and toward individuals and consumers. This idea of the empowered patient relies on the full participation and activation of consumers to drive these changes (Topol 2012). Empowerment, then, emerges first from individuals having access to personal and personalized data and second from individuals being able to translate and reveal

oneself in data. This discourse refers to users as sources of data and innovators around their own care solutions. For example, "e-patient" Dave Brokhart organized a movement calling to "Give Me my DAM Data" to push healthcare organizations to make their records open to patients, removing barriers to individuals' access to their information.

In the consumer health narrative of democratization in health, individuals' access to information and tools of digital production empowers them to act in the service of their own health and wellness and to challenge and evaluate expert knowledge. In the process this access is predicted to disrupt the status quo configurations of institutional power (Eysenbach 2008; Hardey 2001; Topol 2012). Henwood, Wyatt, Hart, & Smith (2003) point to the dominant discourse of "rights" inherent in the emergence of consumer health informatics and to the emergence of Gidden's concept of the "reflexive consumer". The concept of "reflexive consumer" bears the assumption that individuals want to take more responsibility for their own health beyond the standard visit to the doctor. As the authors point out, this is not the case with all individuals: "'Rights,'" they note, "carry 'responsibilities'" (p. 604), and from this perspective empowerment serves to shift a burden of responsibility away from institutions onto individual (see, for example Rose 1999).

For disruption advocates, digital health tools and data empower consumers by reducing or removing mediation that is perceived as necessary or wasteful, and thereby enabling the consumer to perform activities such as diagnosis, monitoring, experimentation and data sharing outside of clinical and scientific settings. This is sometimes described as "DIY medicine," where consumers can autonomously conduct an array of at-home diagnostic testing and internet-based medical information searching (Khosla 2012; Swan 2012b). This is what we call *disintermediation*, and democratization in disruption theory relies on disintermediation. In other

words, for disruption to be democratizing, direct access to personal health data must empower individuals to change their behavior, make informed decisions about their healthcare, and actively engage particular research or drug development agendas.

Countering discourses of ICTs and empowerment in health and wellness, scholars have pointed to the corollary neoliberal logic of responsibilization, in which the "power" to act is also construed as the responsibility to act (Henwood et al. 2003; Lupton 1997; Mol 2008). In the realm of digital health, the democratization of technology and data and the empowerment of the user are promoted as two sides of the same coin. Around this theme of democratizing power, emerge very different configurations of the so-called "empowered" user and scripts for that use in relation to institutional power. This leads to very different configurations of the user in relationship to empowerment and to different configurations of how empowerment is defined in each context. Thus, disruption discourses re-draw professional and occupational boundaries, relationships, and previously held notions of expertise, responsibility, and authority. Many consider consumer-driven medicine to be an essential feature of disruption in healthcare through bringing (free) market logic to entrenched hierarchies and generating a participatory culture in health. For example, Sue Desmond-Hellmann, former chancellor of University of California San Francisco (UCSF), describes how the democratization of information shifts power from the institutions of medicines toward patients and consumer: "If the hierarchy of doctors are the only ones that have that power, that puts patients at a disadvantage. The power dynamic as a partner, as someone who has a stake in it, is different. Think of how much power you have every time you go to a consumer store" (Desmond-Hellmann 2013). Hellmann's reframing of patient as a "consumer" with choice and buying power is an essential part of how this disruption discourse manifests the democratization of power in healthcare. Yet this consumer logic of choice means

the patient bears a greater responsibility for managing their data and then navigating the implications of that data. This frame configures users as empowered within a market-driven logic of choice (Mol 2008). Users, here, are autonomous and naturally inclined to be responsible for optimizing their own health, self-managing their care, and producing, sharing, and creating value with their personal health data. The work of institutions is outsourced to individuals.

For entrepreneurs and technology designers, the discourse around "disruptive innovation" and "creative destruction" has generated a vision of consumer-oriented products, configuring the user as a consumer rather than a patient and healthcare professionals are often completely left out of the equation. This vision may fit squarely within calls for disruptive innovation, but it is shaped by the perception that designing for consumers is much easier and less regulated than designing for the healthcare system, which requires much more investment upfront to comply with FDA and other institutional interoperability standards.

A new product does not need to seek approval from the FDA if it does not make any explicit promises or claims about diagnosis or treatment. For example, an app to help diabetics track data on their blood glucose levels would not need FDA approval as long as the sensing is done with approved medical devices and the data were separate from medical interpretation. This regulatory environment creates a disincentive for technology designers who might have otherwise built applications to inform both physicians and patients. Instead we see the disruption label applied to the explosive growth in consumer-targeted applications aiming to provide personal data separate and distinct from the "incumbent" healthcare system.

Disintermediation is a process that assumes that medical expertise can be codified in other forms to disrupt institutions. Algorithms, thus, are framed as cheaper, more accessible, simpler, and only slightly less skilled doctors of the future (see, for example Khosla 2012).

Disruption discourses fundamentally overlook the work that is required to make data sensible and actionable across contexts. This is what doctors do when they interpret general lab results for particular patients within their own particular medical treatment protocols. A wide array of different practices are needed to make data sensible, meaningful and actionable. Our two cases below illustrate this.

DISRUPTIVE DATA: 23ANDME and UCHEK

The trajectory of the personal genetics testing company, 23andme, embodies the frictions between the notions of democratization of access and democratization of power. On November 22, 2013, the U.S. FDA issued a warning letter to 23andme demanding they halt the marketing of their direct-to-consumer (DTC) genetic test kits until the service has received FDA device marketing authorization. In response, 23andme stopped providing any "interpretation" of health risks with the test results they provided to their customer, and solely provided "ancestry-related information and raw genetic data" while trying to win FDA approval (Fiore-Silfvast 2014).

Until the FDA letter, 23andMe provided a service that straddled a deliberately blurred line between healthcare and personal wellness, between patient and consumer, and between device and data. Similar to a host of other consumer mobile health applications and biosensors (i.e. Fitbit, Basis, InsideTracker, uChek) personal genetic testing is situated at the interstices of institutional regulation, pushing the boundaries of unregulated consumer health and wellness by offering a model of consumer experience with health data that takes place outside of conversations with health care providers and outside of healthcare institutions, leaving the consumer to makes sense of and manage the implications of potential health risk factors in their everyday lives (see Kragh-Furbo et al. in this volume). As a data service, 23andme occupies a gray area between offering consumers entertaining, educational, non-clinical interpretations of

their DNA and offering personalized health risk information that could have medical implications and be clinically actionable. For instance, 23andme's marketing campaign before the FDA censure included a TV commercial presenting what people learn from their 23andme test results. One man says, "So that's why the sun makes me sneeze," right before another woman says "I might have an increased risk of heart disease" (23andMe 2013).

The juxtaposition of these two statements demonstrates the challenge of regulation, which is not about the data *per se,* rather it is about the expectations for what that data will do and mean. This clash with the FDA is discussed by advocates as a testament to the disruptive nature of their service to the conventions of the industry and its regulatory frameworks. As 23andme charts new spaces of personal health data intermediation in the consumer realm that make health predictions, the healthcare industry and the regulatory bodies are framed as impeding this development.

The 23andme case challenges the institutional frameworks for medical knowledge generation, which require clinical and analytical validation, while it also celebrates democratization of power enabled through a data ecology that seamlessly constructs personal health knowledge and expertise as wholly outside of clinical settings. In addition to these mostly non-clinical uses provided through the test, there are increasing amounts of personalized information about health risks and drug responses that have medical implications that the FDA is then responsible for regulating. Individuals cite their right to know about their own genetic health risks and to participate in the ongoing process of discovery that operates ahead of clinical translation. But in doing so they bypass the traditional intermediation of data within the health care system. Genetic testing data become more "democratized," in the sense that consumers have disintermediated access to their own personal genetic information. Yet, without institutional

support and integration into the healthcare system, these data in the hands of consumers fall short of empowering consumers in the clinical realm. Here we see the friction between democratization of access and democratization of power emerge. This disruption discourse claims on the one hand to democratize access to personal genetic testing and data suggesting a new set of relationships will emerge throughout which these data may flow and become meaningful and actionable. But within existing regulations, such data has implications for medical decision making. The time scale for these expected transformations is not discussed, which reinforces a discontinuous break and avoids discussion of new the work and structures that would need to develop. The case of 23andme shows that the power to create medical knowledge and make medical decisions and diagnoses has yet to shift outside of the health care system. While any new, emergent ecology would ostensibly replace existing institutional norms and hierarchies, what it looks like is kept deliberately vague.

Does 23andme simply want to disrupt access to personal genetic testing or do they want to disrupt medical expertise and institutional power in their role of providing medical advice? 23andme framed their service as “potentially” relevant for health with medical implications. They are outside the current institutional norms, while still at the frontier of genetic scientific discovery. They represent a company paving the future of healthcare as their service is personal genetic data intermediation. Without some intermediation, genetic data is meaningless to most people. In other words, the 23andme version of disruption replaces one type of data mediation done by doctors and by clinics with a version that they author the mediation role for themselves.

For the FDA, the service of interpretation that 23andme provides to consumers that links genetic data to health risks and drug responses, which may have clinical implications, is the target of regulation, rather than the data itself. In the FDA’s letter to 23andme, they point to the

marketing language the company uses to describe its services including “health reports on 254 diseases and conditions,” including categories such as “carrier status,” “health risks,” and “drug response,” and specifically as a “first step in prevention” that enables users to “take steps toward mitigating serious diseases” such as diabetes, coronary heart disease, and breast cancer” as overreaching into clinical interpretation with medical implications. From a regulatory perspective, these intended uses fall under the medical device classification, which presents an expectation that the algorithms and delivery system be analytically and clinically validated in particular ways and to particular levels of accuracy.

Even in a clinical context, however, 23andme data is mostly not actionable. Even though the FDA claims that the test could lead to such things as “prophylactic surgery” and “chemo-prevention” this is not too likely as most physicians would conduct further clinical investigation, rather than act based just on 23andme data. However, physicians will still be confronted with 23andme data as well as a range of other patient data generated outside the clinic that they will have to decide to act on or not act on, with potential clinical consequences either way.

This contradicts the notion that disruption is democratizing. Those who produce and consume disintermediated health and wellness data will not only be figuring out problems for themselves but using these tools to confront institutionalized power within the health care industry, asking for medical expertise and knowledge to help them make sense of “their” data, and seeking ways to recreate some of the familiar types of data mediation available within existing social institutions and the current health care system. While they may use a label of disruption, 23andme is offering something more complicated. By offering a version of disintermediated data to consumers they still benefit from the relationship of consumers and their care providers to make sense of that data and to act on that data. In other words, consumers are

not “just” working out for themselves the implications of the data that they get outside of the health care system. This is a key difference in how the FDA has viewed 23andme’s data and the company itself has framed the data. Disruption in this case is not about 23andme offering a better service. Rather the company is disintermediating something the healthcare system cannot provide, delinking health data from medical interpretation. In the process 23andme’s design of service worked to change social institutions by imagining that the genetic data that they provide can be completely outside of a health system.

Taking a step back from this controversy, we see that the consumer health side of 23andme’s personal genome service is a relatively small part of their larger strategy. The strategic vision is to amass enormous amounts of personal genetic data. Anne Wojcicki, co-founder of 23andme, told *Fast Company* that they had a goal of enrolling 25 million people. When aggregated and linked with phenotypic data, such data could fuel unprecedented biomedical discovery and pharmaceutical development. The 23andme arm of the company invites the consumer to learn about their personal genetics and “take a more active role in managing your health” while the 23andWe arm of the company invites the consumer to participate in research because “23andme isn’t just about you” and “with enough data, 23andWe can produce revolutionary findings that will benefit us all.” The FDA’s regulatory focus in this initial controversy only scratches the surface of the range of regulatory and ethical questions around how to manage contested data valences across the multiple contexts for privacy and reuse of big data (see Patterson and Nissenbaum, this volume). It grapples only with different interpretations of what genetic data points mean, by enforcing standards of verification, not yet with the multiple expectations for what data can do and how it will perform within different social contexts (see Fiore-Gartland and Neff forthcoming).

Disruption for 23andme comes by placing themselves and their data fully outside the existing social institutions the health care system. In contrast, there is already a market-driven and consumer-oriented culture around disintermediated health and wellness in urban India. There individuals engage in self-care and self-management using technology that performs as the intermediary. This is due to the fragmented private and public healthcare systems often failing to meet the demands of consumers, growing health insurance penetration, and the increasing burden and awareness of chronic disease. Technological innovation in healthcare in urban India is often centered around creating more autonomy, control, and self-sufficiency for consumers within and outside the formal healthcare system.

Consider the journey of a mobile urinalysis app developed by a startup in India that transforms the mobile phone into a lab. The mobile app with accessories uses urine test strips and a camera phone to analyze colors compared to a color-coded mat on which the strip is placed. The app claims to analyze over 10 different parameters including glucose, bilirubin, ketone, specific gravity, and pH, to name a few. The use scenarios for this app are multiple. The first category of use is for at-home urinalysis for an urban Indian population increasingly burdened with self-managing chronic disease. The second category of use is in clinics and labs, too small to afford the gold standard auto analyzers, which serve Indian populations underserved by doctors, clinics, and hospitals.

Biosense released a downloadable iPhone app for uChek in the U.S. The FDA issued their first ever warning letter to a mobile app explaining that Biosense needed class II medical device approval for uChek. In essence Biosense framed the data they provided as nonmedical data, but regulators disagreed, seeking to regulate the medical interpretation of data. Scanaflo, a similar device, was designed in Silicon Valley with the intention of marketing to U.S. consumers

self-managing and self-diagnosing, but unlike uChek underwent the FDA approval process. The difference between the two apps is relevant because it reveals the multiple imaginations for what the same technologies and data can be across different institutional contexts, motivated by different healthcare problems and thus open to different kinds of regulatory interpretations.

DISRUPTION DISCOURSES AS SPACES FOR DEVELOPMENT

Disruption may not function as a reliable prediction about what will happen in healthcare, but it does important discursive work, and thus shapes technology design. Disruption discourses shape the priorities of technology and data design, emphasizing potential consumers or markets rather than prioritizing health care problems and social institutions of health care. Disruption discourses imagine data as capable of residing outside of social institutions and in the process fail to consider the mechanism that people look to for intermediation. Disruption discourses also imagine that access to data will enable people to act in particular ways, unrestrained by existing practices, norms, and laws.

The FDA has recognized the need to evolve the policies to keep up with the pace of technological innovation and associated risk, developing a medical mobile application policy with a "balanced" approach that "supports continued innovation," while "assuring appropriate patient protections" (Foreman 2013). As of April 2014, of the tens of thousands of health-related apps on the market, the FDA had registered or cleared just over 100 as medical devices (MobiHealthNews 2014).

Disruption discourses in the U.S. consumer health context proscribe how medical and consumer data *should* travel between non-medical and medical settings. In practice, however, data mobility was not supported by infrastructure to get consumer data into clinics or bring medical expertise to such data. The explosion of consumer-oriented biosensing has outpaced any

the development of institutions of sensemaking. Data do not move their own; rather, they require organizational structuring and intermediary labor to support the flow across stakeholder communities. Medical data produced in the consumer realm faced regulatory challenges as U.S. government bodies aimed to regulate medical devices, including medical interpretation or diagnosis, through FDA approval and regulated medical information. Without FDA approval what could occur in these new non-clinical sites and interactions was restricted, and the types of self-care available, and the production of medical data via digital health technologies, were narrowed, regardless of the promise or actuality of the innovation. Various forms of intermediation, such as care managers, nurses, and genetics counselors, would be needed to link home and clinic and to translate between medical expertise and individual cases. Disruption discourses worked in these cases to help imagine home and clinic as distinct and isolated spaces with respect to health data, not as places ready for the social and technological bridges that new kinds of data could have provided.

Thus innovations in these non-clinical spaces tend toward two paths: In order to count in both settings, they can go the route of seeking approval from regulatory bodies in order to afford interoperability between clinical and non-clinical settings. Alternately, they can take the path of focusing on wellness and prevention-oriented measures and interventions that skirt medical jurisdiction by a hair. In the latter case, the metrics around fitness, diet, wellbeing, and interventions may provide data without complete medical interpretation or present disclaimers that the information is “not for medical advice.” This shaky bridging of the divide between official medical information and self-help begins to challenge the boundaries of health and wellness. We have seen wellness metrics and interventions explode in this interstitial medical/non-medical space, along with national policymaking that promotes health through

prevention and through the medicalization of lifestyle and wellbeing outside of the clinic rather than through episodic clinical encounters and disease treatment.

These differently situated technological imaginations bring different configurations of users, appropriate use, and context of use that are important in shaping the processes of digital health innovation. Disruption discourses helped people to imagine the distinctions between categories of medical and non-medical, health and wellness, patient and consumer, and device and data. And these distinctions had important implications for how tools were designed to collect data and data functioned in practice across communities.

At the intersection between home and clinic were social norms and regulations that were not clearly delineated, and 23andme attempted to straddle, but not bridge, these institutional contexts for data. With a disruption discourse that promised more democratic data, 23andme designed a data ecology outside of the current healthcare system, but ultimately dependent upon it for sensemaking and actionability of the data 23andme provides to its customers. Biosense imagined the context for direct-to-consumer health being as global as the market in Apple's iTunes App store, and the technology moving as easily.

Firmly planted in the direct-to-consumer realm, 23andme's disruption discourse seeks to change the *status quo* in healthcare through providing access to a new class of data that defies previous definitions of health and wellness. In this way, 23andme uses access to data to open a space where their company supplants the conventional oversight and curation of the medical establishment. They are essentially making a market for personal genetic data and placing themselves at the center. Their disruption discourse frames this as democratization, tapping into patient rights and empowerment discourses. However 23andme simultaneously represents the shift of power from medical institutions to a corporate body, not to individuals.

Biosense comes from a perspective on disruption that is oriented around creating affordable and accessible healthcare for all, in a place where these gaps are stark. These technologies are imagined as innovations emerging from the massive demand and particular constraints that characterize other healthcare settings in the developing world, in this case, India. The disruption discourse of Biosense holds that affordability and accessibility comes through democratizing access, disrupting the market for more expensive and less accessible ways of obtaining urinalysis. In their India development context, there was not a clear entrenched healthcare incumbent, and thus not the same notion of the democratization of power. Yet as Uchek came to the U.S. they found themselves up against institutional powers that meant they were then framed as disrupting. Digital health advocates celebrate technology innovation as individual empowerment; yet within the disruption discourses empowerment is a process of individualizing the labor of data, placing the responsibility of achieving the appropriate health and wellness in the hands of the consumer (literally). As one author phrased it, individuals become "the CEOs of their health" through their expanded capacity to interface with devices and software algorithms (Khosla 2014). There is enormous possibility for people to use data-driven health innovations for a soft form of resistance (Sherman and Nafus 2014). However, the work of disruption discourses makes it harder for these innovations to work with and within existing social institutions as opposed to against them. At this point in health care innovation is *disruption* doing more harm than good?

IMPLICATIONS FOR SCHOLARS, DESIGNERS, AND BIOSENSING

For many consumer health advocates what is at stake in this controversy is the FDA trying to curtail their individual rights to access their personal health data. Communities of patient rights activists and advocates for consumer-driven disruptions in healthcare are

demanding the liberation of all different types of personal health data from the constraints of clinical and medical settings and the return of that data into the hands of consumers. Information such as physician notes and medical device data have been the target of advocacy campaigns to create more access for patients and consumers.

So-called disruptive, data-intensive technologies in personal health and wellness rely on an assumption that more data in the hands of consumers will lead to better health and wellness and that these data-intensive practices represent the future of healthcare. This assumption tends to overlook questions about the longer term costs and benefits of innovation. There are many examples where worse-cheaper is not necessarily better for patients or healthcare. It also ignores the central role of power for making data across multiple social settings. It also diverts focus from developing the personal genetic testing within healthcare systems--systems that are much more hybrid and plural, more entrench, and yet more adaptive than how disruption discourse frames them to be.

A problem that emerges through disruption discourses in health and wellness is startups' focus on the consumer uses of technology. We have demonstrated how data move from consumers across contexts to suggest that disruption discourses shape how consumer uses of data are imagined in the context of other social institutions. The attempts at disruption in healthcare corners technical innovation into a narrowly scoped context, in which their uses are circumscribed within a both nonclinical and consumer-oriented health and wellness context. Disruption discourses in health and wellness have already inspired challenges to distinctions between categories of medical and non-medical, health and wellness, patient and consumer, and device and data. In circumscribing a context and design space that is just a hair before medical or conflates health and wellness, as many of these technologies do, they are aiming to escape the

institutional and organizational implications of their design, such as regulatory policy, liability, organizational capacity building. For technology designers, disruption discourses may limit their ability to create solutions with existing social institutions in mind.

Common frames in technology design presume that technology is capable of standing in for a whole host of organizational structures and institutional power. These discourses discount the multiple intermediaries that data need and the work that is required for data be meaningful in different settings. In other words, when technology designers talk about data as disruptive they emphasize consumers, and often narrowly scope design around individual users, not multiple social contexts. This popular user-centered design approach in consumer health and wellness ignores the intermediation of data or where data resides and the organizational and institutional contexts for data. As biosensing becomes consumer phenomena how and where the data will go will continue to be an issue. When a technology is framed as disruptive then the answers to where the data will go, who will evaluate it, and how it will help people work within the social institutions that exist are left unanswered.

Disruption discourses do powerful work in the design of data systems by imagining two things that are impossible to do simultaneously, cutting out a middleman while integrating seamlessly all the parts of the middleman's very system that will soon be made obsolete. This is where the discourse of disruption falls apart. Disruption discourses lay bare a tension between a rhetoric that is hostile to the idea that data require mediation, even as these services and technologies rely on new kinds of integration and new data ecologies to work. Disruption presumes convergence on which institutional arrangements and configurations of power are to be transformed, and these can get articulated in the form of expectations for data. However, rather than see disruption as a challenge to social institutions, perhaps social theorists should remember

that data always require norms, practices, and routines for sensemaking, meaning, and action. Perhaps the time is right to put data as disruption aside in favor of data as a social institution.

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