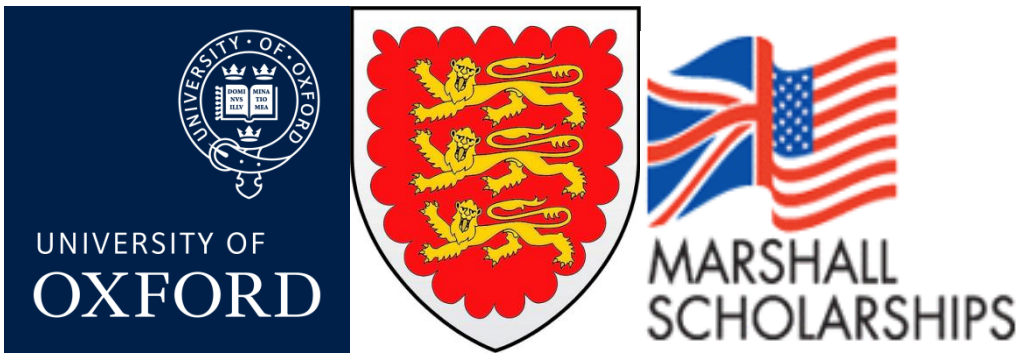

PATIENT AND PUBLIC INVOLVEMENT: ETHICAL JUSTIFICATIONS, EXPERT KNOWLEDGE, AND DELIBERATIVE DEMOCRACY

by

Jonathan U. Warsh

Thesis presented for the degree of Doctor of Philosophy
in Population Health
Oriel College
University of Oxford

Nuffield Department of Population Health
Old Road Campus, University of Oxford
Oxford OX3 7LF

Supervisor: Dr. Mark Sheehan

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For my Mom and Dad

Abstract

Patient and Public Involvement: Ethical Justifications, Expert Knowledge, and Deliberative Democracy

Thesis presented for the degree of Doctor of Philosophy in Public Health at the University of Oxford

Jonathan U. Warsh
Oriel College
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Across many countries worldwide, support for patient and public involvement (PPI) in health care has grown significantly over the last two decades. Calls to democratize the health care system have resulted in a system where patients are increasingly involved in the design of medical research and members of the public have been called upon to help make decisions concerning various elements of national, regional, and local health care policy. In some countries, like the UK, laws on the books now mandate that health care institutions meet certain benchmarks in PPI in order to be eligible for national funding. Though many scholars have sought to understand how society can make PPI efforts more "effective," they have largely neglected to provide an overarching justification for involvement in the first place. This thesis seeks to understand whether such a justification exists.

I examine two sets of arguments in support of PPI: one that maintains PPI simply improves the quality, relevance, or effectiveness of medical research and health care provision (the outcomes-based argument) and one that appeals to notions of democratic legitimacy and representation. I argue that the outcome-centered argument wrongly presupposes an agreement on which outcomes should be prioritized while the democratic legitimacy argument fails to adequately identify the relationship between PPI and greater transparency, accountability, or reasonability. Since supporters of PPI often use the framework of deliberative democracy as support for the democratic legitimacy argument, I use it as well as a starting point for analysis. In short, though PPI may appeal to certain democratic intuitions, there is little reason to think that in practice it has strengthened bonds of democratic legitimacy.

Abstract

I conclude by suggesting ways in which those core democratic virtues might be strengthened outside the realm of PPI. Despite increased patient involvement, the processes of resource allocation (rationing) in health care remain opaque in many countries. In addition, there exist few mechanisms for individual appeal of an unjust decision, a feature that most deliberative democrats consider essential to a just system of resource allocation. Ultimately, I contend that a greater focus on the processes that facilitate transparency and accountability will better serve citizens and their health care systems.

Contents

The idea of citizen participation is a little like eating spinach: no one is against it in principle because it is good for you.

Sherry R. Arnstein, "A Ladder of Citizen Participation," 1969

1
Introduction

No matter how complicated the research, or how brilliant the researcher, patients and the public always offer unique, invaluable insights. Their advice when designing, implementing and evaluating research invariably makes studies more effective, more credible and often more cost efficient as well.[1]
--Professor Dame Sally Davies, Chief Medical Officer, England

Being in favour of better public consultation or more user involvement is rather like being against sin; at a rhetorical level, it is hard to find disagreement.[2]
--Harrison and Mort, "Which Champions, Which People? Public and User Involvement in Health Care as a Technology of Legitimation"

1.1 Introduction – The Argument in Brief

The question of how to allocate scarce resources in health care – in both research and service provision – has been the subject of research and scholarly debate for many years. Much of that history is replete with debates around distributive (or "substantive") justice, or the idea that there exists some identifiable "just" allocation of resources in health care.[3] But for much of the last twenty years, bioethicists have devoted a significant amount of time and energy dedicated to questions of procedural justice, focusing on *how* we make decisions to allocate scarce resources rather than what the final allocation looks like.[4] Deeply enmeshed in this conversation is the rise of patient and public involvement (PPI), a set of policies and theories which represent the idea that individual patients and members of

[1] Kristina Staley, *Exploring Impact: Public involvement in NHS, public health and social care research* (Eastleigh: INVOLVE, 2009).
[2] Stephen Harrison and Maggie Mort, "Which Champions, Which People? Public and User Involvement in Health Care as a Technology of Legitimation," *Social Policy and Administration* 32, no. 1 (1998): 60-70.
[3] Norman Daniels, "Health Care Needs and Distributive Justice," *Philosophy and Public Affairs* 10, no. 2 (1981): 146-179; Richard Cookson and Paul Dolan, "Principles of justice in health care rationing," *Journal of Medical Ethics* 26, no. 5 (2000): 323-329
[4] Norman Daniels, *Just Health: Meeting Health Needs Fairly.* Cambridge: Cambridge University Press, 2007. See also Norman Daniels, *Just Health Care* (Cambridge: Cambridge University Press, 1985).

the public should be involved directly in decisions that are made about the allocation of funds for medical research and health care services, as well as those concerning the governance of research institutions. As we will see, arguments in support of patient and public involvement largely fall under two categories: (1) outcomes-centered arguments that suggest that PPI leads to "better" research or resource allocation and (2) democratic-legitimacy based arguments that locate PPI as a mechanism by which decisions made by government institutions can be more heavily informed by the individuals that stand to be affected by them.

In many ways, these arguments are highly intuitive. Shouldn't we as patients have valuable insights to contribute to the process of research design? After all, we are the ones undergoing treatment – surely we know which elements of therapeutic advancement matter the most to us. In this sense, PPI has understood medical research not just through the lens of scientific advancement but also through the prism of clinical *relevance* and *applicability.* If we are funding the research and will ultimately be the beneficiaries of the research, should our opinions about the content of that research go ignored?

In one sense, this argument dovetails with much of the rhetoric around "patient-centredness" that pervades much of the health care literature. Consider, for example, the arguments from Stewart et al. around the value that patients can and should contribute to research efforts:

> During the last decade healthcare professionals and patients have worked with government, industry and charity to strengthen support for clinical research and make it central to the delivery of healthcare in the UK. The involvement of patients and the public has become key to this process. The involvement of patients, carers and the public in research needs to continue to be embedded in a culture that places the patient at the centre of clinical research.[5]

[5] D. Stewart, R. Wilson, P. Selby and J. Darbyshire, "Patient and public involvement," *Annals of Oncology* 22, no. 7 (2011): vii54- vii56.

In the realm of health care policy and resource allocation, does it not similarly stand to reason that we as users of the health care system know more about what matters to the general public (i.e. us) than nameless technocrats embedded in the massive government bureaucracy that is health care? Why, supporters of PPI ask, should we as average citizens be disengaged from processes that fundamentally alter the health care system when we are the ones who pay for that system and use it to obtain care? This line of argument, which appeals to principles of democratic accountability relies heavily on the notion that government that is *closer* to the people is more transparent, accountable, and effective government.

In this dissertation, I will argue that neither justification proves sufficiently robust. Outcome-based justifications, I maintain, struggle to identify exactly which outcomes are of greatest import and democratic justifications may make sense in theory, but empirical analysis shows them to have little value "on the ground." Which outcomes should we privilege as a society? Clinical relevance? Total number of years of life saved? Palliation and measures to reduce pain and suffering? In addition, I argue that "democracy" simply serves as an amorphous label in this context, and that in reality we should support greater efforts to have resource allocation and health care policy that is more transparent and accountable. Put most simply, my goal in this dissertation is to search for a *general* justification for PPI (as opposed to a situation-specific justification) and to examine critically the general justifications that have been put forward in the literature to this point. To be sure, it will be my contention going forward that the goals elucidated by supporters of PPI are laudable ones: better, more patient-centred, research, more accountable policy-making, and transparent allocation of resources. But this dissertation will question whether

citizen involvement as articulated by scholars and policymakers who support PPI has done little and will continue to do little to advance those objectives.

1.2 Historical Preface

For most of medical history, decisions not just about the health care system but indeed about the care of each individual patient were made with little regard for that patient's individual needs or desires. Though physicians conceived of themselves as sacred custodians of an individual's life and well-being, such service did not require actual consultation with patients or their families until the 1960's. In one sense, the sacredness of that patient-physician relationship is what rendered it exempt from external regulation or control. As the philosopher Hans Jonas said, "the physician is obligated to the patient, and no one else…we may speak of a sacred trust; strictly by its terms, the doctor is, as it were, alone with his patient and God."[6] To try and regulate the nature of that relationship was to violate its sanctity.

Indeed, the Hippocratic Oath, itself the very backbone of physician responsibility and honour even today, is replete with references to paternalistic ideals. It notes, for example, that physicians are to "apply dietetic measures for the benefit of the sick according to [their] ability and judgment; [and to] keep [the sick] from harm and injustice."[7] Notably, patients are described passively by Hippocrates, with physicians occupying the position of control through their sophisticated knowledge and specialized set of skills. This mindset would come to define the patient-physician relationship for the better part of 2000 years.

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[6] Hans Jonas, "Philosophical Reflections on Experimenting with Human Subjects," *Daedalus* 98, no. 2 (Spring 1969): 225.

[7] L. Edelstein, "The Hippocratic Oath: text, translation and interpretation." In O. Temkin and C.L. Temkin (eds.), *Ancient medicine: selected papers of Ludwig Edelstein*. Baltimore: Johns Hopkins University Press (1967): 7.

Slowly but surely, patients and policymakers began to react strongly against the prevailing system of medical paternalism that had characterized the health care system for, quite literally, millennia. Patients began to see themselves not as subjects of treatment or (worse yet) scientific examination and experimentation, but as active partners in the decision-making process around care. Patient engagement in the public square ultimately resulted in regulation of the clinical setting to provide for greater patient authority over clinical decisions.[8] The rise of the active patient found its origins in greater awareness around research with human subjects, with courts in both the United States and Europe ultimately finding in the late 1950's that patients had a right to a certain baseline of information before agreeing to participate in research or undergoing a procedure.[9] Eventually, phrases like "patient autonomy," "shared decision-making," and "informed consent" became part and parcel of the health care systems in Western liberal democracies.

Our whirlwind tour through the evolution of patient autonomy and patient rights provides an important background for the questions of this thesis. Indeed, as patients gained more control over their own care in the clinic, they also sought to have a greater say in reforms to the health care system as a whole – biomedical research, insurance reform, and structural features of the health care system became considerably more prominent subjects of public debate in the 1970's and 1980's as citizens began to reflect the same active mindset in the public square that they had embraced in the clinic.[10] Whereas health

[8] A complete chronicling of the rise of the active patient and the decline of medical paternalism is well outside the bounds of this thesis. For a thorough historical analysis, see David J. Rothman, *Strangers at the Bedside: A History of How Law and Bioethics Transformed Medical Decision Making* (New York: Basic Books, 1991).
[9] Jonathan F. Will, "A Brief Historical and Theoretical Perspective on Patient Autonomy and Medical Decision Making. Part II: The Autonomy Model," *Chest* 139, no. 6 (2011): 1491-1497.
[10] See Ezekiel J. Emanuel, *Reinventing American Health Care* (New York: PublicAffairs, 2014), Chapter 5.

had been an important social issue in many countries in decades prior, in the 1970's and 1980's, debates around health care, biomedical research, and resource allocation took on sharply political tones.

Notably, in those decades, patient advocacy groups grew in both number and influence, representing specific constituencies and their interests, particularly in the United States.[11] Most famously, AIDS activists in the 1980's effectively organized around efforts to have their plight formally recognized by the scientific community and then addressed by securing unprecedented levels of government funded research and lobbying to have experimental drugs approved by the Food and Drug Administration.[12] Operating very much at the intersection of the social, the political, and the personal, "Nothing For Us Without Us" became the heading of AIDS activists in the 1980's, [13] and later, the breast cancer activists of the 1990's.[14]

In certain ways, this historical evidence suggests that patients began to believe that preserving autonomy and democratic control over health required more than activism at the micro level of the clinic. Because, they began to recognize, larger social, political, and economic structures have a profound influence on individual human health, activism could not stop at the clinic. Even though patients had successfully elevated their position within

[11] See Beatrix Hoffman, Nancy Tomes, Rachel Grob, and Mark Schlesinger (ed.), *Patients as Policy Actors: A Century of Changing Markets and Missions* (New Brunswick, NJ: Rutgers University Press, 2011).
[12] For the most comprehensive look at the work of AIDS activists in the 1980's, see Steven Epstein, *Impure Science: AIDS, Activism, and the Politics of Knowledge* (Berkeley, CA: University of California Press, 1996).
[13] Kevin M. De Cock, Harold W. Jaffe, and James W. Curran, "Reflections on 30 Years of AIDS," *Emerging Infectious Diseases* 17, no. 6 (2011): 1044-1048. Note also that the "Nothing For Us/About Us Without Us" paradigm has been the subject of considerable debate and interest amongst scholars of the disability activism community. See James I. Charlton, *Nothing About Us Without Us: Disability Oppression and Empowerment* (Berkeley, CA: University of California Press, 1998).
[14] See Maren Klawiter, *The Biopolitics of Breast Cancer: Changing Cultures of Disease and Activism* (Minneapolis, MN: University of Minnesota Press, 2008).

the realm of the clinical encounter, experts, scientists and technocrats retained significant control over most other facets of, what many termed "the medical industrial complex."[15] Many issues falling under the broad umbrella of health care policy remained well outside the purview of democratic public control: how biomedical research funding was allocated,[16] what types of research projects were funded, the conditions under which drug regulators granted approval to experimental therapies, and how public bodies decided to approve certain treatments or procedures but not others, to name just a few examples.

In the 1970's and 1980's, members of the public became more actively engaged in the politics of health care, though their engagement remained largely in the traditional channels of political participation. In the U.S., powerful lobbyists representing individuals with particular diseases (e.g. the National Breast Cancer Coalition, National Prostate Cancer Coalition, etc.) worked the halls of Congress, advocating for more research dollars for their particular diseases. They also worked to cultivate grassroots political advocacy operations, with the dual goals of generating increased attention around public health and preventive medicine (e.g. mammogram screenings) while generating widespread political support that could be leveraged in Washington, D.C.[17] Though patient advocacy in the U.S. in the 1980's and 1990's focused heavily on individual disease constituencies, some

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[15] G.R. Welter, "From 'Pressure Group Politics' to 'Medical-Industrial Complex': The Development of Approaches to the Politics of Health," *Journal of Health Politics, Policy, and Law* 1, no. 4 (1977): 444-470. See also Arnold S. Relman, "The New Medical-Industrial Complex," *New England Journal of Medicine* 303, no. 17 (1980): 963-970.

[16] Some might very well argue that biomedical research exists in a separate sphere from other parts of health services delivery. Historically, however, many of the same patient advocacy groups discussed here (e.g. breast cancer and AIDS) attacked the paternalism of the clinic at the same time as they were pushing for greater funding for research on their diseases that they maintain had been historically neglected.

[17] Emily S. Kolker, "Framing as a cultural resource in health social movements: funding activism and the breast cancer movement in the US 1990–1993," *Sociology of Health and Illness* 26, no. 6 (2004): 820-844.

advocacy groups focused on more general issues like patient safety[18] and the ability of the health care system to respond to socioeconomically disadvantaged patients.[19]

In the U.K., patient participation health policy found its origin in 1970's Community Health Councils (CHC's) that were formed initially in order to solicit feedback from the general public and to assist in the process of strategic planning within the health care system. Later in the 1970's, patient advocacy groups were formed and advocated in parliament for patients' rights and for structural improvements to the health care system.[20] By the time that Conservatives came to power in 1979, political discourse around health care in the UK focused heavily on notions of patient-centeredness and system responsiveness, with polling showing increasing trends of public dissatisfaction with the basic functioning of the National Health Service (NHS). Major NHS reports (including the 1983 Griffiths NHS Management Inquiry[21] and the 1991 *Patient's Charter*) emphasized the lack of patient-centeredness and advocated for a series of substantive reforms to improve the responsiveness of the NHS as a whole. The Griffiths Report, which largely focused on critical management problems within the NHS later gave way to reforms in the late 1980's

[18] Beatrix Hoffman, "Health Care Reform and Social Movements in the United States," *American Journal of Public Health* 93, no. 1 (2003): 75-85.
[19] Beatrix Hoffman, "Don't Scream Alone," in *Patients as Policy Actors: A Century of Changing Markets and Missions*, ed. Beatrix Hoffman, Nancy Tomes, Rachel Grob, and Mark Schlesinger (New Brunswick, NJ: Rutgers University Press, 2011), pp. 132-147.
[20] Though some groups, like the Patients' Association advocated for general improvements to the health care system, there was increasing focus (as there was in the US) on particular problems (e.g. mental health, maternity care, etc.). See Marjorie Tew, *Safer Childbirth? A Critical History of Childbirth*, 3rd edn. (London: Free Association Books, 1998); and Anne Rogers and David Pilgrim, *Mental Health Policy in Britain* (London: Palgrave, 2001).
[21] Department of Health and Social Security, "Griffiths Report on NHS," accessed 28/7/15 at < http://www.sochealth.co.uk/national-health-service/griffiths-report-october-1983/>. See also David J. Hunter, "NHS Management: Is Griffiths the Last Quick Fix?" *Public Administration* 62, no. 1 (1984): 91-94.

as a result of the *Working for patients (NHS Reforms)* white paper.[22] That report, which proposed a division between the payers and the providers of health care (GP fundholders and the government payers) was an attempt to foster more patient-centred and market driven delivery of care.

1.3 Enter Patient and Public Involvement

By the late 1990's, claims of undemocratic decision-making in health care policymaking had been loudly and forcefully made in countries on both sides of the Atlantic.[23] In the U.K., a powerful report from the Institute for Public Policy Research released in 1995 characterized the NHS as suffering from a "democratic deficit,"[24] while in the U.S., a similarly influential report from the Institute of Medicine entitled "Scientific Opportunities and Public Needs" responded to what was believed to be a highly opaque and overly politicized process of resource allocation in biomedical research at the National Institutes of Health (NIH).[25] What would follow from these reports (as well as reports in other countries and the broader debate about public participation in health care policy-making) were a series of reforms in countries around the world that sought to engage members of the public directly with the details of policy-making around health care. Fundamentally, because all elements of the health care system are intricately bound up in

[22] See Simon J. Williams, Michael Calnan, Sarah L. Cant, and Joanne Coyle, "All Change in the NHS? Implications of the NHS reforms for primary care prevention," *Sociology of Health and Illness* 15, no. 1 (1993): 43-65.

[23] Note that my discussion here is limited to the history of patient and public involvement in the U.S. and the U.K., though similar stories can be told of many other European countries, as well as Canada, Australia, South Africa, and other liberal democracies around the world. My focus on the U.S. and the U.K. in this thesis is primarily intended to (1) provide two instructive and representative and examples and (2) introduce a brief history into the two countries whose systems are the subjects of the case studies that will be examined in greater detail in chapter 6.

[24] Liz Cooper, Anna Coote, Anne Davies, and Christine Jackson, *Voices Off: Tackling the Democratic Deficit in Health* (London: Institute for Public Policy Research, 1995).

[25] Institute of Medicine, *Scientific Opportunities and Public Needs: Improving Priority Setting and Public Input at the National Institutes of Health*, (Washington, DC: The National Academies Press, 1998).

decisions about how to allocate scarce resources, policymakers believed[26] that involving members of the public would help to defuse the notion that technocrats and bureaucrats were making undemocratic decisions that had the ability to tangibly impact individuals most basic ability to survive and flourish.[27]

It should be noted the drive towards greater patient participation in health care was not a stand-alone phenomenon. Indeed, the push for more citizen engagement was, in many countries, reflecting a broader political trend. In the U.K., for example, the Blair government which was largely responsible for many of the policy reforms mandating patient and public involvement spoke in broad terms about the need for a "democratic renewal" and called for reforms across the spectrum of the post-war welfare state that it had deemed increasingly unresponsive and unequal.[28] With that said, it should also be noted that whereas advocates have been fairly successful in pushing an agenda of patient and public involvement in health care, calls for similar citizen engagement in other areas of public policy have been both much quieter and much less successful.[29]

In the years that followed, patient and public involvement would serve as the cornerstone for many major reforms to individual country health care systems, though the impulse towards PPI was embraced much more wholeheartedly in Europe than it was in

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[26] In the US, for example, response to the *Scientific Opportunities and Public Needs* report resulted in Congress directing the NIH to undertake several reforms including the development of the Council of Public Representatives and having NIH encourage lay people to participate in review of grant proposals. See David Resnik, Setting biomedical research priorities (page 182).

[27] For more extensive discussion of the ways in which PPI has historically served as a method of political legitimation, see Mort and Harrison "Which Champions, Which People" at note 2.

[28] Rob Baggott, A Funny Thing Happened on the Way to the Forum? Reforming Patient and Public Involvement in the NHS in England," *Public Administration* 83, no. 3 (2005): 533-551.

[29] One notable exception to this is environmental a policy, an area in which members of the public have been particularly engaged. See Sally Eden, "Public participation in environmental policy: considering scientific, counter-scientific, and non-scientific contributions," *History and Philosophy of Science* 5, no. 3 (1996): 183-204.

North America. The U.K. has in many ways been the most ardent supporter of policies promoting (and in some cases, mandating) patient and public involvement. In England, for example, the *Health and Social Care Act (2001)* legally required all primary care trusts to consult and involve patients when important decisions about the provision of services are being made. The *Health and Social Care Act of 2012* amended the *National Health Service Act (2006*), which had consolidated major reforms in a number of pieces of legislation including the *Health and Social Care Act* as well as the *NHS Act of 1977*, and required all strategic health authorities, primary care trusts, NHS trusts, and Foundation trusts to involve and consult patients in "the planning of the provision of services, the development and consideration of proposals for changes in the way those services are provided, [and] decisions to be made by that body affecting the operation of those services."[30] NHS guidance also provides that research institutions should pursue active patient and public involvement policies as it relates to research design and resource allocation efforts in research.[31]

Similar reform efforts have been pursued in a range of European countries,[32] as well as in both Canada[33] and Australia.[34] In the United States, given the highly fragmented and

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[30] House of Commons. Health and social care bill 2010-2011. Stationery Office, 2011, Chapter 2, Section 242. See also "Patient and Public Involvement," Heatherwood and Wexham Park Hospitals Website, last accessed 26 May 2014, < http://www.heatherwoodandwexham.nhs.uk/info/patient-and-public-involvement-ppi>.

[31] Department of Health, *Patient and public involvement in the NHS* (London: Department of Health, 1999). See also House of Commons Health Committee, *Patient and Public Involvement in the NHS: Third Report of Session 2006-2007, Volume I* (London: House of Commons, 2007), < http://www.publications.parliament.uk/pa/cm200607/cmselect/cmhealth/278/278i.pdf>.

[32] Craig Mitton et al., "Public participation in health care priority setting: A scoping review," *Health Policy* 91, no. 3 (2009): 219-228.

[33] Judith Maxwell, Steven Rosell, and Pierre-Gerlier Forest, "Giving citizens a voice in healthcare policy in Canada," *British Medical Journal* 326 (2003): 1031-1033; Steven Lewis and Denise Kouri, "Regionalization: Making Sense of the Canadian Experience," *Healthcare Papers* 5, no. 1 (2004): 12-31.

to a large extent, decentralized system of health care, the story with regard to PPI is more complicated. As I will argue, the most significant experiment with PPI in health care priority setting took place in the state of Oregon, and there have been additional efforts to involve patients and members of the public in priority setting in biomedical research. However, because a majority of U.S. citizens receive their health care through private insurers and providers rather than through the government, there has been less of a "democratic push" to involve citizens at all levels of the health care system. Nonetheless, examples of PPI in both medical research and resource allocation/priority setting provide an important backdrop for the key arguments of this thesis, and feature prominently in my case study analysis in chapter 6.

1.4 The Question – Why Involve?

With these policy developments as historical background, scholarship on patient and public involvement has largely focused on two questions: (1) when should we involve patients and members of the public? and (2) how should we involve them? As quotes from both Arnstein and Harrison and Mort at the beginning of this thesis suggest, scholars and practitioners have largely bought into the notion that patient and public involvement constitutes a categorical good. After all, as Arnstein notes, "Participation by the governed in their government is, in theory, the cornerstone of democracy – a revered idea that is vigorously applauded by virtually everyone."[35] But in focusing attention on the question of how to make PPI more "effective" and relying on the notion that citizen involvement in this context is a necessary good, scholars have failed to ask what I believe is the more

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[34] V. Wiseman, G. Mooney, G. Berry, and K.C. Tang, "Involving the general public in priority setting: experiences from Australia," *Social Science and Medicine* 56, no. 5 (2003): 1001-1012.
[35] Sherry R. Arnstein, "A Ladder of Citizen Participation," *Journal of the American Institute of Planners* 35, no. 4 (1969): 216-224.

fundamental prior question: what is the general justification for a policy of patient and public involvement? And secondarily, are "patient and public involvement" and "democratic engagement" truly one and the same? Put another way, can patient and public involvement be justified by appeal to the same arguments that justify democratic engagement more broadly?

Broadly speaking, practitioners have articulated two different arguments in support of involvement, both of which are examined in great detail in this thesis. First, they argue that involvement makes the research, the delivery of care, or the health care system "better." This argument – which I refer to as the outcome-centered justification – sees patient and public involvement as of largely instrumental value. As the quote at the beginning of this chapter from England's Chief Medical Officer Sally Davies suggests, there is a strong belief amongst supporters of patient and public involvement that when "average patients" are consulted, research becomes more responsive to the needs of patients suffering from particular conditions. And, as Sir Nick Partridge, former chair of INVOLVE, a leading UK advisory organization promoting patient and public involvement in the NHS has said, "involvement helps to ensure that the entire research process is focused on what is important to people and is therefore more likely to produce results that can be used to improve health and social care services."[36] In the realm of health system reform or priority-setting, the corollary belief is that where those same average citizens are consulted, reforms can be put in place that render the health care system more in line with the needs of patients who use it on a daily basis. In this way, the outcome-centered argument is fairly straightforward: because the health care system (defined broadly) exists to maximize the health of the population, consulting the population is likely to improve the

[36] Staley, *Exploring Impact* at note 1.

maximization of those outcomes. In other words, when patients are consulted, policies can be crafted with greater likelihood of achieving measurable gains in outcomes.

The second argument in support of patient and public involvement appeals to the democratic intuition that individuals in a free society should be engaged directly with decisions about how health care is provided and rationed. Indeed, in 2000, the Council of Europe went so far as to categorize public participation in healthcare decision-making as a fundamental democratic right, proclaiming that "The right of citizens and patients to participate in the decision-making process affecting health care, if they wish to do so, must be viewed as a fundamental and integral part of any democratic society."[37] Because health care spending involves both disbursement of public funds[38] and decision-making around an issue of foundational human importance, appeals to this line of democratic reasoning suggest that citizen engagement is not just instrumental, but rather intrinsically valuable insofar as it furthers democratic goals. In this sense, whether or not involvement makes the research, resource allocation, or health system reforms "better" is largely immaterial to the viability of the democratic legitimacy argument.

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[37] Council of Europe Committee of Ministers, "Recommendation No. R (2000) 5 of the Committee of Ministers to member states on the development of structures for citizen and patient participation in the decision-making process affecting health care," February 24th, 2000, https://wcd.coe.int/ViewDoc.jsp?id=340437&Site=CM. Note that though the Council of Europe recommendation does not mention citizen involvement in research explicitly, it does state that " Citizens/patients should have the possibility of participating in setting priorities in health care." The declaration is written in relatively vague language about "health care" and a straightforward reading suggests it applies primarily (or potentially even exclusively) to citizen involvement in the health care *services* system, but the reference to priority setting could suggest a broader interpretation.

[38] The democratic legitimacy argument undoubtedly raises a more complicated set of questions with regard to a health care system like that of the United States where a significant amount of health care spending occurs without public sector involvement. Where public *funds* are being disbursed (even in private provider organizations, as is the case in much of continental Europe), these same questions around democratic legitimacy arise.

It is important to emphasize that this appeal to democratic legitimacy can be taken to invoke indirectly (if not in certain instances directly) a particular theory of democratic engagement and deliberation. Because in practice patient and public involvement relies on the participation of a select number of lay individuals who are said to represent "the public interest" but who are not themselves elected by the population, PPI cannot reasonably be construed as promoting a representative theory of democracy. Nor, since it does not advocate for total and unlimited public participation in decision-making, can it be said to be invoking a theory of direct or semi-direct democracy. More reasonably, we can construe the democratic argument for patient and public involvement as appealing to principles of deliberative democracy, a democratic theory that understands the legitimacy of decisions as being mediated by the nature of discussion and debate surrounding that decision rather than merely the procedural elements that govern the decision-making process.[39] I will delve more deeply into the philosophy of deliberative democratic theory and its relationship to patient and public involvement in chapters 4 and 5. But given the impossibly broad scope of democratic theory, it is important even at this early stage to highlight the fact that the democratic appeal made by supporters of patient and public involvement must be understood as falling within a particular framework of democratic philosophy.

1.4.1 Evidence for the Two-Pronged PPI Argument

Numerous policy documents, white papers, and advocacy statements from groups supporting patient and public involvement highlight the dual nature of the argument in support of PPI. Consider, for example, the 2007 Department of Health response to the

[39] See, for example, John Dryzek, *Deliberative Democracy and Beyond* (Oxford: Oxford University Press, 2000); Amy Gutmann and Dennis Thompson, *Democracy and Disagreement*, Cambridge, Mass: Harvard University Press, 1996; and Amy Gutmann and Dennis Thompson, *Why Deliberative Democracy*, Princeton: Princeton University Press, 2004.

House of Commons Health Committee Report entitled "Patient and Public Involvement in the NHS." In asking the question, "What is the purpose of patient and public involvement?" the report answers by appealing to both of these principles (underlining added for emphasis):

> The purpose of public involvement is also often confused and conflated. Two main purposes need to be distinguished: improving the design and provision of services and increasing accountability. In a publicly funded service, patients and the public are in a sense the NHS's shareholders as well as customers and their views on larger decisions about spending priorities and service design must also be taken into account.
>
> As we stated in our evidence to the Committee, we believe that the ultimate purpose of user and public involvement is the delivery of improved services, which better meet the needs and wants of service users. Patients, carers and users of services are experts in the care they both need and want, their input is therefore essential to create the user led health and social care system people want, and towards which this Government is driving.
>
> We also feel that it is essential to involve users, as well as the groups that represent them, in the commissioning decisions that are taken, to ensure they have an input into what services are provided in their locality. This involvement in needs assessment, in prioritisation, and decision-making will create and support local ownership of the NHS, delivering transparency and accountability for the multi-million pounds being spent at the local level.
>
> Patient and user involvement also assists in the scrutiny of services through representing people's views, and allowing users a route to assuring the quality of the services they use. We agree with the Committee that enhancing accountability for public spending is also important. As users and funders of the services, patients and the public should be able to directly influence the services provided for them.[40]

The authors of the paper clearly understand patient and public involvement as essential to improving services – given that patients and caregivers are the ones using the services directly, it therefore follows that those individuals are best equipped to guide decisions that alter the existing care structure. But in invoking phrases "representing people's views" and "delivering transparency and accountability" the authors also identify accountability, transparency, and notions of representation as essential features of a PPI structure.

[40] Department of Health, "The Health Committee's Report on Patient and Public Involvement in the NHS: Government Response to the Health Committee's Report on Patient and Public Involvement." 20 April 2007, accessed 8 August 2015 online at < https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/243264/7128.pdf>.

Of course, these arguments have been made not just by government agents, but by others within the medical community, including the influential British Medical Association. In responding to the Health Committee's request for evidence in the 2007 report, the BMA answered the question "why involve" by articulating these two different justifications as well (underlining added for emphasis):

> *Q. What is the purpose of patient and public involvement?*
> 3. The public is concerned about the future of Britain's public services with more than half (57%) thinking that government policies will make public services worse. In health, almost half (46%) think that the NHS will get worse over the next few years. Only one in five (19%) thinks that present government policies will make the NHS better.1
> 4. A recent survey found that the vast majority (90%) of those asked agreed that local people should have a say in how local healthcare services are run, with three-quarters (74%) wanting a say in how their GP surgery and local hospital are run. However, the same survey found that three-quarters (76%) of people had never been asked about what they would like from their local services, and half (50%) felt they had no power to influence service development in their area.2
> 5. The public has had its expectations of the NHS vastly raised as a result of investment and of the government telling people that they can expect more and offering a more consumerist approach to healthcare. Choose and Book is an example of this, where patients can literally vote with their feet by choosing where they want their care delivered. Choice in principle is good, and wanted, but it needs to be properly informed. Words such as "empowerment", "a need for voice" and "patient-centred" are used, but need defining and given greater meaning. At present, the only choice is a choice of hospital.
> 6. At present, policy on patient choice risks worsening inequalities in healthcare. Wealthy and educated populations will be the main beneficiaries. The rise of consumerism and the introduction of markets have created additional drivers for choice. There is no evidence that increasing patient choice will, of itself, improve the quality of patient care. Indeed, some studies suggest that increasing choice may result in a deterioration in the quality and cost-effectiveness of services.3 The aim of choice should be in empowering patients, improving outcomes and contributing to reducing inequity.4
> …
> Why public involvement is necessary for all public services
> 10. Simply put, there is a democratic deficit. It should be a fundamental tenet of organisations that those paying for a service and those affected by it have a right to be engaged in its design and development. One problem with public involvement is that it is, at present, too often merely placatory.
> 11. Public involvement should be necessary for decisions as to what services are provided, how they are provided, quality setting, and monitoring and the maintenance of standards. A service can only be responsive to users if users are involved. Public involvement offers service providers and commissioners the opportunity to better understand the needs of the public.

> 12. Public involvement has never been more important than it is now, at a time of reconfiguration and when crucial decisions are being made by commissioners which impact on local services. If providers are to purchase services on behalf of taxpayers it makes sense that commissioners talk to them about the services they buy and forge relationships with them so as to increase their knowledge about the quality of the services for which they pay.
> 13. Reconfiguration will involve difficult decisions that it is important to get right. In the context of limited resources, the service needs to consult with the public to identify what they need rather than what they want.[41]

Debates about the value of patient and public involvement continued through debates in the UK around the passage of the *Health and Social Care Act (2012),* which made some of the most significant reforms to the NHS (largely outside the realm of PPI) in several decades.[42] In responding to questions about the value of PPI, the National Institute for Health Research and INVOLVE issued a briefing paper outlining the virtues of patient and public involvement. In it, they argued the following:

> As well as the practical benefits of helping to ensure research quality and relevance, the underlying reasons for involving members of the public in research are also informed by broader democratic principles of citizenship, accountability and transparency. The reasons for involvement might not always be clearly defined and at times will overlap each other. However understanding why you want to involve members of the public in your research will help you think who you want to involve and how you want to involve people.
>
> Democratic principles
> It is a core democratic principle that people who are affected by research have a right to have a say in what and how publicly funded research is undertaken. Public involvement is an intrinsic part of citizenship, public accountability and transparency. In addition public involvement in research can lead to empowering people who use health and social care services, providing a route to influencing change and improvement in issues which concern people most.
> Research quality and relevance
> Providing a different perspective
> Members of the public might have personal knowledge and experience of your research topic or be able to provide a more general perspective. Even if you are an expert in your field, your knowledge and experience will be different to the experience of someone who is using the service or living with a health condition. Improving the quality of the research
> This might be by:

[41] British Medical Association, "Evidence submitted by the British Medical Association's Patient Liaison Group (PPI 148)," *Select Committee on Health Written Evidence* (25 January 2007): accessed online 1 August 2015 at http://www.publications.parliament.uk/pa/cm200607/cmselect/cmhealth/278/278we13.htm.
[42] Ibid.

- making the language and content of information provided more appropriate and accessible (for example in questionnaires, and patient/participant information leaflets)
- helping to ensure that the methods proposed for the study are acceptable and sensitive to the situations of potential research participants
- helping to ensure that research uses outcomes that are important to the public
- increasing participation in research through:
    - making the research more appropriate and acceptable to potential participants
    - improving the information provided so people can make informed choices
    - helping to include seldom heard groups.

Making the research more relevant
For example through:

- identifying a wider set of research topics than if health or social care professionals had worked alone
- suggesting ideas for new research areas
- ensuring research is focused on the public's interests and concerns and that money and resources are used efficiently
- helping to reshape and clarify the research[43]

In addition to these principles there is a growing interest in public involvement by research funders and research organisations as well as the commitment to public involvement in health and social care policy.

The approach identified by the NIHR and INVOLVE track clearly along the conceptual lines articulated by the previous parliamentary reports, relying on arguments rooted in outcome improvement and democratic engagement to support a continued focus on PPI. One of the results of the passage of the 2012 *Health and Social Care Act* was the creation of "Healthwatch England," a national body entrusted with the responsibility to act as the national body overseeing citizen engagement and the responsiveness of the NHS across local communities throughout the country. In addressing what it sees as the value of greater citizen engagement, Healthwatch describes the virtue of involvement as follows:

> There are two elements to the right to be involved. Often people are experts in their own condition or the condition of people they care for. Their views must be taken seriously by professionals as they can have valuable insight to add.

[43] INVOLVE, "Briefing note three: Why involve members of the public in research," *accessed online 4/5/15* at http://www.invo.org.uk/posttyperesource/why-should-members-of-the-public-be-involved-in-research/.

> People are also citizens and part of the wider community. They should have the right to be consulted and involved about decisions that affect health and social care services in their area.[44]

This approach is not, however, limited to the policy community within the UK. In 2013, the World Health Organization published a wide ranging report on pharmaceutical spending, research, and innovation entitled "Priority Medicines for Europe and the World: 2013 Update." The report, which addressed a range of questions around pharmaceutical spending, devoted a significant amount of attention to the question of how to prioritize pharmaceutical research spending and in that discussion, advocated for greater patient and public involvement in the realm of priority-setting for biomedical research and pharmaceutical development. The arguments in this context also fall into the two categories that have been discussed to this point: improving responsiveness to patient need and patient outcomes, and accountability and transparency (underlining added for emphasis):

> A variety of underlying motivations drive the efforts to involve patients and citizens in priority setting for pharmaceutical innovation.
>
> First there are political reasons, based on the desire to promote democratic ideals of legitimacy, transparency and accountability. In the year 2000, The Council of Europe declared that the right of the public to be involved in the decision-making processes affecting health care is a basic and essential part of any democratic society. This democratic right is echoed in government reports, legislation and in statements from patient and citizen groups. Setting (research) priorities affects the use of limited public resources, and research demonstrates that values and ethical considerations play a role in recommendations on, for example, guideline development. Therefore, societal values should be considered and decisions should be informed by input from patients and citizens since they are affected by the decisions.
>
> The promotion of patient and citizen involvement can be driven by arguments of transparency and trust. For example, an analysis of the benefits of patient involvement by the EMA led the agency to conclude that: "participation of patients in the scientific committees leads to increased transparency and trust in regulatory processes and develops mutual respect between regulators and the community of patients."

[44] Healthwatch, "Being Involved Homepage", accessed online 6/3/15 at http://www.healthwatch.co.uk/rights/involved.

> A second category is health-related motivation that stems from the need to better align pharmaceutical innovation with the real, unmet needs of patients. Pharmaceutical innovations do not always meet the needs of patients effectively. Biases within the health research system may tend to favour certain research and topics over others. This could result, for example, in a lack of interdisciplinary and integral approaches and little attention paid to recovery of patient function. In addition, important questions may be overlooked because of an emphasis on chronic but not acute conditions, severe but not common health problems, and disease-specific but not cross-cutting issues, such as social care, improved surgery, and anaesthesia. Evidence shows that health professionals' values of different health states and research priorities differ from those of patients.
>
> Another health-related motivation focuses on the actual contribution which especially patients can make to the decision-making process, and thus to the rationality of the process and the quality of its direct or long-term outcome. Patients not only have a right to engage in discussions on decision making about priorities (the political stance), their input is also needed because they have a specific, relevant type of knowledge: their 'experiential knowledge'.
>
> These motivations provide a strong justification for efforts to further develop patient and citizen involvement in priority setting.[45]

Though obviously in a slightly different realm of public health policy (priority setting for pharmaceutical spending), the nature of the WHO arguments are strikingly similar. It is argued that patients might both contribute to a process that is better for overall health and outcomes and that patients have a fundamental interest to participate on democratic grounds. Indeed, in invoking the language of the 2000 Council of Europe declaration, the WHO goes so far as to identify patient and public involvement in these determinations as a core democratic right.

1.5 Towards a More Nuanced View of Patient and Public Involvement

In examining the strength of these two justifications, this thesis makes arguments that fall under three main categories. First, in chapter 2, I suggest that the patient and public involvement is a heading that encompasses a wide range of activities, some of which

[45] Ghislaine van Thiel and Pieter Stolk, "Background Paper 8.5: Patient and Citizen Involvement," *World Health Organization*, accessed online 6/5/15 at < http://www.who.int/medicines/areas/priority_medicines/BP8_5Stakeholder.pdf>.

raise normative questions that others do not. Whether to involve members of the public in decisions about resource allocation or priority setting for a primary care trust raises a set of questions about democratic accountability and political representation that are inapplicable in a discussion about whether to involve patients with Parkinson's disease in an effort to reformulate the research agenda around Parkinson's. Rather than *only* trying to ask the question, "what is the justification for patient and public involvement?" this thesis aims to further complicate the discussion by highlighting the ways in which different kinds of involvement (based on context, issue, and "level" of engagement) are different in normatively meaningful ways. Though this may point may initially seem self-evident, in both academic and policy circles, few distinctions (if any) are made between different kinds of involvement and many of the arguments in this thesis flow from these distinctions.

Second, I argue that the outcome-centered framework, as described above, provides only limited value in practice. As I suggest in chapter 3, the evidence base surrounding the effectiveness of PPI interventions is remarkably thin and largely confined to individual case studies that do little to rigorously show why PPI is successful in certain instances but not others. More fundamentally, however, I contend that outcome-based frameworks impose a set of assumptions about welfare that may prove inapplicable in debates about resource allocation or priority setting. As the case studies in chapter 6 will show, resource allocating and priority setting bodies might have sound ethical reasons to pursue policies that do not comport with outcome-centered analyses. In these contexts, asking whether patient and public involvement makes the health care system "better" is to wrongly assume that resource allocators and priority-setters agree about what a "better" system looks like in the first place.

In chapters 4 and 5, I examine the strength of the relationship between patient and public involvement and deliberative democracy and argue that patient and public involvement does little to advance transparency, reciprocity, or accountability – the cornerstones of deliberative democratic theory. I also suggest that in certain instances, the way in which individuals are selected for participation in PPI initiatives can have a deleterious effect on political accountability. By relying on the idea that lay individuals can represent a unified lay perspective, PPI often overlooks the nuances within public opinion and fails to provide members of the general public with a means of removing an individual who is not effectively representing the public interest or appealing a decision that is believed to be unjust. Finally, I look at the requirements placed on participants within the deliberative process and dispute the idea that lay participation is openly available to all members of the general public equally. In this way, PPI based programs and initiatives can have the unintended effect of reifying social and economic divisions within society.

Ultimately, in chapter 7 I conclude by articulating the ways in which governments, private payers and providers, and citizens can work together to create a system that is more transparent, accountable, and reciprocal. Relying on a framework for process legitimacy developed by Norm Daniels and James Sabin for private sector health care providers,[46] I maintain that resource allocating and priority setting entities can and should devote more attention to explaining publically why individual decisions are made and develop independent appeals processes that provide members of the public with both moral and political recourse when unjust decisions have been rendered. In this way, the aim of this thesis is not merely to cast doubt on the value of patient and public involvement, but to

[46] Norman Daniels and James Sabin, "Limits to Health Care: Fair Procedures, Democratic Deliberation, and the Legitimacy Problem for Insurers," *Philosophy and Public Affairs* 26, no. 4 (1997): 303-350.

better understand the goals of PPI *as articulated by PPI's supporters* and to advocate for structural changes that more successfully advance those goals.

1.6 Approach and Methodology

The approach of this thesis can most aptly be described as applied normative philosophical inquiry. A theoretical analysis of the basis for outcome-centred and democratic theories of involvement must, therefore, be our starting point. Because our goal is to understand not just the ways in which PPI works in practice, but also what arguments support that practice, theoretical arguments play a role in structuring our discussion. But insofar as our interest in patient and public involvement stems from a set of activities that have been implemented in numerous countries around the world, the theoretical arguments made here are more useful if they can respond in practice to the way in which PPI manifests "on the ground."

In short, then, my goal is to use case study analysis to determine how PPI works in practice while examining the arguments that are levied in support of PPI. Throughout that process, I attempt to both scrutinize the philosophical assumptions that underlie PPI-based policies while also evaluating the extent to which PPI as a theory matches with the way in which PPI works in practice.

Empirical analysis of entities implementing deliberative democracy in practice is, to be sure, somewhat precarious. As John Parkinson rightly notes, "Anyone attempting to connect deliberative democratic theory and practice must, however, face up to a serious difficulty: it is hard to ask empirical questions about fully deliberative institutions when such institutions do not exist in the real world."[47] With that said, critics of the approach

[47] John Parkinson, *Deliberating in the Real World: Problems of Legitimacy in Deliberative Democracy* (New York: Oxford University Press, 2006), p.8.

taken here might suggest that my appraisal of patient and public involvement is unfair given that I only look at how PPI is implemented in practice but not how it *could be* implemented given a set of alternative conditions. This critique, however, relies on a misunderstanding of the practice of deliberative democracy and ignores the fact that it is difficult analytically to separate the theory of deliberative democracy from the way in which it is practised. As Parkinson explains, "…real practices are embedded in our present liberal democratic system, and are fundamentally affected by the assumptions, motivations, discourses and power structures of that system."[48] Working within that system is taken as a given by this thesis, and the strength of my theoretical arguments should be judged by their applicability to the way in which PPI is pursued in practice.

It should be noted that the case studies in this thesis are drawn exclusively from the U.S. and the U.K.[49] There are several reasons for this decision. First, the vast majority of existing case studies of patient and public involvement (from which this chapter draws) are from the U.S. and the U.K. Since this thesis relies on already existing literature for the case studies, I chose to draw from countries with the widest available literature base of existing case studies. One systematic review, for example, found that approximately 2/3 of all existing literature case studies are U.S. (40%) and U.K. (26%) based.[50] Second, drawing from two markedly different health care systems enables us to better understand the ways in which both political factors and health care system dynamics have affected (or not affected) the implementation and support of PPI-based policies in practice. The U.S. and U.K.

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[48] Ibid.
[49] Note that my focus is primarily on PPI as it is practised in developed countries. Though public engagement in the developing world is a continued topic of debate and research, PPI in the developing world raises certain ethical questions that are largely inapplicable in the developed country context. For greater discussion in this question, see note 49 below.
[50] Mitton et al., "Public participation in health priority setting" at note 32.

represent two countries with distinctly different health care systems – the U.K's being almost exclusively public, while the U.S. system reflecting much greater fragmentation with a majority of the market being controlled by private payers and providers. In addition, whereas the political dynamics in the U.K. have tended to support greater citizen involvement, the highly privatized nature of the U.S. system has limited the extent to which individuals feel entitled to participate in direct policy-making with regard to the health care system.[51]

The diversity of the case studies here notwithstanding, in no sense should they be considered a comprehensive representation of all PPI activities in the US or the UK, much less the world. The role of the case studies is not to represent the universe of current initiatives, but to highlight the ways in which the theoretical arguments I develop earlier in this thesis hold relevance when applied in practice. In that sense, the case studies here are merely one argumentative tool intended to demonstrate a broader point about citizen engagement and the fundamental tenets of deliberative democracy as it manifests on the ground.

It should nonetheless be noted that there is little reason to think that geographically limiting case study analysis should reduce the extent to which my conclusions are generalizable. Much of the patient and public involvement taking place globally is centered in Western Europe, and though the health care systems in many of those countries (Denmark, Sweden, Norway, France, Spain) are obviously not perfectly analogous to that

[51] Edmund D. Pellegrino, "The Commodification of Medical and Health Care: The Moral Consequences of a Paradigm Shift from a Professional to a Market Ethic," *Journal of Medicine and Philosophy* 24, no. 3 (1999): 243-266.

of the United Kingdom, their differences should not bear directly or significantly on the conceptual or practical implications of my analysis.

1.6.1 Methodological Challenges

This thesis must grapple with two critical methodological challenges: (1) understanding "who" exactly is a supporter of PPI; and (2) identifying what the perspective of "PPI supporters" is in a philosophical context. Supporters of PPI approach questions of public engagement from a range of perspectives (who is involved, to what extent they are involved, on what issues they are involved, etc.) and so identifying what exactly is "the PPI perspective" is a difficult challenge.

Despite the fact that (at least in the UK) PPI has gained significant political traction[52] in recent decades, investigations of the PPI literature reveal that identifying precisely "who" is a "supporter of PPI" proves surprisingly difficult. Within the academic literature, there are very few scholars arguing explicitly for greater patient and public involvement and a much greater number evaluating, from an academic perspective, whether PPI appears to be having its desired effect. A growing number of scholars[53] lament the lack of studies critically evaluating the success of PPI, but (perhaps because of this lack of evidence), very few scholars take a strong position on whether not PPI has been a successful set of policies. Similarly, though many politicians talk in very broad terms about

[52] See Rob Baggott, "A funny thing happened on the way to the forum? Reforming patient and public involvement in the NHS and England," *Public Administration* 83, no. 3 (2005): 533-551.
[53] See Sophie Staniszewska, Sandy Herron-Marx, and Carole Mockford. "Measuring the Impact of Patient and Public Involvement: The Need for an Evidence Base." *International Journal for Quality in Health Care* 20, no. 6 (December 1, 2008): 373–74; Kristina Staley, "'Is it worth doing?' Measuring the impact of patient and public involvement in research, *Research Involvement and Engagement* 1, no. 6 (2015): online; and Carrol Gamble, Louise Dudley, and Jennifer Newman, "Evidence base for patient and public involvement in clinical trials (EPIC)," *Trials* 14, suppl. 1 (2013): O34.

the importance of citizen engagement, very few talk in detailed terms about how PPI can further better health outcomes and democratic accountability.

Many of the most detailed statements about patient and public involvement emerge in the literature from parliamentary debates about specific legislation and come from either government officials, relevant professional societies, or affected interest groups. Because the process of crafting legislation is a detailed one that lends itself to testimony and the submission of public comments, many of the claims that I attribute to "supporters of PPI" or "the PPI community" stem from these debates. As we will see in chapter 2, the term "PPI" can very well refer to a broad and diverse set of activities, but in order for this thesis to proceed in a logical and cogent manner, I have attempted at the outset to identify what I have found as the most common and credible arguments in support of greater patient and public involvement.

This thesis also aims to take a philosophically rigorous approach in evaluating the merits of the claims made by supporters of PPI. Unfortunately, as was seen in the review of the claims of some PPI supporters earlier in this chapter, those claims are often made in extremely broad terms. Supporters talk about "improving the design…of services"[54] or about the vague principles of democracy and accountability. Consider, for example, this argument from INVOLVE regarding the democratic argument in favor of greater patient and public involvement:

> It is a core democratic principle that people who are affected by research have a right to have a say in what and how publicly funded research is undertaken. Public involvement is an intrinsic part of citizenship, public accountability and transparency.[55]

[54] See Department of Health, "Government's Response" at note 40.
[55] INVOLVE, "Involving the public in NHS, public health, and social care research: Briefing notes for researchers," accessed online 27/11/13 at

But under what particular theory of decision-making do these two arguments fall? In the case of the first argument, are we to evaluate the success of PPI through the lens of consequentialist or utilitarian theories, cost-effectiveness paradigms, or more rudimentary cost/benefit analyses? In the case of the democratic argument, are we to take it as a given that greater citizen involvement results in more democratic decision-making or is there a particular theory of democracy (participatory democracy, representative democracy, deliberative democracy, etc.) through which we can understand the effect of patient and public involvement on government decision-making and accountability?

As a result, the overarching approach of this thesis was to put forward what I saw as the *most credible and persuasive* argument from the perspective of PPI supporters and to map those arguments onto logical philosophical frameworks. So, for example, because many deliberative democrats discuss implementation of deliberative democracy with reference to the kind of mechanisms that are often used in various patient and public involvement schemes, I elected to analyze PPI through the lens of deliberative democracy. In the vast majority of cases that are cited throughout this thesis, supporters of PPI to not describe their democratic arguments with granular reference to a particular theory of democratic legitimacy. Therefore, in order to rigorously examine arguments that make an appeal to accountability and democracy, I analyzed those arguments through the claims made by deliberative democrats. This, to be sure, is an imperfect solution, but because citizen involvement is often treated as part and parcel of greater democratic accountability, we need a way in which to examine the mechanism by which PPI purports to further its espoused objectives.

<http://www.twocanassociates.co.uk/perch/resources/files/Briefing%20Note%20Final_dat(2).pdf>, at page 20.

1.6.2 Search Strategy

Determining what arguments to attribute to "PPI advocates" is a central challenge facing this thesis. In order to be sure that I had a robust understanding of what PPI supporters truly believed, I began my search with white papers, interest group policy papers, and pieces of legislation. Most of these white papers, policy papers, and pieces of legislation were UK-based both because the literature on patient and public involvement is UK-centred and in the few instances where I could find other European documents, they were in foreign languages. I focused on key pieces of legislation and parliamentary reports over the last ten to fifteen years[56] in the UK, since the legislation itself can be useful and it also provides an opportunity for public comment. I read comments from a variety of organizations, including patient advocacy groups and professional societies, as well as academics.

In addition, I also relied heavily on the academic literature to determine what supporters of patient and public involvement in an academic context were arguing. At the outset, I employed a wide search strategy, using the search terms "'Patient and Public Involvement' and health care" and combing through the first 250 articles through the search engine Google Scholar, organizing the search results by those that had been most heavily cited. By the time I reached the end of that literature review, it had become clear that novel arguments in support of PPI were not emerging and that most articles were either reiterating previous claims or not taking an explicit position on the desirability or viability of greater involvement.

[56] For example, the 2006-2007 House of Commons Health Committee Report on Patient and Public Involvement and the 2001 Health and Social Care Act.

1.7 Outline of the Argument

Now that I have established historical and policy context, identified the key normative questions, and explained my methodological approach, I turn now to a brief overview of the architecture of this thesis.

As many of my arguments about PPI proceed from the premise that PPI is a complicated set of related – but meaningfully different – activities, I begin in chapter 2 by surveying the literature on patient and public involvement in order to begin to construct a more nuanced picture of the category. My goal here is not to develop an encyclopedic entry for "patient and public involvement" but rather to isolate the ways in which different types of involvement raise different types of normative concerns. In this chapter, for example, I ask if patient and public involvement in research should be considered comparable to patient and public involvement in resource allocation. I also explore different "levels" of involvement and suggest that the degree of responsibility and authority granted to unelected lay members of the public also bears on the normative analysis.

After developing a more complete picture of PPI, I turn to address the first of the two main arguments leveled by its proponents. To some degree the outcome-focused justification rests on a very straightforward empirical analysis – whether strong evidence exists to support the idea that PPI improves health outcomes, the functioning of the health care system, etc. is thus in some sense crucial to the argument. But in another sense this justification invokes a series of assumptions about welfare and utility that I suggest hold limited value in certain areas of public health policy.

After concluding that focusing on outcomes proves insufficient, I turn to examine the democratic rights argument in chapters 4 and 5. In chapter 4, I begin by constructing a

historical and philosophical framework for understanding deliberative democracy. My goal here is not simply to review the basic tenets of deliberative democratic thinking, but to begin to explore the ways in which deliberative democracy could conceivably be used to support a broad-based policy of patient and public involvement. This analysis must begin, nonetheless, with a deconstruction of deliberative democratic philosophy and an examination of its procedural requirements: a focus on (1) reason-giving in decision-making, (2) accessible and publically available decisions, (3) binding decisions, and (4) revisable decisions.

Importantly, in this chapter I consider not merely why democratic deliberation is considered intrinsically valuable but also what the relationship is between deliberation and the legitimacy of the overall policymaking and implementation processes. Expanding the conversation to include a discussion of legitimacy is vital to the analysis here – doing so requires us to go a level deeper and ask what legitimacy and accountability should mean in an engaged liberal democracy. Too often, I maintain, PPI supporters speak in abstractions and generalities about "transparency," "accountability" and "legitimacy" without providing and specific account of what those ideals should mean in practice.

In chapter 5, I move to evaluate the strength of the relationship between patient and public involvement and those foundational deliberative democratic ideals. Rather than simply accepting on its face the idea that direct citizen participation produces a more legitimate policy-making process, I show that the links between patient and public involvement and transparency (publicity), reason-giving, and the accountability of the process writ large are more tenuous than we may initially have thought. Both theoretical and empirical analyses suggest that there are not particularly strong reasons to believe that

simply involving members of the public directly in decision-making will have a significant impact on these democratic ideals.

The crux of my argument, however, lies not merely in questioning the strength of this relationship but in determining if patient and public involvement can actually have a detrimental effect on accountable decision-making. Towards the end of chapter 5, I suggest that where lay members of the public are selected (and not elected), the individuals they ostensibly represent are left without the ability to either recall a representative who is not acting in the public interest or to appeal a decision that is believed to be unjust. I also look at the way in which patient and public involvement takes place in practice. Who is likely to participate? Put more specifically, who has the time and resources to participate, and to what extent should we deem those likely to participate as representative of the "general public interest"?

Still, at the end of the day, patient and public involvement remains not a philosophical theory, but a set of practices that are implemented daily in countries around the world. To that end, chapter 6 is interested in applying the theoretical arguments I have developed in chapters 2-5 to case studies of patient and public involvement from both the United States and the United Kingdom. As I have already noted, the examples in this chapter are intended to reflect the diversity of activities that fall under the umbrella of PPI: they vary in terms of the issue on which involvement is taking place (medical research vs. resource allocation; they reflect different philosophical conceptions of political and demographic representation; they vary in terms of scale and level of involvement (local/hospital, regional/state, federal/national); and, they concern involvement of different types (e.g. consultation, collaboration, delegation, etc.).

Two of the case studies look at patient and public involvement in medical research design while the other three consider involvement in decisions about resource allocation (one in biomedical research and the others in health care services). Perhaps more than anything, the examples in this chapter serve to underscore the most basic conclusion of chapter 2: PPI activities are unified by certain ideas and ideals, but the broad range of activities included under the heading raise a similarly broad spectrum of normative questions. Finally, the examples in this chapter highlight the fact that in practice, governments under public pressure to democratize the policy-making process have tended to use PPI as a tool to avoid taking more difficult but potentially impactful steps to foster a more accountable, transparent, and deliberative process.

Chapter 7 starts by reviewing the main conclusions of the thesis, before highlighting areas for future research. The argument up until chapter 7 will primarily constitute a critique of patient and public involvement, with little to say about how to improve accountability and transparency in the health policy formulation and implementation processes. Though I do ultimately conclude that patient and public involvement may do more harm than good *in certain contexts*, I do maintain that there are steps resource allocators and priority setters can take to foster greater transparency, accountability, and deliberative reasoning in the policymaking and implementation processes. Using the case studies of chapter 6 as a starting point, I suggest reforms that the subjects of those case studies could implement that would likely do more for transparency and accountability than the PPI-based reforms undertaken to this point. These reforms, to be sure, may generate political controversy; asking resource allocators (otherwise known as rationing bodies) to be open about the nature of their moral decision-making (e.g. how is the £ value placed on

a life determined?) is to pull back the curtain on a process that most citizens recognize as necessary but few wholeheartedly embrace. Nonetheless, if policymakers are to elevate the level of moral discourse in society, openness about moral decision-making is a pivotal first step.

Before beginning, it is worth emphasizing that this thesis does not constitute an answer to the question "is patient and public involvement a 'good' thing?" My goal here is not to disparage the (admirable) work of actively engaged citizens who simply want to have a greater say in the inner-workings of their government, particularly on an issue as personal and fundamental as health. What I hope to do instead is to show that in many instances, patient and public involvement may actually do very little to accomplish its own espoused objectives. Going forward, I can only hope that this analysis sparks conversations around the effectiveness of PPI and encourages citizens and their political representatives to pursue additional reforms that put the moral concerns of health care policy front and center in the public square.

2
The Landscape of Patient and Public Involvement

2.1 Introduction

Over the past few decades, "patient and public involvement" is a concept that has been invoked in a variety of policy contexts. As was noted in chapter 1 of this thesis, policymakers and activists have advocated for greater public engagement in research settings, resource allocation debates, and discussions more broadly about public health policy. In addition, involvement by patients and general members of the public has varied in a number of different ways – ways that I suggest are not just descriptively distinct, but normatively meaningful. As a result, it is important at the outset to disentangle (and to some extent, problematize) the concept of "patient and public involvement," as in reality, it stands to represent a diverse set of practices that have been advocated for across countries, regions, types of health care systems, and time.

One central goal of my work here is to contribute to the growing body of research on patient and public involvement, and to suggest ways in which that research might be refined going forward. To that end, this chapter serves not simply to provide a taxonomy of terms related to patient and public involvement, but rather to suggest that the phrase itself encompasses a complex range of ideas and concepts that should perhaps be considered in a more systematic way. In other words, my contention here is that in many respects, "patient and public involvement" is a phrase too cumbersome and all-encompassing to be meaningful as we engage in specific conversations about public involvement in health care (among other things). Very little work has been done in these questions of classification and conceptual mapping, much to the detriment of the quality of debate surrounding PPI.

Chapter 2. The Landscape of Patient and Public Involvement.

This chapter proceeds by examining the terms and ideas that are relevant to three main "axes" that structure the foundations of patient and public involvement: (1) the search nature of "involvement" and what it means; (2) an understanding of what constitutes "patients" or the "public" and why, conceptually, should we consider involvement by these two groups under the same philosophical umbrella?; and (3) the issues within health care which patients and members of the public might be involved (e.g. medical research, allocation of scarce resources, etc.). There may very well be other axes that are not considered here (e.g. the size/magnitude of the problem being discussed), but an understanding of these three is essential to unpacking the conglomerate concept that is "patient and public involvement."[57]

In many ways, how we are to respond to and evaluate the merits of patient and public involvement depends very much on the nature of that involvement, the individuals involved, and the type of issue that is at stake. Though I recognize that the various kinds of involvement explained below are unified, at the very least, by certain philosophical and practical features, I maintain that they are also sufficiently different so as to warrant different kinds of evaluations going forward.

[57] Note, for example, the following quote from the House of Commons Health Committee in its 2006-2007 report on Patient and Public Involvement: "Patient and public involvement often appears to be a nebulous and ill-defined concept, used as an umbrella term to cover a multiplicity of interactions that patients and the public have with the NHS. Discussion of patient and public involvement often focuses on institutions dedicated to securing and promoting involvement; however, in reality, patients and the public are involved in decisions about healthcare and health services at many different levels, ranging from input into individual decisions about their treatment to large scale consultations on the broad direction of national policy and health spending. Some patient involvement is spontaneous, some is systematic; some is well resourced, some depends on the goodwill of interested parties; mechanisms for involving patients and the public are as complex as the many interlacing structures that make up the NHS." See http://www.publications.parliament.uk/pa/cm200607/cmselect/cmhealth/278/278i.pdf

2.2 Patient and Public Involvement in the Clinical Context

Before continuing, I want to briefly note one important realm of patient and public involvement with which this dissertation is not concerned: the clinic. A prime example of the conglomerated concept problem I described above can be found in literature that describes the value of patient involvement in the clinical setting (regarding, for example, an individual's treatment and care) in the same breath as patient and public involvement at the level of the health care system. While I believe that the two are of course related (as I argue in the introductory chapter, PPI at the system level may well have grown philosophically out of the reaction against paternalism in the clinic), for the purposes of this discussion and debate, they are – and should be – considered distinct.

To be clear, this dissertation does not at all dispute the notion that in clinical contexts, patients should be maximally empowered to make decisions about their own care, in consultation with their physicians and other care providers. In that sense, my arguments against the universal implementation of PPI standards across health care systems and research institutions are not at all rooted in a defence of the medical paternalism that characterized most clinical encounters until the 1970's. Of course, the line between clinical involvement and health-system involvement can be blurry; undoubtedly, the decisions that affect patients in the clinical setting are affected by decisions made upstream, as it were, at the level of the health care system. Nonetheless, there are important differences between the two that should be recognized.

The most salient difference between patient involvement in the clinical setting and patient involvement in the health care system setting concerns notions of transparency, accountability, and scale. The reaction against paternalism that formed the bedrock of the

patient empowerment movement of the 1970's and 1980's was based on the idea that individuals should be able to make decisions for themselves about their *own* care. The idea that "the doctor knew better" was shunned in favor of autonomy, or the right of individuals to determine their own best course of action, even if it was not considered "best" by the expert medical establishment. In this way, the patient empowerment movement almost challenged the very notion that there was an objective "best," but at the very least it rejected the idea that if such a "best" did exist, it could be determined exclusively by those with technical medical expertise.

This underlying logic, however, does not hold when it comes to participation by the public or patients at the level of the health care system. Whereas we value patient autonomy in the clinic because that individual's – and *only* that individual's – interests are at stake, decisions about the health care system carry the potential to affect the health and well-being of all those who use health care services (which is to say, almost everyone). As a result, the concerns raised by PPI have more to do with political accountability and transparency and less to do with the power of medical experts to wield their badge of expertise over the population. Whereas in the case of the clinic, the only individuals are involved are those "in the room, so to speak, the same cannot be said of the case of the health care system as a whole. As a result, the context in which decisions about the allocation of scarce resources or medical research are made is substantively different from the context in which *individual* clinical decisions are made. Put simply, an endorsement of patient autonomy in the clinical setting does not imply endorsement of lay involvement in all components of the policy planning process as it pertains to health care.

2.3 Constructing the Taxonomy

I turn now to developing a broader and more nuanced conceptual understanding of patient and public involvement by disaggregating various components of PPI that, for the purposes of ethical reasoning, should be considered substantively different. I begin my analysis with an examination of the concept of "involvement, turn then to look at who "the public" and "patients" are, and finally look at PPI in different policy contexts (medical research, resource allocation, local vs. national level, etc.).

2.4 State of the Current Literature

This dissertation is not the first to at least raise the question of the heterogeneity of "patient and public involvement" as a concept. Numerous papers have addressed the need to chart a "conceptual map" or "conceptual framework"[58] with regard to PPI. And others have similarly suggested that the difference between types of involvement is complex and nuanced. As Boote et al. explain, "The boundaries between collaboration and consultation in particular are ambiguous, suggesting the need for tighter definitions. Drawing on work in the field of consumer involvement in service development, the conceptualisation of consumer involvement in health research appears to imply more than the notion of levels."[59] Byrt elaborates further in articulating the difference between different types of consumer involvement: "consumer involvement depends on the recognition that it is a complex multi-faceted phenomenon consisting of differences in degrees and levels, components, types and methods and modes of intervention. In addition, a variety of possible participants may be involved, and the amounts of openness, consciousness and

[58] S.R. Oliver, R.W. Rees, L. Clarke-Jones, and R. Milne, et al., "A multidimensional conceptual framework for analysing public involvement in health services research," *Health Expectations* 11, no. 2 (2008): 72-84.
[59] J. Boote, R. Telford, and C. Cooper, "Consumer involvement in health research: a review and research agenda," *Health Policy* 61, no. 2 (2002): 213-236, p. 229.

formality can vary."[60]

Though Boote et al. (among others) have taken the time to classify the various kinds of involvement and the different settings in which individuals might be involved, their analysis leaves important questions unanswered. My goal here is, in part, to generate a more comprehensive understanding of the elements that make up patient and public involvement, but in a broader sense, it is to explain the ways in which that understanding informs the normative analysis of involvement. "Conceptualizing involvement," as it were, may be provide us with an interesting taxonomy that problematizes the notion of involvement, but it will do little in terms of policy analysis if we fail to explain how that problematizing affects the ways in which we should understand or normatively evaluate involvement. For example, in what ways does the degree to which individuals are delegated authority in decision-making relate to notions of democratic accountability and the ability of citizens to recall unelected representatives? Does the nature of those questions around democratic accountability change substantially if the policy question at hand is at the local level versus the state/regional or national level? This chapter attempts to fill that gap within the literature.

2.5 Understanding "Involvement"

As I have already discussed, involvement can mean a variety of different things to different people. Some, for instance, consider the ways in which patients participate in the decisions about their own care "involvement"[61] while others take involvement to mean participation in decisions about medical research or health care that do not directly affect

[60] R. Byrt, "Empowering service users: a study of participation (unpublished PhD thesis). Loughborough University, Loughborough, 1994.
[61] See, for example, Halsted Holman and Kate Lorig, "Patients as partners in managing chronic illness," *British Medical Journal* 320 (2000): 526-527.

the individuals "involved." The goal of this section is to disentangle the notion of involvement, and to highlight the ways in which thinking about involvement in this disaggregated way might impact the normative analysis later in this dissertation.

This dissertation attempts to categorize and classify user involvement along the continuum of "levels" of involvement, ranging from low to high. This corresponds with much of the work that has been done by other scholars in the field who have relied heavily on Arnstein's "ladder of citizen participation" to guide thinking about the conceptualization of user involvement.[62] For Arnstein, there were essentially 8 levels of involvement that fell under 3 major subheadings: (1) manipulation and (2) therapy (non-participation); (3) informing, (4) consultation, and (5) placation (degrees of tokenism); and (6) partnership, (7) delegated power, and (8) citizen control (degrees of citizen power).[63] I choose to use this overarching paradigm of "levels" of user involvement because the degree to which lay individuals impact the eventual outcomes of research or the policy process can serve as a critical distinguishing factor between kinds of involvement. I proceed then, with an explication of the various types of user involvement, in increasing order of "influence" over the ultimate outcomes of the decision-making processes.

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[62] Arnstein's work on citizen participation was not originally restricted to understanding involvement in decisions about health care. Nonetheless, her work has been used as the standard against which other conceptualizations of citizen involvement are judged. See Sherry R. Arnstein, "A Ladder of Citizen Participation," at note 35. For a more thorough explanation of the ways in which later scholars of involvement in health care specifically have invoked and are in conversation with Arnstein, see Andrea Litva, Joanna Coast, Jenny Donovan, and John Eyles, et al., "'The Public is Too Subjective': Public Involvement at Different Levels of Health-Care Decision Making," *Social Science & Medicine*, 54, no. 12 (2002): 1825-1837; Jonathan Q. Tritter, "Revolution or Evolution: The Challenges of Conceptualizing Patient and Public Involvement in a Consumerist World," *Health Expectations*, 12, no. 3 (2009): 275-287; and Jonathan Q. Tritter and Alison McCallum, "The Snakes and Ladders of User Involvement: Moving Beyond Arnstein," *Health Expectations*, 76, no. 2 (2006): 156-168.

[63] Ibid (Arnstein).

2.5.1 Types of "Involvement"

2.5.1.1 Participation as a Research Subject

Many scholars fail to include participation as a research subject under the umbrella of user involvement, despite the fact that research subjects are intimately involved in the process of producing research. This ostensibly results from the fact that the justification for lay participation in research in this context is substantially different from the justification given for other types of involvement. Nonetheless, within the literature on PPI, members of the public are often described as "participating" in the process of research, which might mean a variety of different things. For the sake of clarity and specificity, when involvement is referring to individuals' participation in research as research subjects, I advocate that they be referred to "being a research subject" rather than "participation in research."

Naturally, this element of involvement is often left off of the spectrum because participation as a research subject does not raise the same normative issues as do those kinds of involvement that are likely to affect the outcome of decisions. Where individuals are acting as research subjects, the nature of our ethical concerns surrounds primarily notions of consent and autonomy – the only individual who stands to be potentially adversely affected by the participation is the research subject him/herself. In the majority of cases that are being discussed here, the primary normative questions surround notions of representativeness and accountability. For that reason, cases concerning participation by research subjects will not be considered as relevant to my analysis here.

2.5.1.2 "Consultation"

Consultation, in contrast, asks patients or members of the public for their views on a particular research or resource-use matter and then purports to use the outcomes of those interviews, focus group meetings, etc. to inform the ultimate decision-making process. For example, researchers intent on strengthening their patient-consent process might convene a panel of members of the public to elicit feedback on the readability and understandability of the form. Importantly, consultation cannot simply be an exercise in window dressing – feedback received from the consultative process must consequently be used in the ultimate process of decision-making or reform. Still, at the end of the day, ultimate authority for the final decision still rests with the policymakers (be they researchers or health care bureaucrats), though a failure to rely at least in part on the recommendations of the consulted public would require significant explanation.

Though consultation does empower citizens or "consumers" to take somewhat of an active role in the process of formulating research design or providing input into resource allocation decisions, it remains largely a role characterized by passivity. As Boote et al. note, "Consultations are often service-provider-led in the sense that consumers are asked to provide comments either to a fully developed research proposal, or to provide guidance on how the researchers' ideas may be developed into a programme of work. Therefore, in many consultations, consumers are often more passive in the research process, due to their role as a 'product-tester' of researchers' ideas and methodologies."[64]

[64] Boote, Telford, and Cooper, "Consumer involvement in health research: a review and research agenda," at note 59.

2.5.1.3 "Collaboration" or "Partnership" or "User-Led"

The next level up in the direction of greater consumer/patient influence is in the realm of "partnership" or "collaborative" designs in patient and public involvement. These iterations of PPI typically involve the "expert" (e.g. researcher, health-system bureaucrat, etc.) working in conjunction with members of the public from the very beginning. Though the experts may be more likely to be the originators of ideas, the process of policy formation and implementation is largely considered iterative and dynamic. There may still be some expectation that the experts bring their specific knowledge to bear, but the responsibility for the final decision is considered "shared" between these experts and lay members of the public.

2.5.1.4 Consumer-Driven

The last category of citizen participation envisions citizens as being the ones driving decision-making with experts being consulted only on matters that require certain technical or specialized knowledge. Truly consumer-driven policies (i.e. those where citizens are given *full* control over the outcomes of the process) are exceedingly rare in the realm of broader health policy, and exist in only small quantities in the realm of medical research.

In the area of consumer-driven research, consumers (including patients, survivors, and other members of the public) design, commission, and disseminate a particular piece of research, one which often has been failed to be considered scientifically important by the establishment medical community. These advocates will then use the results of their research to advocate for a particular change in policy or medical practice. In that sense, this research is sometimes considered tainted or biased by that medical community insofar as its very undertaking is motivated by a particular political or scientific agenda. In many cases,

these particular research topics are in the realm of "applied science" and attempt to bolster research on elements of living and dealing with a disease that are often neglected by the scientific community which typically places its focus on treatments and cures for illnesses.

Consumer-driven involvement is significantly less common in the realm of health policy or resource allocation, where decisions to involve the public have typically been made in more consultative contexts. In these areas, where impacts on the general public are (either in reality, or perceptually) more immediately felt, there is perhaps greater aversion to entrusting a significant amount of authority in a group of individuals that are not immediately or even indirectly accountable to the general public.

2.5.1.5 A Final Term – 'Engagement'

Though the aforementioned three categories encompass the broad range of activities generally discussed in the realm of "involvement," it is worth noting that at least one other term appears extremely frequently within the literature on PPI and therefore merits some attention: "engagement." Engagement is perhaps the paradigmatic example of a word that means entirely different things to entirely different people. In certain areas, so-called "community engagement activities" are examined, particularly in the realm of medical research in the developing world. In these settings, "engagement" refers to a process by which individuals within a particular community are consulted about culturally specific norms related to research and the consent process.[65] In other contexts, however,

[65] Though it is well outside the scope of this dissertation, community engagement in research in the developing world has been a major source of discussion and debate amongst bioethicists for the better part of the last 20 years. Though some of the challenges underlying research in the developing world overlap with those discussed here, the primary issues confronting researchers and policymakers are distinct. For example, may researchers studying public engagement in the developing world are concerned about the historical relationship between researchers and research subjects and the ways in which historical power dynamics have served to disempower developing country populations. Historically, much of the research conducted in developing countries did not

"engagement" is often used to describe a unidirectional transmission of information from experts to members of the public; in these settings, "engagement" consists largely of disseminating important information to individuals, patient advocacy groups, and others through information sessions and awareness raising activities. In this sense, the term "engagement" is meant to imply that the "experts," so to speak, are *engaging* the public by providing them additional information, despite the fact that their input is not sought.

I digress here only briefly since the term engagement is highly prevalent throughout the literature on PPI, but there is not a generally agreed upon consensus as to whether "engagement" is passive or active. As a result, I will seek to avoid invoking the notion of engagement in such an amorphous way throughout the course of this dissertation.

2.6 Understanding Who is Involved

With a general understanding of the types of involvement discussed within the literature on PPI now in mind, I turn now to a discussion of "who" is involved, and why advocates of involvement are interested in the roles of both "patients" and members of the "public." An understanding of why certain individuals should be involved (i.e. they add an independent perspective, or contribute value from their personal experience) holds the potential to impact my analysis. If, for example, the impetus for involvement derives from

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directly benefit the inhabitants of those countries, and the legacy of those research efforts still reverberates through conversations within the literature about the proper relationship between researchers and research subjects today. Those issues are not completely absent in the developed world, but they are far less prevalent and salient. As a result, I have elected to focus the analysis in this thesis on PPI in the developed world. For a discussion of community engagement in health research in the developing world, see P. Tindana, J. Singh, C.S. Tracy, R.E.G. Upshur, A.S. Daar, P.A. Singer, J. Frohlich, and J.V. Lavery, "Grand Challenges in Global Health: Community Engagement in Research in Developing Countries, *PLOS Medicine* 4, no. 9 (2007): e273; E.J. Emanuel, D. Wendler, J. Killen, and C. Grady, "What Makes Clinical Research in Developing Countries Ethical? The Benchmarks of Ethical Research, *Journal of Infectious Diseases* 189, no. 5 (2004): 930-937; and S.W. Glickman, J.G. McHutchison, and E.D. Peterson et al., "Ethical and Scientific Implications of the Globalization of Clinical Research," *New England Journal of Medicine* 360 (2009): 816-823.

a consequence-based argument that involvement produces "better" (i.e. more responsive, patient-focused) research, my analysis will be substantially different than if the argument derives from a rights-based theory about democratic participation and the value of an engaged citizenry.

2.6.1 Patients and "The Public"

Developing the taxonomy in this section requires significantly less effort than in the realm of involvement, where the term is sufficiently vague as to provide little helpful guidance or constraints. After all, it should seem clear that the "Patient and Public" in "Patient and Public Involvement" refers in the first case to patients suffering from a particular condition and in the second, to members of the general public who are considered "lay" or "non-expert." Precisely why we might value the participation of so-called "non-experts" is a question I will explore in greater detail.

First, it seems noteworthy that in the realm of medical research, "patients" refers not to "any patient currently within the health care system" or "any *potential* patient," but rather to those who have the specific condition about which research is currently being conducted." I take this to be the case because were it not, there would be no meaningful substantive distinction between "patients" and "the public." Though in some instances, researchers might seek the input of the general public when it comes to general consent procedures or research protocols, more often they seek (or are instructed to seek) the input of those suffering from the disease in order to gain insight into the kinds of questions that patients themselves want researched.[66]

[66] J. Francisca Caron-Flinterman, Jacqueline E.W. Broerse and Joske F.G. Bunders, "The experiential knowledge of patients: a new resource for biomedical research?" *Social Science and Medicine* 60, no. 11 (2005): 2575-2584.

This, of course, is not the case with regard to issues of health care policy or resource allocation where all individuals are plausibly affected by the decisions that are made as to how to allocate resources or structure health services, even if not immediately. But it is worth emphasizing the fact that in involving the public (as opposed to patients), practitioners of PPI are ostensibly interested in furthering at least one of two aims: (1) enforcing a perceived "democratic right"; or (2) bringing what are believed to be impartial or independent observers to a process that is largely dominated by stakeholders whose expertise predisposes them towards taking a particular kind of opinion. In this sense, the reasons for involving members of the lay public appear to be not just different, but *fundamentally opposite* to the reasons for involving individual patients. Patients, at least in theory, are brought in *because* of their particular experiences with disease whereas members of the public are brought in precisely because they are believed to have unbiased opinions. This, conversely, is why we rarely see efforts to involve "patients" in the policy formulation process as it concerns broader issues concerning resource allocation. Those patients, because of their attachment to their particular illnesses and conditions, are presumably not as likely to bring the same objectivity or independence to the process as is the unattached, unbiased, and dispassionate lay public observer.

For this reason, I argue, the term "patient and public involvement" begins to lose its meaning as a cohesive term. In practice, of course, there is little evidence to suggest that these (the unbiased, detached ones) are the individuals who are actually selected for various types of involvement as it concerns health care policy or resource allocation. Indeed, one of my primary objections later in this dissertation is directly to the concept that the individuals who end up involved are representative in any meaningful way of "Joe Public"

or that they are independent, dispassionate observers, as the theory would lead us to believe. But for now, my focus is merely on elucidating the differences between patient involvement and public involvement.

2.7 On What Issues Is Involvement Taking Place?

Scholars previously have dealt, at least to some extent, with some of the considerations that I have outlined above. Since Arnstein's well-studied "ladder" of user involvement, others have devoted significant attention to the nature of – or level of – involvement.[67] Significantly less – but still some – scholarship has addressed the differences between patient involvement and public involvement. And yet, both scholars and practitioners have left the question of "involvement on what" largely unexamined. This section seeks to fill that gap by exploring the various types of issues around which involvement generally takes place, and to highlight the ways in which the diversity of issues has implications for the ethical analysis undertaken here.

2.7.1 Medical Research

Though no formal data exist on the matter, the size and scope of the literature on patient involvement in medical research suggest that involvement in medical or health services research is more common than involvement in any type of public policy or health care resource allocation efforts. But, just as is the case with "patient and public involvement," "medical research" is also a term that needs to be disentangled and disaggregated. According to a handbook for researchers published by INVOLVE, researchers have involved patients in any number of the following: identifying topics, prioritizing, commissioning, designing research, managing research, undertaking research,

[67] See Tritter, "The Snakes and Ladders of User Involvement" at note 62; and Peter Beresford, "User Involvement in Research and Evaluation: Liberation of Regulation," *Social Policy and Society* 1, no. 2 (2002): 95-105.

analyzing and interpreting, disseminating, and evaluating.[68] INVOLVE goes on to note that the means by which researchers can engage and have engaged individuals in research include "surveys, inviting people to an event to 'thought shower' ideas, workshops or focus groups, outreach work, taped interviews, peer group interviews, and work with independent facilitators."[69] In short, it is difficult – if not impossible – to boil down involvement in medical research to a narrowly defined set of activities or issues.

When considering the implications of how involvement takes place in the realm of medical research, it is important to consider the underlying motivations for the involvement. As I have already noted, involvement is – at least in theory – to some extent a means of assuring political accountability, but more often discussed as a way to improve research.[70] Supporters of this approach maintain that researchers often narrow the scope of their inquiry to highly technical or academic questions without paying sufficient attention to the needs of individuals who are themselves afflicted with a condition or disease; on this account, involving those individuals facilitates the refining and reorienting of the research agenda around questions that hold more relevance for public health and medicine.

Of course, an entirely separate conversation need take place about what constitutes "better" research in the first place. For some, better research may mean that the research is more ethically sound (e.g. has a more robust and readily understandable consent process)

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[68] INVOLVE, "Involving the public in NHS, public health, and social care research: Briefing notes for researchers," accessed online 27/11/13 at <http://www.twocanassociates.co.uk/perch/resources/files/Briefing%20Note%20Final_dat(2).pdf>, at page 20.

[69] Ibid.

[70] V.A. Entwistle, M.J. Renfrew, S. Yearley, J. Forrester, and T. Lamont, "Lay Perspectives: Advantages for Health Research," *British Medical Journal* 316 (1998): 463-466.

while for others, "better" means that the research "more relevant and thus more likely to influence practice and improve health in ways seen as important by service users."[71]

This point bears emphasis since the nature of my objections (or support) for various kinds of involvement hinges not just on the process of involvement itself, but on the underlying motivation for involving in the first place. Consider, for instance, two different PPI projects that vary in neither who is involved nor the "level" at which they are involved, but only in terms of the issue on which they are being involved: one in which the involvement is meant to address consent-issues in research, and the other which is seeking to refine the content of research to render it more relevant to patients and the public. While the two vary not at all in terms of the *process* of involvement, their underlying motivations are substantially different. In the first case, the involvement is used as a means to foster better protection of research subjects while in the second the involvement seeks to change the very structure of research, shifting authority for content-decisions from researchers towards the "lay" public. Even if we were to raise no objections to the idea of involvement, we *might* be concerned with the latter's insistence that the lay public claim a right to insert themselves into a process that requires a high level of technical expertise. Though this particular scenario remains hypothetical, it highlights the fact that both the way in which involvement proceeds *and* what it is motivated by are both relevant in the final philosophical analysis.

2.7.2 Health Services, Health Policy, and Resource Allocation

Though involvement in medical research is much more common than involvement in matters of health services, health policy, or resource allocation, involvement in these

[71] S.R. Oliver, R.W. Rees, L. Clarke-Jones, and R. Milne, et al., "A multidimensional conceptual framework for analysing public involvement in health services research" at note 58.

fields remains a significant matter. When it comes to these larger policy and health services matters, it is conceptually useful to conceive of involvement as existing along two major axes: the type of issue, and the magnitude/scope of the issue (i.e. how many people does the decision at hand affect).

The work of committees, citizens' juries, and other deliberative groups has spanned across a range of health care services and resource allocation issues in terms of both issue content and magnitude. A citizens' jury,[72] for example, was convened in Belfast in the late 1990's in order to gain public input into decisions that were being made concerning the restructuring of primary health care services in Northern Ireland. The British National Health Service used an even larger scale deliberative process in 2000 to influence the direction of policy-making at the NHS at the turn of the century. In that context, patient and public involvement was more informal and less rigorously consistent with the principles of deliberative democracy discussed later in this dissertation, but tens of thousands of citizens provided input into the process over the course of several months.[73] And finally, in Oregon, when a decision was made to expand access to Medicaid (U.S. health care for the poor and disabled), dozens of public meetings were convened at which

[72] A "citizens' jury" is a mechanism of participatory deliberative democracy intended to resemble, in certain respects, an actual jury. Citizens' juries can be convened for different types of policy discussions and deliberations, but typically share at least three main features in common: (1) jurors are selected randomly from a local, regional, or national population; (2) jurors are not experts themselves, but have the authority to call expert "witnesses" to testify about the policy issue at hand; and (3) the process is almost always advisory. The jury is overseen by a policy-making committee or panel that has the ultimate authority to make a final decision in terms of policy. For more information on citizens' juries and their role in deliberative democracy (and in particular with regard to health care), see Susan Pickard, "Citizenship and Consumerism in Health Care: A Critique of Citizens' Juries," *Social Policy and Administration* 32, no. 3 (1998): 226-244.
[73] Parkinson, *Deliberating in the Real World*, 15.

public input was sought in terms of how to make rationing decisions.[74] Though the public here was not involved in the minutia of whether to approve one individual treatment over another, there is evidence to suggest that the committee with final decision-making authority eventually took their contributions into account.

But decision about resource allocation need not – and indeed rarely do – occur at the national level. In some sense, empirical evidence suggests that there is somewhat of an inverse relationship between the level of involvement (i.e. degree of influence over the eventual policy outcome) and the scale of the project (i.e. number of people ultimately affected). That is to say, where efforts to involve patients and members of the public occur on a larger scale, patients appear to have more "recommending power" and less ultimate influence over the final decision.

At the local level, studies suggest that patients are less likely to be involved in so-called "meta-decisions" about resource allocation, and more likely to be engaged in discussions over how to make health care services delivery more responsive to the needs of the patient/consumer. For example, in their meta-analysis of patient and public involvement in health services, Crawford et al. found that of the studies reviewed, "the most frequently reported effects of involving patients was the production of new or improved sources of information for patients. Other changes included efforts to make services more accessible through simplifying appointment procedures, extending opening

[74] For more information on the experiment with Medicaid funding rationing decisions in Oregon, see Leonard M. Fleck, "Just Caring: Oregon, Health Care Rationing, and Informed Democratic Deliberation," *Journal of Medicine and Philosophy* 19, no. 4 (1994): 367-388.

times, improving transport to treatment units, and improving access for people with disabilities."[75]

2.8 Objecting to Patient and Public Involvement

As I stated earlier, I am interested not just in disaggregating the concept of patient and public involvement for clarity's sake, but also because that disaggregation enables me to be more precise about the nature of my philosophical concerns. To that end, I move now towards trying to understand the ways in which this disaggregation clarifies – or rather, problematizes – my philosophical analysis.

2.8.1 Based on Type of Involvement

On its own, whether the individuals are involved are at a "high" or "low," level, so to speak, does not give us immediate insight into whether a type of PPI ought to be considered justifiable. Involvement that vests significant decision-making authority in the hands of the lay public may very well be considered justified, while involvement with only recommending influence may raise certain problematic questions, dependent on the relationship between the decision-makers and those affected, the type of issue, and the magnitude of the decision at hand. The fact that the level of involvement does not provide immediate insight into how to normatively examine a particular kind of involvement should shift our attention to other relevant variables.

2.8.2 Based on Who is Involved

I have already spent significant time outlining the ways in which patient involvement and public involvement differ from the perspective of normative analysis. Nonetheless, it is worth emphasizing that the critical distinction is not so much in the

[75] M.J. Crawford, D. Rutter, C. Manley, T. Weaver, K. Bhui, N. Fulop, and P. Tyrer, "Systematic Review of Involving Patients in the Planning and Development of Health Care," *British Medical Journal* 325 (2002): 1263.

character or capacity of the individuals themselves but in the *underlying motivation* for involving them in the first place. I argued previously that patient involvement is often sought precisely because patients can bring their own experiences to bear while, at least in theory, public input is sought because the public can bring a "lay expertise" that is detached from the biases that most of the other stakeholders would likely bring to the table. The question of who is involved raises (at least) two sets of normative considerations.

The first concern here is one of moral and political accountability. How, in other words, are the individuals involved in the process representative – either descriptively, politically, or morally – of the individuals outside of the process? It might be arguable, in one sense, that the group "patients" coheres to form a more cohesive and representable group than "the public" which comes with an even more diverse and less unified set of personal experiences. Though patients are not in any general sense less diverse than the population more broadly, because most patient involvement takes place around a particular condition or disease, the patients are at least unified by a critically important variable. The same, of course, cannot be said for involving members of the general public. In either case, my goal here is not so much to articulate precisely whether one group's involvement should be considered more legitimate than another's, but simply to show that the question of accountability should be taken seriously in debates about patient and public involvement. And that question of accountability is inextricably linked to understanding both who is involved and why they were chosen to be involved in the first place.

The second set of normative questions raised by the issue of who is involved concerns the notion of lay expertise. Those who advocate for a greater emphasis on lay expertise in policy-making understand the production of scientific knowledge as a more

diffuse, less technocratic enterprise. For them, expertise in the realm of science (defined broadly to include advances in medical research, clinical treatments, and the structure of health care deliver) exists across society and not merely amongst those with highly specialized scientific backgrounds. A particularly strong version of this argument is articulated by Steven Epstein, as part of his seminal research on the AIDS movements of the 1980's claims:

> "The arena of fact making encompasses not just immunologists, virologists, molecular biologists, epidemiologists, physicians, and federal health authorities…it also encompasses a strong and internally differentiated activist movement…this case demonstrates that activist movements, through amassing different forms of credibility, can in certain circumstances become genuine participants in the construction of scientific knowledge –…This surprising result is, of course, at variance with the popular notion of science as a relatively autonomous arena with high barriers to entry."[76]

But this vision articulated by Epstein is not a morally neutral sociological reality. Whether or not we choose to conceive of scientific knowledge in the realm of health care as specialized and, as Epstein notes, "relatively autonomous," has ethical implications for the structure of our health care systems. This dissertation will investigate these implications in greater detail, cognizant of the fact that this democratization of expertise could have significant theoretical and practical ramifications.

2.9 Issues Under Debate

Much like the level of involvement, the issue on which individuals are being involved is not, in and of itself, normatively determinative, but must rather be understood in context. Given my discussion earlier around these various issues, we might consider involvement as taking place under one of three main categories: medical research, resource

[76] Steven Epstein, "The Construction of Lay Expertise: AIDS Activism and the Forging of Credibility in the Reform of Clinical Trials," *Science, Technology, & Human Values* 20, no. 4 (1995): 408-437, at 409.

allocation, and health services. For many of the same reasons discussed above in relation to the difference between patient involvement and public involvement, involvement in the decisions about medical research raises fewer normative considerations since it does not invoke questions of political or moral accountability. Decisions about resource allocation and health services administration, insofar as they involve the spending of public funds, raise larger questions regarding the relationship of the individuals involved and the broader population for whom they are ostensibly providing representation. As such, my focus later in this dissertation will primarily be on involvement in the context of resource allocation (in both health care generally and medical research budgeting).

2.10 How Do We Know Where Activities Fall?

Though I have just outlined a broad theoretical spectrum of involvement, – ranging from purely consultative to truly consumer/patient-driven – in practice, trying to place any specific activity neatly in a single box proves challenging. As I have argued, my concern with the justifiability of a particular kind of patient and public involvement varies based on the type of involvement, who is being involved, the issue on which involvement is taking place, and the number of individuals affected by the policy change.

But insofar as this chapter sought to conceptually clarify and some of the distinctions between various types of involvement, the implications for the normative analysis are by no means clear-cut. We cannot, for example, simply construct a three-dimensional map of the aforementioned three axes and draw straight lines to distinguish justifiable and non-justifiable actions. My goal here instead was to highlight the spectra along which patient and public involvement takes place and to show the ways in which certain kinds of involvement raise normative questions in ways that other kinds do not.

2.11 Conclusion

This chapter sought – somewhat paradoxically – to both clarify the contours of my analysis while simultaneously problematizing the notion of patient and public involvement as a coherent, unified entity. The problem, of course, is not simply that patient and public involvement encompasses a wide range of activities, many of which have little common with each other, but rather that the differences between them are significant in the context of the philosophical analysis of this dissertation.

This effort to problematize the notion of patient and public involvement does not, however, mean that the term is *so* disunified as to render it entirely meaningless. Decisions as to whether a certain kind of involvement (based on the level, individuals involved, and issue at stake) is justified will undoubtedly need to be made on an individual basis. Nonetheless, underlying substantively distinct efforts to increase patient and public involvement are similar motivations: a desire to improve the quality and "responsiveness" of medical research and a belief that where public funds are being spent on something as basic as health care that the public has an inherent democratic right to be actively involved in directly making decisions about how those funds are disbursed.

Though supporters of PPI have largely pushed for broad based agendas to elevate the role of patients and members of the public in decisions about both medical research and resource allocation, I argue that when undertaking such broad endeavours, policy-makers do a disservice to the nuance in this debate. As I argued earlier, for example, the reasons for involving members of the public as opposed to patients are not just different, but *fundamentally opposed* to one another. As a result, in both conversations about PPI and

policy-making around it, greater attention need be paid to the ways in which types of involvement are similar, and importantly, to the substantive ways in which they differ.

Finally, before continuing, it is important to note that for the purposes of this dissertation, I will understand patient and public involvement in generally broad terms, including consultative and delegative actions in medical research, resource allocation, and general health policy settings. Engaging with PPI as a concept in this broad way will enable us to draw broader conclusions about the overall usefulness of the different justifications that have been put forward.

3
PPI and Health Outcomes

3.1 Introduction

The central issue this chapter addresses originates from one of the two overarching justifications for patient and public involvement: put simply, that such involvement improves the quality, relevance, and impact of medical research and broader public health policy decisions. Whereas this thesis has been and will be more concerned with addressing philosophical arguments – both moral and political – underlying greater public participation in policymaking, the most obvious argument in favor of greater patient and public involvement is this very simple, cost/benefit-oriented argument. If involvement creates better care and/or better research at very little cost, should that not be justification enough? If the goal of the health care system is to provide excellent care for patients while fostering medical and pharmaceutical innovation in research, why can we not simply use standard health metrics to understand whether or not PPI has been effective in achieving its goal?

Fundamentally, my argument in this chapter is that outcomes-based arguments only take us so far. Because a focus on outcomes presupposes that there are a set of outcomes that we can all agree take precedence and should be maximized, they fail to ask the prior question of what outcomes society considers most important. This is particularly true in the realm of resource allocation where priority setting bodies often face mutually exclusive choices between options that both are good for the public health but might maximize two different kinds of outcomes. It is difficult, therefore, for us to judge whether PPI "improves health" insofar as we need to have agreement on what it means to improve health in the first place.

Chapter 3. PPI and Health Outcomes.

This chapter proceeds in two main sections. First, I examine in greater detail the arguments that are made about outcomes from the perspective of PPI supporters. Though some of the "outcomes" deal with better accountability and transparency, this chapter will focus on the argument that PPI improves the health, the quality, and the responsiveness of both medical research and the health care system. Second, I put forward an argument against the notion that an outcomes-centred framework can reasonably answer the question of whether or not to pursue PPI-based policies. I then distinguish between the usefulness of outcomes-centred frameworks in medical research and priority-setting and suggest that an evaluation of the "democratic justification" for PPI needs to be evaluated as well.

3.1.1 A Note on Methodology

It should be emphasized that this chapter is much more concerned with policy than it is with philosophy. At certain points, I will make reference to certain consequentialist or utilitarian theories, but it is vital that we locate arguments about PPI from PPI advocates within a *policy* framework more than a *philosophical* framework. In that sense, the goal of this thesis is not really philosophical – that is to say, I do not intend to reach broad conclusions about the justness of utilitarianism or consequentialism. Instead, my aim is to ask whether the arguments that *PPI advocates make themselves* make sense in a policy framework and to examine how those arguments apply to the ways in which PPI works in practice. Asking that question may lead us to the underlying frameworks supporting those arguments, but we will not delve into the details of consequentialist or utilitarian theory in any truly significant way.

3.2 What are the arguments from PPI's advocates?

Part of the challenge with using an outcome-based framework to evaluate the "effectiveness" of PPI is, I will argue, a real uncertainty about what kinds of outcomes we are trying to maximize. As we will see (and have seen already in chapter 2), many supporters of PPI argue that involvement will increase the "quality" of health services or the "responsiveness" of the health care system. But what exactly this means, how we should measure it, and which of these outcomes should be prioritized over others where scarce resources are involved remains murky. This, I contend, is the central problem with using an outcomes-based framework to determine whether or not to support policies of patient and public involvement.

3.2.1 Argument #1: PPI makes research and health care "better" or "more relevant" or "of higher quality"

Perhaps the most common argument brought forward in support of PPI is the (relatively straightforward) and, admittedly, facially logical claim that when individuals are involved in making decisions either about research or about the functioning of the health care system, that the research or the system will be "better" or "more responsive" to the needs of the general public.

Consider, for example, England's Chief Medical Officer, Dame Sally Davies, who in talking about the value of patient and public involvement remarked that patient contributions to research design "*invariably* makes studies more effective, more credible and often more cost efficient" [emphasis added].[77] And INVOLVE contends that patient involvement is responsible for "ensuring high quality, relevant research" by "helping to ensure that research uses outcomes that are important to the public," "suggesting ideas for

[77] Staley, *Exploring Impact*, at note 1.

new research areas," "ensuring research is focused on the public's interests and concerns and that money and resources are used efficiently" and "helping to reshape and clarify the research."[78]

It is worth pausing at this point to also review several of the arguments that emerged out of stakeholder policy papers and other government white papers from Chapter 2. Recall that the Ministry of Health, in its 2007 report to the House of Commons argued that PPI had "two main purposes": "improving the design and provision of services and increasing accountability."[79] INVOLVE, in a policy paper on the virtues of involvement, spells out in greater detail the particular ways in which citizen involvement can make the research or the public health decisions "better":

> Members of the public might have personal knowledge and experience of your research topic or be able to provide a more general perspective. Even if you are an expert in your field, your knowledge and experience will be different to the experience of someone who is using the service or living with a health condition. Improving the quality of the research. This might be by:
> - making the language and content of information provided more appropriate and accessible (for example in questionnaires, and patient/participant information leaflets)
> - helping to ensure that the methods proposed for the study are acceptable and sensitive to the situations of potential research participants
> - helping to ensure that research uses outcomes that are important to the public
> - increasing participation in research through:
>   - making the research more appropriate and acceptable to potential participants
>   - improving the information provided so people can make informed choices
>   - helping to include seldom heard groups[80]

Consider, also, the questions posed by one set of researchers in this landmark meta-analysis of the effectiveness of PPI published in the *British Medical Journal*:

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[78] INVOLVE, "Briefing Note Three: Why involve members of the public in research?" accessed 26 May 2014, <http://www.invo.org.uk/posttyperesource/why-should-members-of-the-public-be-involved-in-research/>.
[79] See Ministry of Health at note ___.
[80] See INVOLVE at note 78.

> Over the past 20 years, governments throughout western Europe and North America have encouraged patients to contribute to the planning and development of health services. In England and Wales the involvement of patients is central to current efforts to improve the quality of health care. Underlying these changes is the belief that involving patients leads to more accessible and acceptable services and improves the health and quality of life of patients This view is endorsed by government policy, which states that involving patients leads to 'more responsive services and better outcomes of care.'… Involving patients is becoming less discretionary and more compulsory for the providers of services, but engaging patients is not an easy task, and no consensus on which methods are most effective under different circumstances exists.[81]

It would be a mistake, of course, to draw too many generalizations about the state of the literature from just one sample, but the framing here is representative of a noticeable trend within the literature: to begin with the starting point that PPI is a good that simply needs to be refined and harnessed in the right way.

Perhaps some of the reason why the literature has largely focused on how to make PPI more effective as opposed to whether or not to involve in the first place has to do with the overwhelming trend – both cultural and legal – towards greater involvement. As I discussed in chapters 1 and 2, since the 1990's, there has been a cultural push in Europe (and particularly in the UK) towards greater involvement. Some of that cultural momentum towards greater participation and involvement has been accompanied by legal changes that, in some instances, have made patient and public involvement compulsory. Notably, the *Health and Social Care Act*, passed by the UK parliament in 2001, made it a legal requirement for NHS-funded institutions to involve patients and members of the public in the process of developing and implementing policies around research and resource

[81] Crawford, Rutter, and Manley, et al., "Systematic review of involving patients in the planning and development of health care," at note 75.

allocation.[82] Though the U.K. has undoubtedly been a leader in pushing the agenda for greater public involvement, similar legislation has been passed in other European countries as well.[83] As a result, it may very well be the case that the literature is largely responding to what has become, in effect, a requirement in many major health systems. With that said, we should be wary of accepting cultural or legal trends as sufficient justification for the justness of the policy in the first place.

Interestingly, the language used to discuss PPI in research is relatively similar to the language used to discuss PPI in the realm of public health policy planning. Supporters want research and public health decision-making that is "responsive" to the needs of the general public and that decisions produce research and a health system that produces health outcomes that are important to the general public. There is a general belief underlying the arguments here (as well as several others cited in chapter 2) that technocrats and scientists believe they know what's best for the public but that that belief is often not aligned with the actual desires or needs of the general public. It stands to reason, then, that consulting members of the public will improve the responsiveness and therefore the quality of both the health care system generally as well as the system of medical research and pharmaceutical innovation within.

My primary contention going forward will be that these types of arguments take for granted the notion that there is a unified set of outcomes that members of the public agree should be maximized. At the margins, there are certain things that very well may fall in that category – mortality morbidity, pain reduction, etc. But where resources are

[82] Rudolf Forster and Jonathan Gabe, "Voice or Choice? Patient and Public Involvement in the National Health Service in England under New Labour," *International Journal of Health Services* 38, no. 2 (2008): 333-356.
[83] Crawford, et al., "Systematic review of involving patients in the planning and development of health care" at note 75.

constrained and values need to be weighed against one another, deciding whether or not PPI was "successful" begs a prior question about which values should be prioritized when two more of them conflict. We will return to this argument in greater detail later in this chapter.

3.2.2 Argument #2: PPI creates greater accountability and transparency

The second main "outcomes" based argument for PPI deals not with health outcomes but with democratic outcomes. In many cases, supporters of PPI contend that involving members of the public either in decisions about research or in those about public health will create a more transparent and accountable government.

Consider, for example, the 2007 Ministry of Health Report which argued that patient and public involvement would improve the quality of health research. It also went further in stating that the "the ultimate purpose of user and public involvement is the delivery of improved services, which better meet the needs and wants of service users" and that the desirable outcome of PPI was to foster a culture of "transparency and accountability for the multi-million pounds being spent at the local level."[84] Alternatively, we can recall the arguments of the British Medical Association, which argued: "Simply put, there is a democratic deficit. It should be a fundamental tenet of organisations that those paying for a service and those affected by it have a right to be engaged in its design and development. One problem with public involvement is that it is, at present, too often merely placatory."[85] Finally, the World Health Organization report that was examined in chapter 2 went even further, citing a 2000 Council of Europe declaration that characterized public involvement in health care priority setting as a fundamental democratic right:

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[84] Ibid.

[85] British Medical Association, "Evidence submitted by the British Medical Association's Patient Liaison Group (PPI 148)" at note 41.

> In the year 2000, The Council of Europe declared that the right of the public to be involved in the decision-making processes affecting health care is a basic and essential part of any democratic society. This democratic right is echoed in government reports, legislation and in statements from patient and citizen groups. Setting (research) priorities affects the use of limited public resources, and research demonstrates that values and ethical considerations play a role in recommendations on, for example, guideline development. Therefore, societal values should be considered and decisions should be informed by input from patients and citizens since they are affected by the decisions.[86]

Measuring abstract concepts like "transparency" and "accountability" is of course a task far more complicated than measuring standard health outcomes like mortality, QALYs, DALYs, etc. In many ways, as we have seen, the arguments from supporters of PPI can be characterized in these two ways: those that appeal to notions of "relevance" and "quality" and "responsiveness" and those that appeal to democratic principles like transparency and accountability. While in certain cases those latter ideals are characterized as "outcomes," we will not consider them as part of the "outcomes-based arguments" that are being evaluated here. For the purposes of this chapter, we will be evaluating the first argument around health outcomes as the primary component of the "outcomes-centred" framework insofar as those arguments around transparency and accountability will be evaluated as part of our larger examination of PPI in the context of deliberative democracy.

3.3 Why Focusing on Outcomes is Insufficient

With a more robust understanding of what is meant by "outcomes" in the realm of PPI, we return now to the question with which this chapter opened: if we can demonstrate that PPI improves health outcomes, why is that not justification enough to pursue it is a policy? My central contentions in this section are two-fold. First, I explain more fully the argument that has been a thread throughout this chapter: outcome-based frameworks

[86] Council of Europe Committee of Ministers, "Recommendation No. R (2000)," at note 37.

presuppose common agreement on what values and outcomes matter, an assumption that I will show runs into serious problems, particularly in debates about how to prioritise health care spending. Secondly, I argue that focusing on outcomes in the realm of medical research raises substantively different issues that focusing on outcomes where priority setting is concerned. Focusing on outcomes is naturally – and rightly – a part of any policy formulation, development, and analysis. But understanding where agreement on outcomes is most likely can help us focus the debate on PPI to a narrower subset of activities.

3.3.1 Defining and Weighing "Outcomes" in Health Care

The first challenge confronting outcome-centred frameworks in health care is the question of how to define, measure, and weigh "outcomes." In the paper cited earlier in this chapter,[87] the authors espoused a particular concern with the "effectiveness" of PPI. But what appears to be missing from the aforementioned review (and from many others[88]) is a robust discussion concerning how we are to measure "effectiveness," "quality," or "welfare" in the first place. Is the system effective simply if patients are satisfied? If patients *feel* that the health system is responding to them and their particular needs? Should our evaluation of the quality of the health care system include a discussion about whether patients feel as if they are being regularly consulted on important matters of policy? And

[87] See Crawford et al., at note 72.

[88] The general mentality that patient and public involvement is a necessary good that simply needs to be harnessed in the right way is present elsewhere in the literature as well. See, for example, the discussion in L. Tait and H. Lester, "Encouraging user involvement in mental health services," *Advances in Psychiatric Treatment* 11, no. 3 (Apr 2005): 168-175; D. Stewart, R. Wilson, P. Selby, and J. Darbyshire, "Patient and public involvement," *Annals of Oncology* 22, suppl. 7 (2011): vii54-vii56; Julia Abelson, Mita Giacomini, Pascale Lehoux, and Francois-Pierre Gauvin, "Bringing 'the public' into health technology assessment and coverage policy decisions: From principles to practice," *Health Policy* 82, no. 1 (2007) 37-50; and Sabrina McCormick, Julia Brody, Phil Brown, and Ruth Polk, "Public Involvement in Breast Cancer Research: An Analysis and Model for Future Research," *Health Care Sciences & Services* 34, no. 4 (2004): 625-646.

how, in the realm of medical research, are we to determine if patients are "making the research better"?

In many ways, the answers to some of these questions seem simple. Yes, most would argue, the "effectiveness" or "quality" of the health care system should, at least to some extent, be judged on whether or not it is responsive to the needs of its primary consumers. And, perhaps where involving members of the public in key decisions imposes little cost on the health care system and where the definition of "effectiveness" or "quality" is clear, there may very well be sufficient reason to involve members of the public. But it is my contention that in the majority of cases – particularly those surrounding resource allocation – a definition of what constitutes "effectiveness" or "welfare" or "utility" is *itself* the subject of debate and deliberation.

Consider, for example, a regional health authority that is attempting to make a decision about whether or not to fund in-vitro fertilization (IVF) for couples for whom natural reproduction has not been successful. The "treatment," as it were, demonstrably improves the quality of life as defined by the individuals who are receiving it and has a relatively high success rate. In that sense, the IVF may very well be said to contribute positively to the region's overall health outcomes. But policy analysts focused solely or primarily on outcomes might struggle to answer the question as to whether providing couples with a method of producing biologically related children is itself a right that individuals should come to expect. Central to the debate about whether or not to approve the funding for IVF is a discussion about what the responsibilities of the health care system are in the first place and yet outcome-centred thinking sidesteps this question, concerning

itself only with whether or not the policy's outcomes coincide with the revealed or indicated preferences of the population.

Or instead, consider instead a scenario where a similar health authority has sufficient funds provide for one – but only one – of the following: (1) better palliative care for ~20 patients per year; (2) a more nutritious school meal program for 2000 students per year; or (3) obesity surgery for 50 patients per year. A determination as to which course of action would maximize welfare or outcomes presumes, without justification, that we have the ability to define welfare in some standardized way. Though, to be sure, economists and public health practitioners have developed metrics to do just that (e.g. DALY's,[89] QALY's,[90] etc.), the ethical justifications for the use of those metrics is by no means a consensus matter.[91] Indeed, one may very well imagine one set of reasonable individuals reaching a completely different conclusion than another set given diverging views on questions of "self-inflicted illness," age, and the responsibilities that society does or does not have to individuals who are dying. These are controversial moral questions, and whereas outcome-centred frameworks would impose a set of values on the above debate, it is my contention that the debate should be over how we understand the very concept of welfare itself.

It might very well be the case that in some of these instances, the outcome of the debate would be to use what we might think of as conventional outcome variables: years of

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[89] See Christopher J.L. Murray and Arnab K. Acharya, "Understanding DALYs," *Journal of Health Economics* 16, no. 6 (1997): 703-730.
[90] See Graham Loomes and Lynda McKenzie, "The use of QALYs in health care decision making," *Social Science and Medicine* 28, no. 4 (1989): 299-308.
[91] For a comparative analysis of different population health metrics in health care decision-making, see Marthe R. Gold, David Stevenson, and Dennis G. Fryback, "HALYS AND QALYS AND DALYS, OH MY: Similarities and Differences in Summary Measures of Population Health," *Public Health* 23 (2002): 115-134.

life lost, disability-adjusted life years, etc. In those instances, this framework might provide the appropriate lens for normative evaluation. The problem, nonetheless, is that in predetermining the norms of ethical evaluation, outcome-centred frameworks foreclose a central element of the political process, thereby bringing an ardent focus on outcomes into conflict with a commitment to core democratic ideals.

To be sure, this is a problem that confronts policy analysis in a range of issues: environmental protection, national defence, education, etc. But in most other areas, policymakers are likely, at the very least, to agree on what metrics might be used to evaluate outcomes. In a case of environmental protection, policymakers are likely to agree that the benefits maximized are things like jobs or economic growth, while the costs are human health and threats to the environment (which may pose instrumental risk to human beings and/or be seen as threats in and of themselves). Scholars will of course disagree about how to weigh those various costs and benefits – many of which cannot be measured in some kind of standard scale – against one another. Nonetheless, they will be more likely to come to the table agreeing as to what the various costs and benefits are, and attempt to standardize them according to some common currency scale.

In health care, however, the very concept of "benefit" is itself a contested one. Policymakers will rather easily be able to come to the table outlining costs – largely, these are economic costs associated with the consumption of health care goods and the opportunity costs of failing to spend health care funds on other government-funded projects. But in order to calculate benefits, policymakers and members of the general public need to first agree on what we are trying to optimize in the first place. As I have already alluded to, the question of what health care systems should try to optimize (years

lived, quality of life, equality of opportunity, etc.) is fraught. And in a system where the question of what *ought* to be maximized is itself contested, analysis based solely on outcomes confront a problem of the first-order variety.

3.3.2 Distinguishing Between Medical Research and Priority Setting/Resource Allocation

In chapter 2, I devoted significant attention to the notion that PPI was a heterogeneous concept and that policy analysis that tried to group all of PPI into one domain was misguided. But my intention there was not simply to be descriptively precise; rather, it is my contention that there are important policy questions that must be asked of PPI in the realm of priority setting that need not be asked where medical research is concerned. My main concern with using an outcome-centred framework to evaluate the effectiveness of PPI is it presupposes agreement on what outcomes should be measures and maximized. This, as I have outlined, is particularly true in health care where two positive competing values (like length of life lived and quality of life lived) may very well be in competition. But for this very reason, I think it is also important to distinguish between PPI in the realm of research design and PPI in the realm of priority setting in resource allocation.

Where research *design* is concerned, we may have some disagreement about certain value statements. For example, to what extent should patient privacy be protected at the expense of conducting research that might benefit the population? What if safeguards to protect that privacy take an additional 6 months or 1 year to implement while patients' lives hang in the balance? Alternatively, should research funds already designated to Alzheimer's research focus on extending the life of Alzheimer's patients or detecting the disease earlier in life?

Given this, I do not mean to suggest that all researchers, clinicians, and patients will agree on a universal set of outcomes around which we can measure the "success" of research. But because medical research exists within a broad context of scientific inquiry, it would be naïve to think that there are not a certain set of generally established metrics around which we can judge the success of medical research. It should be reasonable to inquire as to whether patient involvement is creating "better" or "more relevant" research according to the widely established standards of medical research, scientific inquiry, and pharmaceutical or treatment benefit to patients. There will of course be complications (e.g. is X question *more* relevant than Y question, etc.), but outcome-centred frameworks are reasonable tools to judge the effectiveness of PPI in research.

With that said, PPI in the realm of public health policy and resource allocation can also be judged by established health metrics (e.g. mortality, morbidity, etc.). Unfortunately, however, given the *nature* of resource allocation and priority settings, decisions often need to be made between two or more mutually exclusive options, all of which might give some health benefit to some subset of the population. In that sense, whether to spend money on one intervention that does X or another intervention that does Y may very well not be a debate about whether X or Y maximizes "health outcomes" to a greater extent; rather, it may be a debate about whether, as a society, we think the health outcomes maximized by X are more important than those maximized by Y.

It would be overly simplistic to think that questions around research can be governed *solely* by outcomes and those around resource allocation and priority setting *solely* by social value judgments. But on the spectrum, it is my contention that given the much narrower scope of the questions, that outcome-centred frameworks are much more

useful tools in medical research than in priority setting or resource allocation. This argument will be developed in even greater detail in the case study chapter, which will highlight the ways in which success as defined by health outcomes can and cannot be measured in different PPI contexts.

3.4 Conclusion

This chapter has argued that an outcomes-based framework does not provide a sufficiently robust justification for a broad based system of patient and public involvement. Importantly, where debates about how to allocate resources are concerned, deliberation by members of the general public must address the question of how to weigh competing values against one another. Focusing solely on whether or not PPI improves health outcomes passes over this prior question of the types of health outcomes with which we should be primarily concerned.

If outcome-centred frameworks provide an insufficient justification for implementing an overarching policy of involvement (such as the one currently in place in the United Kingdom), to what can and do PPI proponents appeal? Whereas most advocates of PPI are concerned at least to some extent with the ways in which PPI affects the outcomes of research and health care provision, many have also held that PPI represents a crucial democratic fixture. It is this appeal to democratic principles and ideals that is the focus of my attention in the coming chapters. Consider, for example, the argument put forward by INVOLVE:

"It is a core democratic principle that people who are affected by research have a right to have a say in what and how publicly funded research is undertaken. Public involvement is an intrinsic part of citizenship, public accountability and transparency."[92] This contention, in many ways, appeals to our natural sensibilities about democracy and participation. But its formulation – perhaps purposefully so – remains ambiguous and somewhat amorphous. In the coming chapters, I evaluate the crux of this argument: do individuals funding research have a *right* to have a say in *how* that research is undertaken? If so, does that right extend beyond the normal political process in a way that it does not in matters like drug regulation or national security? To this point, scholars have largely accepted the premise that greater involvement is *necessarily* more democratic without meticulously exploring the bases for that claim. In the chapters that follow I attempt to examine this argument carefully, asking most fundamentally: does democratic accountability with regard to medical research and resource allocation demand *direct* public involvement?

[92] INVOLVE, "Briefing Note Three: Why involve members of the public in research?" accessed 26 May 2014, <http://www.invo.org.uk/posttyperesource/why-should-members-of-the-public-be-involved-in-research/>.

4
Deliberative Democracy: A Conceptual Framework for Understanding Patient and Public Involvement

4.1 Introduction

In the previous chapter, I argued that given the existence of a certain set of conditions (an ability to agree on what constituted ideal outcomes, a sufficient body of empirical work evaluating the efficacy of various kinds of patient and public involvement, etc.) that a cost-benefit outcomes-centered approach represented a suitable framework for understanding whether or not to pursue various PPI interventions with regard to research governance. I maintained, however, that in the realm of resource allocation, this framework proved insufficient; insofar as the argument from an outcomes-perspective rests on the assumption that we can agree on what outcomes should be prioritized and optimized, the debate about how to allocate resources *is itself* a debate about what constitutes a desirable outcome.

But in their efforts to affirm the value of patient and public involvement, supporters have appealed to broader, more foundational claims about the relationship between the people and the state. In asserting that involving the public directly in health care system decisions (particularly those concerning resource allocation), PPI proponents have sought to ally themselves with a theory about and approach to democratic decision-making that, in recent decades, has gained increasing prominence amongst both theorists and policymakers: deliberative democracy. Advocates have claimed that where citizens are directly involved with the process of decision-making, greater accountability is produced

and a more robust, thoughtful engagement with the issues at hand takes place.[93] Arguments from the deliberative democratic perspective can be effectively be separated into two main categories: (1) those that assess the impact of public deliberation on procedural legitimacy and accountability and (2) those that ascribe intrinsic value and importance to the process of deliberating.

My discussion of deliberative democracy and its value in the debate concerning PPI spans the next two chapters. An argument that examines the invocation of deliberative democracy must first examine the nature of deliberative democratic theory and the ways in which it might plausibly be seen to support greater patient and public involvement. Rather than offering a comprehensive analysis of deliberative democracy, which is well outside the scope of this thesis, I will focus primarily on those aspects that are most salient for an analysis of patient and public involvement.

This chapter proceeds in three main sections. First, I examine the historical and philosophical foundations of deliberative democratic theory. My aim here is to flesh out the ways in which deliberative democratic theory might reasonably be summoned to support patient and public involvement. A thorough philosophical consideration of deliberative democratic theory is also essential insofar as I will argue later in this dissertation that deliberative democracy's underlying principles *should* be upheld. In this way, an understanding of deliberative democracy's foundational principles will enable us to disentangle and deconstruct the web of PPI-deliberative democracy connections. Next, I

[93] Hazel Blears, *Communities in Control—Public Services and Local Socialism* (London: Fabian Society, 2003). See also A. Coote, "Direct Public and Patient Involvement in Rationing," in *Rationing: Talk and Action in Health Care*, ed. B. New (London: British Medical Association, 1997), 158–64; J. Lenaghan, B. New, and E. Mitchell, Lenaghan, J., B. New, and E. Mitchell, "Setting Priorities: Is there a Role for Citizens' Juries?," *British Medical Journal* 312 (1996): 1591–4.

ask: where does deliberative democracy take place? While some theorists conceive of deliberative democracy as occurring amongst a small group of people around a discrete issue, that "micro" version of deliberation does not go uncontested. How we think about the very *nature* of deliberative democracy may indeed go a long way in helping to answer some of our questions about its account of legitimacy. Finally, I introduce the concept of legitimacy and ask how deliberative democracy asserts a claim on accountable and legitimate action. To do so requires that we must expand the contours of our discussion to ask more broadly why any government decision should be considered legitimate in the eyes of citizens, and how various concepts of legitimacy inform deliberative democracy and PPI's claim to enhance it. To seriously investigate this claim, we will need to be explicit about what exactly we mean when we say "legitimacy" or "accountability."

4.1.1 Three Words of Caution

Before proceeding, I pause to note three important caveats to the following discussion. First, as will soon be made clear, there is no single consensus definition or interpretation of what constitutes "deliberative democracy." I will argue that deliberative democracy is best defined by a number of overarching (and widely agreed upon) principles, but there is fierce debate amongst theorists – all of whom might self-identify as deliberative democrats – about the particulars. In constructing a vision of deliberative democracy, I rely primarily on the work of Amy Gutmann and Dennis Thompson, two theorists who have been at the center of the discussion about deliberative democracy, and in many ways, have been responsible for driving the debate about it in the last two decades.[94]

[94] It should be emphasized, however, that Gutmann and Thompson are not the "originators" of deliberative democratic theory, nor should their prescriptions be taken as universally accepted amongst deliberative democrats. It should also be noted that Gutmann and Thompson advance a particular kind of deliberative democracy – one that promotes balancing procedural justice with

Second, it is important to note that the focus of my analysis is not the success of deliberative democracy as a political theory, but rather whether appealing to deliberative democratic principles offers a persuasive justification for pursuing policies of patient and public involvement. This point bears emphasis insofar as a central feature of my argument is that it would *not* be reasonable to use the terms "PPI" and "deliberative democracy" interchangeably. While some of my claims below may be construed as broad-based criticisms of deliberative democracy, they are intended to be specific responses to the particular ways in which supporters of PPI have drawn on deliberative democratic theory. Further, it will also be my contention that in many ways, lay involvement in decision-making undermines rather than furthers the underlying principles of deliberative democracy (many of which I concede to be essential to robust democratic engagement). Many of my criticisms, therefore, are explicitly *not* directed towards deliberative democracy and are instead focused on what I believe to be a faulty conflation of PPI and deliberative democracy. The ways in which the theoretical support for PPI and deliberative democratic theory writ large diverge will be elucidated later in this chapter, but the conceptual distinction should be clarified at the outset.

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substantive constraints on the outcomes reached by deliberative bodies. This is a conclusion that is not necessarily widely accepted, even by outspoken proponents of deliberative democracy. For a wider range of literature on deliberative democracy and its multitude of proponents, see John Dryzek, *Deliberative Democracy and Beyond* (Oxford: Oxford University Press, 2000); James Bohman and William Rehg, *Deliberative Democracy: Essays on Reason and Politics* (Cambridge, MA: MIT Press, 1997); Seyla Benhabib, *Democracy and Difference: Contesting the Boundaries of the Political* (Princeton: Princeton University Press, 1996). A thorough understanding of deliberative democracy would also require a reading into the works of Jürgen Habermas. Habermas, unlike Gutmann and Thompson, is far more concerned with satisfying procedural conditions for deliberation and argues that substantive principles like basic liberty and opportunity should not necessarily constrain the outcomes of deliberation. My use of Gutmann and Thompson's work as a guide notwithstanding, the importance of this debate amongst deliberate democratic theorists should not be underappreciated. For what is perhaps one of the most foundational works in this area, see Jürgen Habermas, *Between Facts and Norms: Contributions to a Discourse Theory of Law and Democracy* (Cambridge, UK: Polity Press, 1996).

Finally, an important but as-of-yet unstated assumption of this dissertation is that deliberative democracy serves to foster more vigorous democratic debate and, at least in theory, advances core democratic principles like transparency and accountability. My goal, therefore, is not to engage in a meta-debate about deliberative democracy, but rather to contest the arguments made by PPI supporters *on their own terms*. I thus start from the premise that deliberative democracy (as opposed to aggregative/procedural or constitutional theories of democracy) provides a just account of democratic governance. The larger debate concerning procedural[95] and constitutional theories[96] of democracy has been examined at great length elsewhere.

4.2 Deliberative Democracy Examined

4.2.1 The Foundations of Deliberative Democratic Theory

Political theorist Joseph Bessette coined the phrase "deliberative democracy" in 1980 as part of his larger critique of elitist understandings of the US constitution in favor of a more participatory vision for democratic engagement.[97] Bessette was one of many

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[95] Proceduralism, rooted firmly in the notion that democracy that invoke rule by only a subset of the population, focuses on the notion of political equality. Prominent proceduralists who defend the importance of majority rule (itself the most basic form of procedural democracy) include Elaine Spitz, *Majority Rule* (Chatham, N.J.: Chatham House, 1984); Douglas Rae, "Decision Rules and Individual Values in Constitutional Choice," *American Political Science Review* 63, no. 1 (March 1969): 40-56. The aforementioned works defend majoritarianism while conceding that there may be instances in which fundamental values need be protected. Other proceduralists go a step further in arguing that indeed there are no fundamental values that are worthy of superseding the principles undergirding majority rule. See, for example, John Hart Ely, *Democracy and Distrust* (Cambridge, MA: Harvard University Press, 1981).

[96] Defenses of constitutional theories of democracy (vis-à-vis proceduralism) are diverse and wide ranging. For a small sample, see Jeremy Waldron, "A Rights-Based Critique of Constitutional Rights," *Oxford Journal of Legal Studies* 13, no. 1 (Spring 1993): 18-51; Ran Hirschl, *Towards Juristocracy* (Cambridge, MA: Harvard University Press, 2004); Ronald Dworkin, *A Matter of Principle* (Cambridge, MA: Harvard University Press, 1985), Chapters 2 and 3; and Cass Sunstein, *The Partial Constitution* (Cambridge, MA: Harvard University Press, 1993).

[97] Joseph M. Bessette, "Deliberative Democracy: The Majority Principle in Republican Government," in *How Democratic is the Constitution?,* eds. Robert A. Goldwin and William A. Schambra (Washington: American Enterprise Institute, 1980), pp. 102-116. Bessette went on to

theorists who, in the 1970's and 1980's, criticized theories of democracy that saw politics as fundamentally competitive, confrontational, and zero-sum. As James Bohman and William Rehg explain:

> These theorists questioned the key assumptions underlying the earlier economic and pluralist models: that politics should be understood mainly in terms of a conflict of competing interests – and thus in terms more of bargaining than of public reason; that rational-choice frameworks provide the sole model for rational decision making; that legitimate government is minimalist, dedicated to the preservation of the negative liberty of atomic individuals; that democratic participation reduces to voting; and so on.[98]

One of the main principles of deliberative democracy is thus a rejection of a "rational-choice" theory of politics, opting instead to embrace the idea that politics *necessarily* involves more give-and-take and less market-based bargaining. For some of the aforementioned theorists, deliberative democracy is a response to the increasing bureaucratization and "technocratisation" of our politics – political decisions, they maintain, have become centralized in the hands of a very few individuals who, by virtue of their position, background, and qualifications, use the power of the state to simply re-entrench their own individual positions of authority.[99] For other theorists, deliberative democracy is a response to what is perceived to be an unequal distribution of power in our politics – a world of highly entrenched and powerful institutional interests (corporations, pressure groups, etc.), a disengaged or otherwise under-engaged public, and government agents with insufficient ties of accountability to that public.

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elaborate and develop his conception of "deliberative democracy" in *The Mild Voice of Reason: Deliberative Democracy and American National Government* (Chicago: University of Chicago Press, 1994).

[98] Bohman and Rehg, *Deliberative Democracy: Essays on Reason and Politics*, xii-xiii.

[99] Habermas, perhaps more than anyone else, best expresses this concern in *The Theory of Communicative Action* (Boston: Beacon Press, 1984).

4.2.2 Deliberative Democracy Deconstructed

Of course, a conception of democracy that rejects technocratic rule or the undue influence of narrowly focused corporations and interest groups provides a very open-ended starting point for analysis. As Gutmann and Thompson note, "The moral basis for [deliberative democracy] is common to many conceptions of democracy. Persons should be treated not merely as objects of legislation, as passive subjects to be ruled, but as autonomous agents who take part in the governance of their own society, directly or through their representatives."[100] While this broad overarching vision of the role of citizens vis-à-vis their government provides a useful starting point for my analysis, its lack of specificity proves problematic if we are to better understand the relationship between deliberative democracy's account of legitimacy and PPI. What, then, distinguishes deliberative democratic theory from a host of other participatory theories of democracy (direct democracy, consensus democracy, or demarchy, to name but three examples)?

Since Bessette's seminal work, the term "deliberative democracy" has been used in a wide range of contexts and may well be said to mean very different things to different people. As John Parkinson notes, "Theorists and practitioners from starkly contrasting traditions have applied the deliberative democratic label to everything from radical activism and protest to consultative forums engaged with the state, to representative assemblies, to the deliberations of small groups of judges, even to the internal processes of making others 'present' in an individual's own internal deliberations."[101] In another sense, theorists also

[100] Amy Gutmann and Dennis Thompson, *Why Deliberative Democracy* (Princeton: Princeton University Press, 2004), 3.
[101] Parkinson, *Deliberating in the Real World*, 2-3.

disagree over whether deliberative democracy must take place in small forums, [102] commissions, and groups,[103] or whether broader public debate and discourse can be part of an aggregative and cumulative process called "deliberative democracy." Still, despite their seeming disagreement over what *precisely* constitutes deliberative democracy, theorists appear to be in general agreement that deliberative democracy is at least principally defined by two main features: (1) its commitment to policymaking and compromise through active *discussion* and *reasoning* as opposed to competition, power, and bargaining and (2) its insistence that this deliberation occur in an explicitly public way. More generally, we might say that deliberative democracy espouses a view of democracy as an exchange of ideas in an inclusive public square between free and equal people.

In developing a more specific account of deliberative democracy's core ideals, Gutmann and Thompson maintain that deliberative democracy is most fundamentally defined by four key principles: (1) reason-giving, (2) accessibility, (3) "binding-ness," and (4) revisability. I will now examine these four guiding principles and the ways in which they might manifest in the policy formulation and implementation processes.

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[102] Some theorists have implicitly (if not explicitly) conceived of deliberative democracy as occurring amongst a relatively small group of people. See, for example, Jon Elster, "The Market and the Forum: Three Varieties of Political Theory," in *Contemporary Political Philosophy: An Anthology*, R.E. Goodin and P. Petit (eds.) (Oxford: Blackwell, 1997); and Joshua Cohen, "Deliberation and Democratic Legitimacy," in *Contemporary Political Philosophy: An Anthology*, R.E. Goodin and P. Petit (eds.), (Oxford: Blackwell, 1989).

[103] For examples of deliberative principles applied to citizens' juries and "consensus conferences" see John Stewart, Elizabeth Kendall, and Anna Coote, *Citizens' Juries* (London: Institute for Public Policy Research, 1994); Graham Smith and Corinne Wales, "Citizens' Juries and Deliberative Democracy," *Political Studies* 48, no. 1 (2000): 51-65; and Edna F. Einsiedel and Deborah L. Eastlick, "Consensus Conferences as Deliberative Democracy: A Communications Perspective," *Science Communication* 21, no. 4 (2000): 323-343.

4.2.2.1 Reason-giving

Perhaps above all else, deliberative democracy asserts that in the course of deliberations over a particular course of policy action, citizens are entitled to justifications for the decisions made by public officials or policymakers. But deliberative democrats, in an effort to foster a more robust and substantive political conversation, go further in specifying the *types* of justifications that should be considered acceptable in a pluralistic liberal democracy. As Gutmann and Thompson explain, "The reasons that deliberative democracy asks citizens and their representatives to give should appeal to principles that individuals who are trying to find fair terms of cooperation cannot reasonably reject…They are reasons that should be accepted by free and equal persons seeking fair terms of cooperation"[104]

Gutmann and Thompson understand this requirement as central to their theory of democratic deliberation. It is important because the ability of individuals to understand and accept decisions made by the state *even when they disagree with them* provides a crucial link between the theory and its claim to confer broader legitimacy and accountability. They make this point explicitly: "Even with regard to political decisions with which they disagree, citizens are likely to take a different attitude toward those that are adopted after careful consideration of the relevant conflicting moral claims and those that are adopted only after calculation of the relative strength of the competing political interests."[105] In this sense, the "reason-giving" requirement of democratic deliberation proves central (at least theoretically) to accomplishing many of deliberative democracy's most important stated goals: legitimizing the process of policymaking, spurring vigorous public debate on matters

[104] Gutmann and Thompson, *Why Deliberative Democracy*, 3.
[105] Gutmann and Thompson, *Democracy and Disagreement*, 41-42.

of consequence, and raising the level of civility and "mutual respect" in the course of public policy deliberation and decision-making.

These assertions beg two important sets of questions, both of which we will return to later in this chapter. First, "who exactly are these free and equal persons, how might we find them, and what precisely does it mean to be 'free and equal' in the first place?" And second, "why is it the case that individuals who fundamentally disagree with the outcome of a political process will be comforted by the fact that their approach was considered and then summarily rejected?" Answers to neither of these sets of questions are obvious, and will later be a focus of my attention. Nonetheless, determining what reasons rise to the level of deliberative democracy's enunciated standards is essential.

4.2.2.2 *Accessibility*

The second stated characteristic of a deliberative democratic system is that the reasons put forward in the process of decision-making should be "accessible" to all citizens that are subsequently affected by the decision. Deliberative democrats understand this notion of accessibility in two different and distinct senses. First (and perhaps most obviously), they argue that the actual process of deliberation should take place *in public*. Gutmann and Thompson recognize that certain kinds of deliberation (for example, the decision whether or not to take a particular kind of military action where sensitive intelligence is involved) might occur in private, but they maintain that the decision to confer that authority to a smaller subset of private individuals must itself be the product of a public deliberation.

The second meaning of "accessibility" concerns the substance of the reason itself and is therefore intimately connected to the reason-giving requirement discussed above.

Gutmann and Thompson stress that the kind of reasons being given during the course of deliberation (and in the ultimate justification) must be broadly understandable to a diverse collection of the citizenry. They refer to this concept as "reciprocity," making clear that reciprocal reasoning requires that "when citizens make moral claims in a deliberative democracy, they appeal to reasons or principles that can be shared by fellow citizens who are similarly motivated."[106] As such, they reject the claims of religious fundamentalists, for example, who appeal to divine authority in a way that cannot be understood by the majority of the citizenry which does not accept the basic premise of biblical revelation. They warn too that this requirement should not be construed as a basis on which to exclude technical pieces of information from the debate. For national security reasons, for example, the particular details of intelligence might reasonably be kept secret, but the fact that average citizens might need to rely on experts to assess that intelligence should not, in their view, preclude vigorous public debate on matters of national security and war.

4.2.2.3 *Binding Decisions*

The third distinguishing feature of deliberative democracy is that the decisions produced through the deliberative process must be binding on the citizenry for a non-insignificant period of time. While this point may seem obvious, it is worth emphasizing that the "binding-ness" of the decision-making process is what distinguishes deliberative democracy from simple deliberation. The binding-ness of decisions is important insofar as it prescribes a deliberative system that is responsible for more than just information

[106] Gutmann and Thompson, *Democracy and Disagreement*, 55. Note that the authors go on to explain that "the qualifying phrase 'similarly motivated' indicates that a deliberative perspective does not address people who reject the aim of finding fair terms for social cooperation; it cannot reach those who refuse to press their public claims in terms accessible to their fellow citizens. No moral perspective in politics can reach such people, except one that replicates their own comprehensive set of beliefs."

gathering or for the sake of deliberating itself. Indeed, many deliberative theorists proclaim that there is value to be gained from the very process of deliberating – that the give-and-take of deliberation produces a citizenry that is more engaged, more informed, and more able to participate actively in robust civil dialogue. Gutmann and Thompson, for example, argue that "A well-constituted deliberative forum provides an opportunity for advancing both individual and collective understanding…when [citizens] deliberate, they can expand their knowledge, including both their self-understanding and their collective understanding of what will best serve their fellow citizens."[107]

And while it may very well be the case that informal deliberation – that is to say, deliberation disconnected from any formal policy formulation process – proves civically valuable for the citizenry, it is not, as a matter of practice, deliberative *democracy*. Indeed, though deliberative forums need not have the ultimate responsibility of creating and implementing policy, their deliberations cannot be disconnected entirely from other deliberative forums in which the actual policy formulation and implementation is occurring. This is an issue to which I will return in greater detail in reference to many of the committees that have been formed as part of plans to foster greater patient and public involvement.

4.2.2.4 Revisability

The concept of revisability, oft-ignored by even some of the most ardent advocates of deliberative democracy, suggests that the decisions ultimately reached in deliberate forums must be provisional. Gutmann and Thompson maintain that the provisional nature of decisions directly bears on deliberative democracy's account of legitimacy. First, they argue that to allow for permanent decision-making would be to ignore the fact that "in

[107] Gutmann and Thompson, *Why Deliberative Democracy*, 12.

politics as in much of practical life, decision-making processes and the human understanding upon which they depend are imperfect."[108] Secondly, they assert that the deliberative forums are likely to be delegitimized if citizens outside those forums do not feel that they have the capacity to ultimately change a decision with which they disagreed.[109]

But while the aforementioned reasons may seem to appeal to deliberative democracy's links to *procedural* legitimacy, Gutmann and Thompson insist that the provisional nature of the decisions has substantive impact as well. Should decisions remain temporary (though, as was stated earlier, be binding for a non-insignificant period of time), citizens making those decisions will have greater incentive to abide what Gutmann and Thompson refer to as "the economy of moral disagreement."[110] Finding more robust terms of agreement or compromise, they allege, enables citizens in decision-making roles the opportunity to generate a longer-lasting and consequentially more influential policy.

4.2.3 Where Does (and Should) Deliberation Take Place?

Just as theorists cannot themselves come to agreement on what type of deliberation constitutes deliberative democracy, so too is there widespread disagreement about what forums should be considered deliberative forums. Because patient and public involvement can take a range of different forms (deliberative polls, small focus-study groups, town-hall style meetings), it is important that we take stock of the different ways in which deliberation might manifest. This is critical not just for the sake of comprehensiveness, but because the various arguments levied against patient and public involvement vary significantly based on the type of forum in which that deliberation is constituted. More

[108] Gutmann and Thompson, *Why Deliberative Democracy*, 6.
[109] Ibid.
[110] Ibid, 7.

specifically, I will be dealing shortly with the account of legitimacy that PPI professes to uphold, and our concern with the so-called "legitimacy problem" will vary between different kinds of deliberative forums.

Despite the strong focus on deliberative democracy in theory, research on the practical implementation of deliberative democratic ideals has only gained traction in earnest in recent years.[111] The theoretical literature[112] largely assumes that deliberation is occurring amongst a small group of (highly rational, perhaps even dispassionate) people in a single room at a single moment in time. Gutmann and Thompson term this kind of "micro-deliberation," "middle democracy":

> Deliberation…should extend throughout the political process – to what we call the land of middle democracy. The forums of deliberation in middle democracy embrace virtually any setting in which citizens come together on a regular basis to reach collective decisions about public issues – governmental as well as nongovernmental institutions. They include not only legislative sessions, court proceedings, and administrative hearings at all levels of government but also meetings of grass roots organizations, professional associations, shareholders meetings, and citizens' committees in hospitals and other similar institutions.[113]

Though the range of options for "middle democratic" forums is fairly broad, Gutmann and Thompson's list primarily assumes relatively small deliberative bodies: small groups of people meeting to discuss a discrete set of issues in a considered and reasoned fashion. In

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[111] In recent years, scholars have begun to pay more attention to the ways in which deliberative principles have been implemented in practice. The work on this question is particularly wide ranging in health care and environmental policy, but has been used in connection with a wide range of policy issues. See Julia Abelson, Pierre-Gerlier Forest, John Eyles, et al., "Deliberations about deliberative methods: issues in the design and evaluation of public participation processes," *Social Science and Medicine* 67 (2003): 239-251; Mark Button and Kevin Mattson, "Deliberative Democracy in Practice: Challenges and Prospects for Civic Deliberation," *Polity* 31, no. 4 (Summer 1999): 609-637; David J. Kahane, *Deliberative Democracy in Practice*, (Vancouver: UBC Press, 2010); and Edward C. Weeks, "The Practice of Deliberative Democracy: Results from Four Large-Scale Trials," *Public Administration Review* 60, no. 4 (July/August 2000): 360-372.

[112] Of course, in a field such as this, it is overly simplistic to bifurcate literature into just two categories ("theoretical" and "practical"). Nonetheless, it is clear that even in research that seeks to blend the two, there are nonetheless assumptions about the nature of deliberation that emerge from the theoretical discussions in many influential works.

[113] Gutmann and Thompson, *Democracy and Disagreement*, 12-13.

many of these forums, there appear to be relatively formal standards and rules that govern the proceedings, and a moderator to advance the process in a systematic fashion.

There are, to be sure, clear advantages to conceiving of deliberation in this way. This focus on the micro level of deliberation makes a good deal of sense insofar as the ability for citizens to reason together, debate with one another, and allow themselves to be persuaded by another's arguments appears to be strengthened by deliberation in a relatively small forum. Indeed, as Dahl points out, participants must have the ability to have equal time to speak, and further studies have shown that the number of participants for the most "effective" deliberation is somewhere between 5 and 7.[114] As a result, it seems somewhat natural that the bulk of my attention would be on these smaller, middle democratic/micro-deliberative forums.

But theorists have also considered deliberative democracy in what we might call its "macro" iterations. This form, argues Parkinson, "conceives of deliberation as conversations carried on across time and space, the threads of which are picked up by people at different times, in different places, and with different interlocutors."[115] Under this theory, democratic discussion is thought of as a web of ever evolving, shifting threads of conversation that ultimately coalesce (organically, perhaps) at some kind of ultimate outcome. Central to this view is not necessarily the notion that each individual conversation, discussion, or debate abide by all of the aforementioned standards of deliberative democracy, but rather that that expansive web of discourses are transparent

[114] See Weeks, "The Practice of Deliberative Democracy" at note 111; Lloyd H. Goodall, *Small Group Communication in Organizations*, 2nd ed. (Dubuque, IA: W.C. Brown, 1990); and James S. Fishkin and Robert C. Luskin, "Experimenting with a Democratic Ideal: Deliberative Polling and Public Opinion," *Acta Politica* 40 (2005): 284-298.
[115] Parkinson, *Deliberating in the Real World*, 6.

(i.e. examined in the public sphere) and conducted by rational people who are like-minded in wanting to reach mutually agreeable outcomes.

Though Parkinson concedes that this "discursive view" is "a little abstract," theorists like Jane Mansbridge and Jürgen Habermas have sought to concretize this idea by utilising the conceptual distinction between the informal public sphere of civil society and the formal public sphere of representative bodies. Mansbridge refers to this informal public sphere of discussion and debate as "everyday talk," maintaining that "theorists of deliberation ought to pay as much attention to citizens' everyday talk as to formal deliberation in public arenas."[116] She (and to a similar extent, Habermas[117]) argues that the full range of citizen participation should be thought of, in an aggregate sense, to constitute deliberation that interacts with and informs decisions being made by "decision-makers" or "policy-makers" in the formal public sphere. Direct protests, debate through the media and other public or semi-public forums, informal neighborhood or community meetings and other informal gatherings are thought to be part of a matrix of evolving conversations that are somehow conveyed to the state.

Though the focus on a particular issue – what Parkinson calls a "deliberative moment" – may involve policymakers in one room making a decision at a specific moment in time, Mansbridge and others argue that we should conceive of all of this "everyday talk"

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[116] Jane Mansbridge, "Everyday Talk in the Deliberative System" in *Deliberative Politics: Essays on 'Democracy and Disagreement,*" S. Macedo (ed.) (New York: Oxford University Press, 1999), 212.

[117] Habermas contends that the so-called "informal public sphere" is where opinions are formed, but the formal public sphere is where decisions are actually made. This stands in contrast to those like Mansbridge and Dryzek, who maintain that the processes of opinion formation and decision-making are iterative and *dynamic* in nature and that to limit the informal public sphere to mere opinion formation is to violate the egalitarian character of democracy and deliberation. See Dryzek, *Deliberative Democracy and Beyond* at note 39; Mansbridge, "Everyday Talk"; and Jane Mansbridge, "A Deliberative Theory of Interest Representation," in *The Politics of Interests*, ed. M.P. Petracca (Boulder, CO: Westview Press, 2003), 32-57.

amongst families, co-workers, communities, interest groups, and the media as part of the deliberative process. The advantage, she argues, is that minorities or oppressed groups may need to utilize the informal sphere to assert their beliefs about a particular issue.[118] Within this notion of an expanded informal sphere lies an important premise: that deliberative democracy must make room for the role of self-interest and emotion during the course of argumentation, in effect rejecting Gutmann and Thompson's prescription that deliberation necessarily be defined by its highly rationalist and perhaps even dispassionate nature.

Perhaps even more fundamentally, this broader conception of deliberative democracy is intended to address critiques of deliberative democracy that center on its exclusiveness. If only a limited number of people can be involved in a micro-deliberation (in an effort to live up to deliberative democracy's own enunciated principles) and attempts to promote representation (either through direct or descriptive means) are unsuccessful, perhaps widening our view of deliberation addresses its inherent inequality. While critics might reply that each conversation, discussion and debate is unlikely to meet the standards for true deliberation, Mansbridge and others would likely answer that as long as the decision-making *as a whole* maintains its deliberative character, the integrity of the process is preserved. How to prevent this sort of "unrestricted communication"[119] from devolving into the kind of adversarial interest group politics void of reasonable argument is a question that these deliberative democrats have not addressed at great length or in great detail.[120]

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[118] Jane Mansbridge, "On the Idea that Participation Makes Better Citizens" in *Citizen Competence and Democratic Institutions*, Stephen L. Elkin and Karol Edward Soltan (eds.) (University Park, PA: Pennsylvania State University Press, 1999), 291-324.
[119] Carolyn Hendriks, "Integrated Deliberation: Reconciling Civil Society's Dual Role in Deliberative Democracy," *Political Studies* 54, no. 3 (2006): 486-508, at p. 494.
[120] The danger of interest group politics becoming necessarily adversarial has been a chief concern of many deliberative democrats and is discussed in Joseph M. Bessette, *The Mild Voice of Reason: Deliberative Democracy and American National Government* (Chicago: University of Chicago

It would be simplistic to divide deliberation into just two main categories – micro and macro. We would also want to think about what we might call "meso-deliberation," that might involve larger town hall meetings or deliberative forums that extend beyond the micro-deliberative ideal but fall well short of the near-all-encompassing vision espoused by Mansbridge and Habermas; of course, different kinds of deliberation will fall at various points along that wide spectrum. But for the sake of conceptual and philosophical clarity, I will focus the bulk of my attention on responses to these two contrasting visions of deliberative democracy insofar as the two opposing sides of that spectrum demand starkly different replies from the perspectives of legitimacy, accountability, inclusiveness, and political equality.

In the macro-level system, for example, my concerns about inclusiveness and political equality are more easily addressed; after all, almost all individuals possess the ability to access conversations and discussion in the informal sphere. But the macro level system also runs the risk of quickly becoming adversarial and it assumes that all individuals who are affected by a given issue possess the time and willingness to be attentive to discussions and debates about those issues. It also most clearly runs into the problem of representative accountability. While we might think of deliberation as occurring constantly across time and space, how the individuals ultimately making decisions about policy ought to be accountable to the individuals in that profoundly complicated and interconnected matrix remains unclear.

In the micro-level system, concerns about maintaining the integrity of the deliberative ideal are much less acute. With fewer than 10 people (specifically selected as

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Press, 1994), 56-63; and John Rawls, *A Theory of Justice* (Oxford: Oxford University Press, 1999 [1971]), 360-361.

capable deliberators) in a room addressing a specific policy issue, we are more likely to live up to the deliberative democrats' espoused principles of reciprocity and reason-giving. But it is in the micro-level system that legitimacy concerns arise. How ought the policy-makers in the room be accountable or representative of those who are affected by the issue at hand? My inquiry into deliberative democracy's account of process legitimation will proceed in greater detail later in this chapter, but an understanding of the different forms that deliberative democracy can take is vital to framing this discussion.

4.3 Deliberation and Legitimacy

As has already been discussed, deliberative democracy seeks to accomplish goals like encouraging broader public debate around important issues and fostering a process of decision-making that more respectfully incorporates concerns from a diversity of viewpoints. But above all else, we are likely to dispatch with deliberative democracy as a useful theory if it does not strengthen the legitimacy of that decision-making process. A focus, therefore, on the means through which deliberative democracy claims to lend legitimacy to the democratic process of decision-making is central to my investigation. It should be noted at the outset of this section that this review of the concept of legitimacy is not intended to be exhaustive or comprehensive, but rather to provide important background that will frame some of the objections to PPI in the following chapter. As such, it is my goal not to engage in a scoping review of legitimacy and all related philosophical concepts (e.g. legitimation, representation, coercion, etc.), but rather to highlight particularly relevant concepts and the ways in which they relate to my analysis of deliberative democracy and its relationship to PPI.

This is not merely an abstract claim, but indeed one that is invoked with great frequency and force by advocates of PPI. When, for example, a recent government proposal in the UK meant to increase patient and public involvement was announced, it was framed as a strategy intended to bring "real local democratic accountability and legitimacy" to the National Health Service "for the first time in 40 years."[121] Or, as Harrison and Mort explain: "…in circumstances where officials do not agree with users it makes sense to challenge their legitimacy by means of various criticisms. Thus, for instance, they might be dismissed as extremists, unrepresentative of some unspecified broader social group; in other words, the wrong 'people'…"[122]

Taken broadly, there appear to be at least two main reasons why PPI (or deliberation more generally) might be seen to enhance the legitimacy of a process distributing scarce resources. First, the involvement of so-called "lay" individuals in the process of decision-making (either through direct participation on committees and councils or indirectly through citizens' councils, deliberative polls, etc.) is seen to somehow bring average citizens inside the process. The closer the people are to decisions being made about them – so the argument goes – the better, or at least more democratic the process stands to be.

The second argument relies less on the procedural principles of participatory democracy, and more on the substantive content that deliberative democracy demands. According to this line of reasoning, decisions about how to allocate scarce resources are likely to be (or at least be perceived as) more legitimate if it is clear that those making the

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[121] Sarah Calkin and Dave West, "Flagship involvement policy faces funding threat," *Health Service Journal*, August 4, 2011, accessed May 27, 2013, http://www.hsj.co.uk/news/policy/flagship-involvement-policy-faces-funding-threat/5033236.article.

[122] Harrison and Mort, "Which Champions, Which People?" at note 2.

decisions have considered all potential viewpoints carefully (something that is at least in theory made more likely by the inclusion of lay perspectives). As Gutmann and Thompson maintain, "The hard choices that public officials have to make should be more acceptable, even to those who receive less than they deserve, if everyone's claims have been considered on the merits, rather than on the basis of the party's bargaining power."[123] It is important to be clear that for Gutmann and Thompson, the issue is not necessarily *intrinsic* to lay participation; rather, their argument is rooted primarily in the notion that the deliberative body act in accordance with principles of reciprocity, transparency, and reason-giving. I will return to this distinction shortly.

4.3.1 What is Legitimacy?

Before transitioning to a more specific discussion concerning the ways in which PPI does and does not enhance the legitimacy of the democratic process, it is important for us to (at least briefly) consider the nature of legitimacy in government[124] decision-making. Political scientists[125] have often discussed the nature of legitimacy with reference to

[123] Gutmann and Thompson, *Why Deliberative Democracy*, 10.

[124] It should be noted here that while this dissertation focuses on the decisions made by government policymakers, there may be ample opportunity to apply the principles discussed to decisions made by private entities with regard to health care. Under the broad theory that even where health care resources are acquired in a market, their distribution must adhere to principles of justice that would hold for public sector agents, a range of scholars have argued that similar principles of accountability and transparency need apply to private sector agents like private hospitals and health insurance companies. See Norman Daniels and James Sabin, "Limits to Health Care: Fair Procedures, Democratic Deliberation" at note 46.

[125] See, for example, Morris Zelditch, Jr. "Theories of Legitimacy" in *The Psychology of Legitimacy: Emerging Perspectives on Ideology, Justice, and Intergroup Relations*, John T. Jost and Brenda Major (eds.), Cambridge: Cambridge University Press, 2001; S.S. Wolin, "Max Weber: Legitimation, Method, and the Politics of Theory," *Political Theory* 9 (1981): 401-424; Bernard Manin, Elly Stein, and Jane Mansbridge, "On Legitimacy and Political Deliberation," *Political Theory* 15, no. 3 (1987): 338-368; and Thomas Nagel, "Moral Conflict and Political Legitimacy," *Philosophy and Public Affairs* 16, no. 3 (1987): 215-240.

Weber's three sources: charismatic, traditional, and rational authority.[126] Weber's argument, however, was explicitly sociological and historical. In other words, the idea that legitimate authority emanated either from a leader's charisma, his/her place in a line of other leaders, or from popular assent through legal (but not necessarily democratic) means only went so far as to establish what produced authority but did not assert whether that authority was *normatively* legitimate. We might still think of that descriptive notion of legitimacy as important (sociologically) insofar as, according to Weber, it results in the maintenance of a social order that is more stable than that facilitated by mere self-interest.[127] But from the perspective of normative philosophy, Weber's account can only take us so far.

4.3.1.1 Normative Accounts (Procedurally)

If legitimacy is not just be a descriptive concept but rests instead on certain moral foundations, we must explore whether those foundations rest primarily in procedural or substantive considerations (or both). Broadly speaking, those concerned with normative accounts of legitimacy understand that it is a concept that relates the *authority* of an actor (namely, government) to make a decision and the *justifiability* of those decisions. Perhaps most famously, Rawls presented a sweeping understanding of the mandates for establishing legitimacy, arguing via the principle of reciprocity that citizens must be free and willing to endorse a particular arrangement of law enforcement (i.e. not through coercion): "Our exercise of political power is fully proper only when it is exercised in accordance with a constitution the essentials of which all citizens as free and equal may reasonably be expected to endorse in the light of principles and ideals acceptable to their common human

[126] Max Weber, *The Theory of Social and Economic Organization*, (translated by Talcott Parsons) (New York: Free Press, 1964).
[127] Ibid.

reason."[128] Other accounts of legitimacy propose caveats or subtleties attached to Rawls proposition, holding that legitimate authority might exist even in coercive contexts (if the people acquiesce to the demands of the leadership) but that there is a fundamental difference between this *de facto* rule and the rule of a government that has established a moral right to make decision.

4.3.1.2 Normative Accounts (Substantively)

Rawls' account of political legitimacy is certainly not void of discussion about substantive constraints on the decisions made by legitimate political authorities, but these constraints are not the focus of his analysis. According to another strain of thinking that emphasizes the role of political ends in legitimizing policy action, obligations under the law should only be considered binding where a series of normative constraints on that action are observed. Traditionally, many philosophers held that the very constitution of a legitimate government body *itself* created the conditions for political obligations. As Locke argued, "every man, by consenting with others to make one body politic under one government, puts himself under an obligation to every one of that society to submit to the determination of the majority, and to be concluded by it; or else this original compact, whereby he with others incorporates into one society, would signify nothing, and be no compact if he be left free and under no other ties than he was in before in the state of nature."[129]

But for many contemporary scholars, a legitimate authority may call for policy action that does not abide by certain normative considerations of justice that thus exempt individuals from political obligation. Dworkin, for example, contends that the obligations that one has in a political system arise not because of any kind of government to person

[128] John Rawls, *Political Liberalism* (New York: Columbia University Press, 1993), 137.
[129] John Locke, *Second Treatise on Civil Government* (ed. C.B. MacPherson) (Indianapolis: Hackett, 1990 [1690]), 52.

social-contract but rather because of the "associative obligations" that derive from one's membership in a more broadly construed social community.[130] Beetham makes the distinction between procedural and substantive constraints on legitimate action more explicit, dividing legitimacy into what he refers to as "source norms" and "content norms." The source norms are the legitimate sources of democratic authority which, for Beetham, are all of the individuals who may be affected by a particular decision.[131] Because, he argues, liberals must be principally concerned with the protection of the moral equality of persons, authority to make decisions must emanate from the people themselves as opposed to some "external" source like religious revelation, scientific dogma, or any other mind of mere cultural tradition. The content norms are instead the kinds of substantive constraints that we put on legitimate government action; these may include, but are most certainly not limited to liberty, equality of opportunity, and freedom. Because of the problem of scale – it is almost always impossible for all of the individuals being affected by a decision to deliberate together about it – Beetham concedes that a reasonable system of representation may be needed, but maintains that the deliberators be held directly accountable by those affected.[132]

4.3.2. Procedure and Substance in Deliberative Democracy

This distinction between procedure and substance – though perhaps seemingly little more than a theoretical digression – has a profound impact on my discussion around

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[130] Ronald Dworkin, *Law's Empire* (Cambridge, MA: Harvard University Press, 1986). See also John A. Simmons, *Justification and Legitimacy: Essays on Rights and Obligations* (Cambridge: Cambridge University Press); and Christopher Wellman, "Liberalism, Samaritanism, and Political Legitimacy," *Philosophy and Public Affairs* 25, no. 3 (1996): 211-237.

[131] David Beetham, *The Legitimation of Power* (Basingstoke: Macmillan, 1991). For a more complete exposition of Beetham's work on this matter, consult Parkinson, *Deliberating in the Real World*, 22-25.

[132] Beetham, *The Legitimation of Power*, Chapters 5 and 6.

deliberative democracy. Though I have just established that some theorists (Rawls, for example) emphasize the value of procedural limitations on legitimate government action while others (e.g. Dworkin) are more concerned with the outcomes produced by those governments, for deliberative democrats, the choice appears to be a false one.

Despite the fact that there is some disagreement amongst deliberative theorists about the extent to which a legitimate process depends on just procedures and/or just outcomes, there is general agreement that both are essential.[133] There is, of course, disagreement about which political ends are most in need of protecting and as to which substantive values are worth preserving even at the expense of upholding procedural norms of deliberation. Most deliberative democrats maintain that robust democratic flourishing requires that at the very least, principles of liberty, equality, and freedom be protected, alongside the basic physical needs of the population (being seen as a gateway/prerequisite to all other rights). But how exactly we are to determine what exactly "liberty" or "basic opportunity" demand and how to weigh those values against one another remains a source of disagreement amongst deliberative theorists and democratic theorists more broadly.

But in an effort to safeguard these democratic ideals, how precisely is the process of policy legitimation to proceed? As Parkinson argues, there appear to be two contrasting visions: "one which focuses on the bottom-up process of granting consent, the other which

[133] Agreement on this basic point is widespread amongst deliberative democrats. See Joshua Cohen, "Deliberation and Democratic Legitimacy" in *Essays on Reason and Politics: Deliberative Democracy* ed. James Bohman and William Rehg (MIT Press: Cambridge, MA, 1997); James Bohman, "Survey Article: The Coming of Age of Deliberative Democracy," *The Journal of Political Philosophy* 6, no. 4 (1998): 400-425; Emily Hauptmann, "Can Less Be More? Leftist Deliberative Democrats' Critique of Participatory Democracy" *Polity* 33, no. 3 (2001): 397-421; David Estlund, "Beyond Fairness of Deliberation: The Epistemic Dimension of Democratic Authority" in *Essays on Reason and Politics*; and Simone Chambers, "Deliberative Democratic Theory," *Annual Review of Political Science* 6 (2003): 307-26.

focuses on the top-down exercise of authority and persuasion."[134] For Beetham, the bottom-up approach is deemed superior through its use of a range of different consent-granting mechanisms ranging from voting, lobbying of elected representatives and party officials, and activism through pressure groups. In less formal contexts, these kinds of interactions might extend to include things like political rallies, civic education and activism, and efforts to change policy through civil society.

Still, many theorists highlight the fact that though the basics of consent require that the public grant authority through explicit mechanisms like voting, the process of legitimation is fundamentally dynamic and iterative process. In any democratic society, power and authority must necessarily emanate from the bottom-up, but the reason-giving element of deliberative democracy, which is at the very core of deliberative democracy's aspirations, requires an element of top-down communication. And from an empirical perspective, it is clear that the dynamic process of policy legitimation necessitates both bottom-up consent and top-down efforts to put reasons for policy forward for public consideration, debate, and dialogue.

Finally, it is worth noting that the process of legitimation – by its iterative nature – is not an all-or-nothing affair. By participating in various actions that grant authoritative consent to policy-makers, citizens are not to be seen as granting authority for all time in all instances. Because legitimacy is itself both a concept with moral force and, from an empirical perspective, a socially constructed ideal, there is no sense in which we might construct a scale that includes both procedural and substantive elements and know that past point x, legitimacy has been "achieved." This is perhaps the fundamental point: legitimacy must be seen to be a dynamic political *aspiration* that makes room for adjustments and

[134] Parkinson, *Deliberating in the Real World*, 24.

changes and allows for debate and disagreement about the legitimacy of individual decisions even within a system that is broadly understood to uphold standards of legitimate procedures. Put most simply, my argument here is that a focus on procedures is of only limited value.

4.4 Legitimacy and Representation

If we accept the fact that an important constitutive element of deliberative democracy's account of legitimacy is the consent granted to policy-makers to make their decisions (if not the only important element), the question of how authority is transferred in a legitimate fashion becomes central. This section deals with what some scholars have referred to as deliberative democracy's "scale problem" (which will be addressed in greater detail in the following chapter): namely, that for effective and useful debate and dialogue, deliberative democracy requires a minimal number of people to be present and yet legitimacy for those decisions has been conferred by an entire segment of the population not present for the deliberation itself.[135]

My discussion of the scale problem will proceed in greater detail in the next chapter, but for now, it is important to engage (at least theoretically) with what is commonly thought to be the most useful response to the problem: representation. This section does not purport to be a comprehensive review of the literature on representation –

[135] A more robust discussion about potential strategies one might employ to tackle the so-called scale problem follows in the following chapter. For reference to the scale problem within the literature, see John S. Dryzek, "Deliberative Democracy in Divided Societies: Alternatives to Agonism and Analgesia," *Political Theory* 33, no. 2 (2005): 218-242 ; Parkinson, *Deliberating in the Real World*, 7-8, 26-28; Jan Teorell, "Political Participation and three theories of democracy: A research inventory and agenda," *European Journal of Political Research* 45, no. 5 (2006): 787-810; John Parkinson, "Legitimacy Problems in Deliberative Democracy," *Political Studies* 51, no. 1 (2003): 180-196.

such a review is well beyond the scope of this dissertation.[136] That said, a specific account of the ways in which representation (of different varieties) can purport to provide legitimacy to the policy-making process will prove helpful as we proceed to examine the relationship between deliberation, policy formulation, and policy legitimation. This section, rather than engaging in a broad review of theories of representation and democracy, seeks to better understand the ways in which representation might be seen to enhance accountability and consequently, the legitimacy of the process.

4.4.1 Representation Examined

At first glance, a system of representation seems to be a sound approach to dealing with the scale problem described above. Since it is impossible for deliberation to function (according to its own espoused standards) with a massive number of people "in the room" (let alone the entire population affected by any meaningful policy issue), people not in the room might reasonably feel that their views are expressed if a representative represents them at the deliberative meeting. Indeed, the United States Senate has been described as the most "deliberative body in the world"[137] (whether it actually lives up to that reputation in today's political environment is, of course, another matter entirely).

[136] In particular, the notion of the trustee/delegate model of representation has been the subject of considerable debate amongst theorists for seemingly as long as scholars have been debating the virtue of representative democracy. For a broad, scoping review of the matter, see Adam Przeworski, Susan C. Stokes, and Bernand Manin (eds.), *Democracy, Accountability, and Representation* (Cambridge, UK: Cambridge University Press, 1999); and Guillermo A. O'Donell, "Delegative Democracy," *Journal of Democracy* 5, no. 1 (1994): 55-69. Perhaps the most historically influential work in the matter is Hanna Pitkin, *The Concept of Representation* (Berkeley, CA: University of California Press, 1967). For a strong defense of the moral superiority of representation, see Bernard Manin, "On Legitimacy and Political Deliberation," *Political Theory* 15, no. 3 (1987): 338-68.

[137] Robert G. Lehnen, "Behavior on the Senate Floor: An Analysis of Debate in the U.S. Senate," *Midwest Journal of Political Science* 11, no. 4 (1967): 505-521.

But in many of the deliberative environments discussed in this book, the lines of delegation and accountability between those deliberating (in citizens' juries, priorities committees, etc.) and the people affected by the policies they stand to implement remain unclear. While the account of legitimacy I present below maintains that lines of delegated authority must be articulated explicitly, I will investigate different conceptions of representation and legitimacy in order to address the plausible contention that a different model of representation serves as a sufficient basis on which to safeguard the legitimacy of the process and the convictions of the public. Indeed, there is a strong case to be made that, in certain instances, unelected representatives of the public should be considered legitimate (commonly observed examples include judges, regulators with technical expertise, members of the military/national security apparatus, etc.).[138] My digression into a discussion of the various theories of representation will prove vital when I return to the more specific questions related to PPI, its theory of representation, and its account of legitimacy.

4.4.2 Modes of Representation

According to Pitkin[139] (whose work on this question remains seminal), we might think of representation within a democracy as falling under one of four major categories:

1. Formalistic Representation
    a. Accountability (Delegate)
    b. Authorization (Trustee)
2. Descriptive Representation
3. Symbolic Representation

[138] Michael Saward, "Authorisation and Authenticity: Representation and the Unelected," *The Journal of Political Philosophy* 17, no. 1 (2009): 1-22.
[139] Pitkin, *The Concept of Representation,* 11.

4. Substantive Representation

Substantive representation, conceived of in opposition to descriptive representation, assesses the extent to which a political representative advocates on behalf of a particular cause or a group of people. Rather than existing as separate method of selecting (or electing) representatives, the framework of substantive representation merely proposes a means by which to evaluate representatives.

Symbolic representation, on the other hand, describes a scenario in which an individual symbolizes a group of people but is not necessarily specifically or explicitly selected by that group of people to represent them. We might think of the use of political parties, for example, as symbolically representative of a group of people. Thinking less formally, we could point to popular monarchs (like the Queen of England) as symbolically representative of a group of people. Despite the fact that she is neither elected nor directly accountable to members of the public, those very same members may feel as if she *legitimately* represents the people of Britain when she travels abroad and speaks with other foreign leaders. As Pitkin noted of a British textbook of the 1960's: "[The textbook] tells us that the monarch 'stands for the majesty, the authority, the unity of the British nation, and each of the units of the Commonwealth…he represents its statehood.'"[140] Pitkin observes that although symbolic representation provides a useful way to think, *sociologically*, about the reasons why certain leaders or institutions are perceived to be legitimate, that in the realm of normative democratic theory, it is limited. Insofar as most symbolic symbols exist precisely in spite of any directly delegated authority from the population, this theory provides little value to my discussion about deliberation, representation, and legitimacy.

[140] Pitkin, *The Concept of Representation*, 93.

Descriptive representation exists when an individual representative exemplifies certain descriptive characteristics of the people that he or she is said to represent – so, for example, when a woman represents the interests of women, a Sunni of Sunnis, etc. Through this understanding, representation may be said to be successful when the representative body "looks like" the population at large rather than whether the representative body represents the beliefs, values, and convictions of the population (substantive representation). Of course, proponents of the theory maintain that this process of essentialising can prove valuable insofar as there are discrete groups of people who share political beliefs, interests, and values. But essentialising in this way can also prove problematic; naturally, in the United States, all poor workers don't vote for Democrats, all women don't vote for women candidates, etc. This, as Will Kymlicka argues, can actually serve to reinforce stereotypes and worsen the process of marginalization: "the claim that whites cannot understand the needs of blacks, or that men cannot understand the needs of women, can become an excuse for white men not to try to understand or represent the needs of others."[141] I will return to this concept in greater detail in my discussion of PPI and its methods of selecting representatives in chapter 5.

The final – and most ubiquitous – form of representation is that of formal representation and it describes a direct relationship between the representative and the represented. Pitkin divides this formal account of representation into two distinct varieties – authorization and accountability, but more commonly referred to as the "trustee" and "delegate" models, respectively. The delegate account understands the representative as being held accountable to the desires of his/her constituents, while the trustee model sees the representative as being authorized to act as he/she likes and to use discretion to act in

[141] Will Kymlicka, *Multicultural Citizenship* (Oxford: Oxford University Press, 1995), 139.

the best interests of the constituency. Of course, as even novice political observers would note, most political representation involves a combination of these two models and there is considerable debate within the literature as to whether certain elements of the relationship should be emphasized under certain conditions and with regard to certain issues.[142]

In deliberative democracy, the tension between the trustee and delegate models is particularly pronounced. Because "real deliberation," so to speak, requires that participants enter the deliberative space willing to be persuaded by sound argument and reason, it would appear to be the case that deliberation requires an embrace of the trustee model of representation. But in the trustee model, it is difficult to see how accountability between agents and principals is preserved. Those selected to deliberate are then caught in somewhat of a bind – are they to represent the views of the community (who either elected or them or from which they themselves were simply selected) or merely enter the process free of prior bias. Since deliberative theory places so much emphasis on the forum as a space where arguments reign supreme, it is very well possible that a decision reached by a deliberating body bears little to no resemblance to the predominating views amongst the general public. In this case, how exactly can deliberative democracy (or in our case more specifically, PPI) purport to enhance the legitimacy of the process?

Any number of solutions have been proposed to this problem. Many democratic theorists suggest that the distinction between trustee and delegate is itself artificial, arguing that in practice representatives are responsible both for representing the views of their

[142] See Heinz Eulau, John C. Wahlke, William Buchanan, and Leroy C. Ferguson, "The Role of the Representative: Some Empirical Observations on the Theory of Edmund Burke," *American Political Science Review* 53, no. 3 (1959): 742-756; James G. March and Jonathan P. Olsen, *Democratic Governance* (New York: Free Press, 1995), 25-35; and Andrew Rehfield, "Representation Rethought: On Trustees, Delegates, and Gyroscopes in the Study of Political Representation and Democracy," *American Political Science Review* 103, no. 2 (2009): 214-230.

constituents while also transmitting information back to those same constituents. On this view, deliberation is one part of a broader *dialogue* that occurs between the representative and the represented and the deliberative process bolsters legitimacy. Others have suggested that selection by random lot may solve some of the delegate/trustee problems insofar as the individuals selected represent a group of people without being directly accountable to those people. We may still think of those people as accountable to society writ large (e.g. jury duty) without requiring them to answer specifically to any individual or group of people. I will examine these arguments in greater detail in the next chapter.

4.5 Conclusion

This chapter did not seek to make any truly normative judgments about deliberative democracy or PPI; rather, my goal was to set forth a theoretical framework through which we might understand some of the problems raised by PPI and deliberative democracy. I reviewed the fundamental elements of authentic deliberation, examined the ways in which deliberation can occur in society, and importantly, reviewed the relationship between deliberation and the legitimacy of the policy formulation and implementation processes.

In articulating an account of legitimacy, I argued (as most deliberative theorists do) that a moral claim to legitimacy must be grounded in a process that safeguards both procedural and substantive elements of justice. The precise ways in which just outcomes should be judged is, of course, the subject of considerable debate amongst both scholars and practitioners, but the difficulty in pointing to exactly what we mean by "equality," "liberty," or "basic opportunity" should not prevent us from outlining those broad goals.

Finally, I reviewed different conceptions of representation, as it is a fundamental element of any potentially operative deliberative system. Any claim that PPI might make

to strengthen the legitimacy of the policy-process must articulate a specific way in which the individuals selected for participation should be reasonably thought of to be acting as representatives of the population writ large. A foundational claim of this dissertation is that the patient and public involvement movement has relied on overly broad claims about "democratic accountability" and "democratic participation" without explaining exactly how the individuals selected are acting in the interests of those represented.

With this theoretical toolkit assembled, I turn now to a more concrete evaluation of the account that PPI claims to bolster the legitimacy and accountability of the policy constitution process in medical research and resource allocation. In the end, though, it is important to recognize that my claim is not that there is no such thing as a legitimate process nor is it that PPI must create a *perfectly* legitimate process to be considered worthwhile. As was asserted earlier, legitimacy should not be construed as a 0/1 variable, but thought of instead as existing across a broad spectrum of potential outcomes. The process of legitimizing policies is, crucially, a dynamic and iterative process, and attempts to alter policy formulation and implementation should be attentive to that fact. It is with that in mind that I move now to examine PPI's account of legitimacy and proceed to subsequently suggest a series of reforms that might support greater legitimacy and robust democratic accountability.

5
Deliberative Democracy and Patient and Public Involvement

5.1 Introduction

Having constructed a theoretical framework through which to understand deliberative democracy and processes of legitimation, I turn my attention now to the links between patient and public involvement and deliberative democracy. With that theoretical foundation built, this chapter's focus is in interrogating the strength of the relationship between deliberative democratic theory and patient and public involvement and to ask whether direct public involvement really is, as many proponents of greater patient and public involvement have argued, central to furthering robust democratic engagement.

As I have already argued, deliberative democracy may mean many different things to many different people. One of the things that it *might* incorporate is direct involvement in decision-making by members of the public. But what is not clear is whether that *element* of deliberative democracy (as opposed to others – e.g. greater transparency, emphasis on reason-giving) is what renders democratic deliberation more legitimate than other forms of democratic policy-making. At its core, that is our most fundamental task: to determine why – if at all – we should think of *direct public involvement* as important to furthering the ideals of accountability, transparency, and moral reciprocity that lie at the heart of deliberative democratic theory.

My case against the use of deliberative democratic theory to support patient and public involvement breaks down into three main arguments. First, I argue that those outside the deliberative forum have little (if any) reason to deem the process more

legitimate simply because members of the 'lay public' are participating in the deliberation. Second, I contend that the requirements deliberative democrats place on those participating are so stringent as to limit the available pool of participants to a highly elite, exclusive, and in many ways, non-democratic body. Finally, I maintain that patient and public involvement, as it has to this point been implemented, does not conform to some of deliberative democracy's most basic espoused principles. Though many of the challenges I highlight are seemingly empirical ones that might ostensibly be addressed by through policy changes to the PPI system, what we will eventually come to see is that in this realm of policymaking, the line between theory and practice is at best blurry. To be sure, this chapter's focus leans towards the theoretical, but chapter 6 will be dedicated to a cross-country comparison of deliberative democratic efforts in health care and an investigation of the practical issues these theoretical concerns raise upon implementation.

I proceed with an account of how deliberative democracy purports to further the legitimacy and accountability of the policy formulation and implementation processes. PPI's use of deliberative democratic theory relies heavily on the claim that lay involvement is inextricably bound to notions of process legitimation and accountable policymaking. Next, I turn my attention to the relationship between deliberative democratic theory and theories of patient and public involvement. My first task here is to ask whether supporters of patient and public involvement are right to invoke democratic arguments to describe the process of lay involvement. I will then put forth a series of arguments that ask whether deliberative democracy can reasonably be expected to uphold legitimacy or accountability given the profound challenges of scale and motivation. The legitimacy (scale) problem concerns the fact that PPI proponents, in appealing to deliberative democratic norms, have

failed to explain why individuals outside the deliberative forum should bestow legitimacy on a process to which they were completely disconnected. In addressing questions of motivation, I argue that the procedural constraints deliberative democratic theorists have placed on the process are so onerous as to limit participation in a way that has serious effects on the broader legitimacy of the enterprise. Ultimately, as I will show in chapter 7, the principles animating deliberative democracy (transparency, accountability, and appeals to broadly acceptable reasons) are worth pursuing in the process of distributing scarce health care resources. But it is not clear that lay involvement through PPI is the best way to affirm or further those theoretical principles in practice.

5.2 Patient and Public Involvement's Account of Process Legitimation

A determination as to whether or not patient and public involvement is likely to strengthen or enhance the legitimacy of government decision-making must begin with an examination of what those supporting patient and public involvement are setting out to do in the first place. According to INVOLVE, aside from "improving the quality of research" and "making the research more relevant," active patient and public involvement satisfied a core democratic objective: "It is a core democratic principle that people who are affected by research have a right to have a say in what and how publicly funded research is undertaken."[143] But even if one were to accept that the public has a "right to have a say" what and how research is undertaken (itself not a terribly controversial proclamation), it is not necessarily clear or obvious that the kind of public participation envisaged by PPI supporters is, as INVOLVE declares, "an intrinsic part of citizenship."

[143] INVOLVE, "Briefing Note Three: Why involve members of the public in research?" accessed 26 May 2014, <http://www.invo.org.uk/posttyperesource/why-should-members-of-the-public-be-involved-in-research/>.

As such, an examination of the mechanisms through which greater public involvement might enhance legitimacy is needed. Hogg and Williamson explain that the desire to involve patients from the perspective of accountability rests on the premise that doing so might help "to demonstrate openness in decision-making; to confer legitimacy on professional and management decisions, such as around `rationing' services; to ensure probity and provide oversight; to safeguard the public interest by bringing in the views of people who have neither professional self-interest nor commercial links to the health-care industry."[144] Practically, then, we might say that lay involvement holds the potential to (1) open up the method of decision-making to greater public scrutiny, thereby fostering a more transparent process; (2) generate a more *reciprocal* process whereby the needs of "average" or "everyday" citizens are taken into account more than the specialized interests of researchers, private sector corporations, or other professional stakeholders; and (3) create a more responsible process whereby expert-decision-makers and bureaucrats are held accountable by the public for decisions made on its behalf. We might characterize these three arguments as articulating three distinct "pathways" to legitimacy: (1) opening up and creating a more transparent process; (2) creating a more reciprocal process where principles of mutual respect and reason-giving are prioritized; and (3) highlighting more clearly lines of accountability that provide displeased consumers of health care potential options for recourse.

In the pages to follow, I will address claims (1) and (2) – namely, that PPI serves to strengthen the legitimacy of the resource allocation process through greater transparency

[144] C. Hogg and C. Williamson, "Whose interests do lay people represent? Towards an understanding of the role of lay people as members of committees," *Health Expectations* 4, no. 1 (2001): 2-9.

and adherence to norms of reciprocity and mutual respect. I will examine PPI's claim to foster more accountable policymaking at greater length later in this chapter.

5.3 The Process of Legitimation

As was discussed in chapter 4, the process of legitimacy formation should be construed not just sociologically (that is to say – do people, as a descriptive matter, accept a certain regime as "legitimate"), but under normative terms as well. In this section, I examine the three aforementioned features that PPI purports to strengthen and ask whether those principles are the truly significant parts of deliberative democratic efforts to legitimize decision-making efforts.

5.3.1 Transparency and Publicity – General Principles

For deliberative democrats, transparency is a necessary but not sufficient condition for democratic deliberation. As Gutmann and Thompson explain, openness in government "motivates public officials to do their duty. It also encourages citizens to learn about and from public opinion."[145] Importantly, however, transparency appears to be just the first step of the process. It is for this reason that Gutmann and Thompson – among others – focus not just on *tolerating* access to information, but on the concept of publicity which entails a government that actively and aggressively reaches out to its constituents to explain the bases for government decisions.

This public reason-giving requirement and not just a stated willingness to allow members of the public to have access to various hearings and public documents stands separately as an independently important facet of process legitimation. For many deliberative democrats, the publicizing of information and active reason-giving is inextricably linked to effective deliberation itself. First, by this mode of reasoning,

[145] Gutmann and Thompson, *Democracy and Disagreement*, 97.

members of the public should only reasonably be expected to consent to a particular policy if they are made aware of the justification for that policy, with a few notable exceptions.[146] The critical assumption here is that the amount of information, sheer number of policies, and constraints on average citizens' time are so great that the burden of providing information should be on government. Second, publicity encourages a broader exchange of ideas in the public square. When government is forced to assert its position loudly in public, it ostensibly spurs the kind of exchange of ideas amidst citizens, their representatives and institutions like the media that are essential for robust democratic engagement. Third, the failure to vigorously publicize government decisions evinces a lack of mutual respect by failing to define the terms of moral disagreement. Since the clarification of the nature of moral disagreement is at the very heart of deliberative efforts to resolve differences amongst citizens, government must play an active role in elucidating the character of the disagreement itself. Finally, deliberative democracy's stated emphasis on encouraging citizens and officials to change their minds in the course of argument necessitates access to all available arguments. Put simply, debate and disagreement cannot even commence absence a stated justification for policy action put forward by the government or other relevant policymaker (e.g. HMO, health insurance company, etc.).

[146] In *Democracy and Disagreement*, Gutmann and Thompson go to great lengths to describe the kinds of circumstances under which the government might have a legitimate interest in making decisions in secret. Obvious cases like national security might require government secrecy over a prolonged period of time as might certain economic policies. This dissertation does not spend a great deal of time addressing the plausible exceptions to the general principle of publicity insofar as there is little reason to believe that the kind of deliberations discussed here (vis-à-vis PPI) would fall under any of those exceptions. For a more thorough discussion concerning the interaction between deliberative democratic theory and the keeping of government secrets, see Gutmann and Thompson, *Democracy and Disagreement*, 101-126. See also Dennis Thompson, "Democratic Secrecy," *Political Science Quarterly* 114, no. 2 (Summer 1999): 181-193. Some scholars have argued that deliberation itself is much more likely to be successful in a world of less publicity. For an examination of this question see Simone Chambers, "Behind Closed Doors: Publicity, Secrecy, and the Quality of Deliberation," *The Journal of Political Philosophy* 12, no. 4 (December 2004): 389-410.

5.3.1.1 – Transparency, Publicity, and PPI

If we accept the premise that transparency is vital to promoting the deliberative process itself, is it the case that PPI is likely to (or empirically has) expanded access to information or enabled the public to better understand the nature of decisions by resource allocating bodies and rationing boards? The answer to this question might very well depend on the type of PPI involved. As was discussed in chapter 2, to speak about a singular "PPI" is itself a mistake insofar as efforts to include patients and the public in decision-making have ranged from selecting a "lay member" to serve on allocating committees, to using "deliberative polls" to engaging "citizens' juries, as was done in both Belfast and Leicester.[147]

In the case of lay-people serving on committees, it is not at all clear either theoretically or empirically how the cause of publicity is advanced beyond the single individual selected to serve. Theoretically, that single individual might be encouraged to speak to his or her friends, family, or co-workers about the proceedings of the body, but in most instances, the lay-individual is bound by the same rules of confidentiality and privacy as are the professional members of the committee. In the case of citizens' juries, publicity may very well be enhanced insofar as in most cases, the very decision itself to convene a jury proves sufficiently newsworthy to spark debate in communities and within the media. But depending on the way in which the jury is convened, it is by no means clear that when a decision is reached about how to proceed that the government (or other policymaker) is

[147] See John Parkinson, "Why Deliberate? The Encounter Between Deliberation and New Public Managers," *Public Administration* 82, no. 2 (2004): 377-395; 389. Note that both the Belfast and Leicester citizens' juries dealt with issues of public health and care delivery reform. In Belfast, the jury debated the question about reforms to its primary care infrastructure and in Leicester, deliberators discussed what to do with what was seen at the time as a crisis in Leicester's three main hospitals around acute care usage.

under any statutory or other obligation to disclose why a particular decision was made. The critical point here is that deliberative democracy requires not just that debates about issues of public importance occur in the public square in as transparent a fashion as possible, but that the debates *themselves* be characterized by the giving of certain kinds of reasons that abide by deliberative democratic notions of reciprocity and mutual respect. In short, even in instances where a type of patient and public involvement brings the discussion about resource allocation issues into the open, there is no guarantee that the proceeding discussion will in any way resemble ideal deliberation.

In Oregon, for example, efforts to ration health care were buttressed by a series of town-hall meetings in which citizens and health care professionals assembled to "rank" various medical procedures and treatments in terms of highest priority. Gutmann and Thompson praise the effort, maintaining that it "forced officials and citizens to confront a serious problem they had previously evaded and to confront it in a cooperative ('first-person plural') spirit."[148]

But did the process actually open up the means of decision-making to the general public? In one sense, clearly it did. Thousands of peoples (in aggregate) attended the town hall meetings, they were covered widely by the press in Oregon (and in certain instances, around the country given the novelty of the process), and the means by which decisions were made to prioritize care were placed under the metaphorical social x-ray. But insofar as the public debate in Oregon only prompted the state legislature to expand the overall budget for health services rather than dealing with the difficult moral choices rationing demands (more on this later), transparency proved to be a necessary but not sufficient condition for the ideals of deliberative democracy to be upheld. As I will explain later,

[148] Gutmann and Thompson, *Democracy and Disagreement*, 143-144.

deliberation in Oregon – though widely discussed[149] as an example of PPI's potential success – failed to accomplish many of its own enunciated goals, in spite of the fact that it did spark discussion (both formally and informally) around the thorny issues of resource allocation and rationing.

5.3.2 Reciprocity – General Principles

If transparency is not a sufficient condition for producing authentic democratic deliberation, it is because deliberative democrats' espouse a particular concern not just with the processes through which decisions are made (i.e. structures, institutions, etc.) but with the very content of the decisions themselves. Perhaps more than other theories of democracy (e.g. proceduralism, constitutionalism), deliberative democracy understands reciprocity as fundamental to legitimacy.[150] We might think of reciprocity, most simply, as the idea that citizens and policymakers must provide reasons to one another that should be deemed "mutually acceptable." Put perhaps in more negative terms, citizens should not rely on methods of reasoning that require the imposition of a set of doctrines on fellow citizens. Traditionally, theorists have used this formulation to rule out religious reasoning as unacceptable. For Gutmann and Thompson, this restriction on the use of religious reasoning would be an acceptable justification for denying religious fundamentalists the right to not have their children read certain books in schools: "The parents' reasoning appeals to values that can and should be rejected by citizens of a pluralist society

[149] See, for example, Daniel M. Fox and Howard Howard M. Leichter, "Rationing Care in Oregon: The New Accountability," *Health Affairs* 10, no. 2 (1991): 7-27; Michael J. Garland and Romana Hasnain, *The Hastings Center Report* 20, no. 5 (1990): 16-18; Marsha Gold, "Markets and Public Programs: Insights from Oregon and Tennessee," *Journal of Health Politics, Policy, and Law* 22, no. 2 (1997): 633-666; and David C. Hadorn, "The Oregon Priority Setting Exercise: Quality of Life and Public Policy," *Hastings Center Report* 21, no. 3 (1991): 11-16.

[150] Amy Gutmann and Dennis Thompson, "Why Deliberative Democracy is Different," *Social Philosophy and Policy* 17, no. 1 (2000): 161-180.

committed to protecting the basic liberties and opportunities of all citizens."[151] It should be noted that the question of whether religious reasoning should be permitted in the course of deliberative democratic debate is a controversial one,[152] but that should not distract us from the more general principle that deliberative democracy – in order to imbue the policy formulation process with greater legitimacy – relies on restrictions on the kinds of reasons given in the course of debate.

Described in more positive terms, Joshua Cohen argues that the restrictions placed on reasons in deliberation must comport with *substantive* ideals of fairness and equality of opportunity: "if one accepts the democratic process, agreeing that adults are, more or less without exception, to have access to it, then one cannot accept as a reason within that same process that some are worth less than others or that the interests of one group are to count for less than others."[153] Per Cohen's invocation of liberal inclusiveness, we might think that certain religious reasons are acceptable in the course of debate only insofar as they do not impinge on other citizens' rights to equality and fair opportunity. Though this prescription appears more inclusive and pluralistic than Gutmann and Thompson's negative formulation, both agree that mutual respect and civility (in a robust, not merely cosmetic sense) must be hallmark features of deliberative democratic debate.

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[151] Gutmann and Thompson, *Democracy and Disagreement*, 65.

[152] Whether religious reasoning constitutes the imposition of doctrine or should be considered within the realm of reciprocal, mutually-respectful reasoning is a topic of considerable debate within the literature. See, for example, Alan Wertheimer, "Internal Disagreements: Deliberation and Abortion," in *Deliberative Politics* ed. Stephen Macedo (Oxford: Oxford University Press, 1999), 170-183. A particularly strong rebuke to the notion that religious reasoning is out-of-bounds can be found in Robert P. George, "Law Democracy and Moral Disagreement: Reciprocity, Slavery and Abortion," in *Deliberative Politics*, 184-197.

[153] Joshua Cohen, "Procedure and Substance in Deliberative Democracy," in Seyla Benhabib (ed.), *Democracy and Difference* (Princeton, N.J.: Princeton University Press, 1996), 101.

It should be noted here that reciprocity, in the minds of most deliberative theorists, is conceptually distinct from a related concept – impartiality. One might reasonably think that the involvement of patients and the public helps to confer legitimacy on the process through the introduction of impartiality. Current stakeholders responsible for making resource allocation decisions (including pressure group representatives, medical professionals, and other experts) might be seen to be acting according to their respective biases and the introduction of lay members may be seen as a potential solution to correcting this set of professional biases. But the goal of deliberative democracy is not to produce a process that is completely *impartial* (like a system of law) but rather one that is reciprocal and mutually respectful. This difference will be elucidated further in the discussion below about linking norms of reciprocity with the use of PPI.

5.3.2.1 Reciprocity and PPI

If deliberative democracy requires that certain kinds of reasons be given by policy-makers allocating scarce resources, it follows that we ask whether direct involvement by members of the public in the rationing is more likely to produce a process that adheres to this requirement. Or, perhaps more specifically, we might ask whether direct public participation in the process is a constitutive element of reciprocal reasoning.

Supporters of PPI do not often talk about this principle of respect, though they do talk very frequently about the value of contributions that are made by lay members of the public.[154] But while it is certainly the case that the aforementioned perspective of patronizing and condescending to patients has been rightly castigated by patients and

[154] See, e.g., Graham P. Martin, "'Ordinary people only': knowledge, representativeness, and the publics of public participation in healthcare," *Sociology of Health and Illness* 30, no. 1 (2008): 35-54; and Jo Brett, Sophie Staniszewska, and Carole Mockford, et al., "Mapping the impact of patient and public involvement on health and social care research: a systematic review," *Health Expectations* 17, no. 5 (2014): 637-650.

clinicians alike (for the most part), to conflate decisions made at the bedside with those at the policy table is a mistake. First, this sort of reasoning relies on an artificial distinction between "lay people" and experts insofar as it understands lay people as almost an entirely different species. Experts, though they might be inclined towards more technical justifications for particular policies, are likely to still be very well aware of what reasons constitute technical/expert rationales and which ones are more likely to exemplify respect and understanding for average lay individuals.

Second, it is not at all obvious that when patients or members of the public are chosen to participate in various kinds of deliberative forums around health care that the levels of discourse or mutual respect are advanced to any significant degree. And indeed, there is little empirical evidence to support the idea that deliberation fosters more inclusive, tolerant, or respectful discourse, particularly around highly politically charged issues like resource allocation in health care. In her study of town hall meetings in the United States surrounding the 2009 Congressional health care reforms (otherwise known as "Obamacare"), Carrie Menkel-Meadow observed: "Instead of model deliberative sessions, however, most of these sessions turned adversarial (and were then subverted for more 'interrupted' democracy), as they were 'sabotaged' by opponents of national healthcare reform."[155] Of course, not all issues (even those surrounding a contentious issue like health care) will rise to the level of controversy that the 2009 health care reforms did insofar as they represented a fundamental overhaul of the U.S. healthcare system.

[155] Carrie Menkel-Meadow, "Scaling Up Deliberative Democracy As Dispute Resolution in Healthcare Reform: A Work in Progress," *Law and Contemporary Problems* 74, no. 3 (Summer 2011): 1-30.

Similarly, one might respond to this objection by noting, as Fishkin and Luskin have,[156] by claiming that town hall meetings are particularly ill-suited to reason-based deliberation and that other strategies – like deliberative polling – might be more successful in creating the conditions for respectful, reasonable, and dispassionate debate. Though we must, as was noted in the section on transparency, pay particular attention to the ways in which different kinds of PPI advance ideals of reciprocity and mutual respect without drawing blanket over-general conclusions, evidence that PPI efforts as a whole have raised the level of public discourse around health policy issues is scant at best.

5.3.3 Additional Claims Regarding Legitimacy

Two additional arguments tangential to the topic of reciprocity merit mention before continuing. First, Menkel-Meadow takes her criticism of health care reform town halls one step further and argues that one of the principal drawbacks of true deliberation (in the line of Gutmann and Thompson, Cohen, Habermas, and others) is that it dismisses passionate (or what we might otherwise call "emotional") arguments as unworthy. Perhaps more worrisome is that it dismisses passionate or emotional *individuals* from the deliberative discussion insofar as it understands those individuals as unfit for reasonable deliberation despite the fact that their interest in deliberating may very well be linked to the fact that they are passionate about a particular topic. This tension between individuals' motivation for action and the restrictions placed on those very same individuals in the course of deliberation will be a topic of further investigation later in this chapter.

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[156] James S. Fishkin and Robert C. Luskin, "Experimenting with a Democratic Ideal: Deliberative Polling and Public Opinion," *Acta Politica* 40, no. 3 (September 2005): 284-298. See also James S. Fishkin, *When the People Speak: Deliberative Democracy & Public Consultation* (Oxford: Oxford University Press, 2009), esp. Ch. 4-6; Robert C. Luskin, James S. Fishkin, and Roger Jowell, "Considered Opinions: Deliberative Polling in Britain," *British Journal of Political Science* 32, no. 3 (2002): 455-487.

Secondly, while I have briefly addressed the idea that "lay individuals" and experts represent wholly distinct worldviews and thus must both be represented on rationing committees or other resource allocating bodies for mutual respect to be achieved, greater attention is still needed to explain what exactly "lay expertise" is in the first place. Why should we value "lay experts"? Can these lay experts truly remain "lay" after the extensive training required prior to deliberating overly often complex and technical matters? And what, if any value, should we place on the sort of "descriptive representation" on which theories of lay-expertise rely? In other words: is the category "lay person" sufficiently discrete such that an appeal to descriptive representation makes sense?

5.4 Challenges Confronting Patient and Public Involvement

I have argued thus far that PPI's account of legitimacy (through the lens of deliberative democracy) is weak insofar as direct involvement by the public in the policy formulation process does not necessarily provide for greater transparency, accountability, or reciprocal reason-giving. To be sure, the pursuit of these ideals is not incompatible with patient and public involvement, but the mere involvement by the public in the policy-making process does not guarantee or in some cases, even make more likely the furthering of these principles. And though a thorough investigation of the relationship between PPI and deliberative democracy has provided useful background for this discussion, it does not constitute the central thrust of my argument. I move now to articulate the fundamental elements of my argument as to why PPI may actually be detrimental to the democratic character of the policy formulation and implementation processes.

This segment of my argument is divided into three main sections. First, I explore PPI's accountability problem: if individuals deliberating on behalf of their fellow citizens

are not selected directly by those citizens, can PPI uphold democratic accountability? Are there other institutional arrangements that might ensure that principals and agents have a more concrete and clearly defined relationship? Second, I argue that deliberative democracy's focus on dispassionate, rational argument is in tension with the reasons many patients and members of the public elect to participate in deliberations about health care. Absent a reconciling of this tension, PPI cannot live up to deliberative democracy's enunciated standards for debate and discussion. Finally, I posit that PPI promotes a kind of political inequality by deepening the divide between those capable of deliberating and those who cannot. This serves to reify already existing divisions between those of different socio-economic statuses and education levels (among other things), which may itself result in a deficit of diverse democratic participation.

5.5 Accountability Revisited

Put simply, the central thrust of the accountability challenge is that whereas in a representational system of government, lines of accountability between principals (constituents/average citizens) and agents (elected representatives) are clearly delineated, in most PPI regimes, it is entirely unclear how those deliberating on behalf of the public are to be held accountable. As Ian Shapiro writes, regarding the widely heralded case of deliberation around health care in Oregon, "Why should we attach legitimacy at all to a deliberative process that involved very few of those whose health care priorities were actually being discussed?"[157] To be sure, this problem of accountability remains an issue whether or not members of the public are directly involved in the deliberations. But if service by a lay member on a priorities committee or a number of lay members on a

[157] Ian Shapiro, "Enough of Deliberation: Politics is about Interest and Power," in *Deliberative Politics: Essays on Democracy and Disagreement*, ed. Stephen Macedo (New York: Oxford University Press, 1999), 28-38, at 33.

citizens' jury is intended to address that problem, "how" remains to be explained. Of course, this is a fundamental problem not just for PPI but for deliberative democratic theory more broadly as well.

5.5.1 Potential Solutions

For an account of potential solutions to the accountability problem, we turn to one of the most influential recent works on deliberative democracy. In it, John Dryzek articulates three different solutions proposed by other scholars within the literature to the problem of accountability and scale: (1) to limit deliberation to particularly important moments, particularly those of constitutional significance[158]; (2) to "restrict the number of people involved in deliberation," provided that those participating are "in some way representative of those who do not"[159]; and (3) to ask that those who do deliberate "to call to mind the interests of those who do not participate."[160]

But Dryzek forcefully asserts that none of these solutions should be considered good solutions at all. The first, he argues, does not solve the scale problem in any sense – it just limits the number of times that we might encounter the problem. Moreover, if one accepts the premise that most decisions should be made in deliberative frameworks (to be sure, a contentious claim in and of itself but one that is naturally accepted amongst most

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[158] John Dryzek, *Deliberative Democracy and Beyond*, at note 39; See also David Estlund, "Who's Afraid of Deliberative Democracy? The Strategic/Deliberative Dichotomy in Recent Constitutional Jurisprudence," *Texas Law Review* 71 (June 1993): 1437-1477; This argument is also made in more specific historical context by Bruce Ackerman, who argues both that the writing of the U.S. Constitution was one such "deliberative moment" and that because the ability to deliberate should be considered a limited resource, it should only be spent in particularly crucial instances. See Bruce Ackerman, *We The People: Foundations* (Cambridge, MA: Harvard University Press, 1991). Rawls, like Ackerman, suggests that deliberation not be the standard mode of decision-making in government, but rather the method of reasoning when issues concerning "basic justice" and the "equality of opportunity" are at stake. See John Rawls, *Political Liberalism*, at note 128.

[159] John S. Dryzek, "Legitimacy and Economy in Deliberative Democracy," *Political Theory* 29, no. 5 (Oct. 2001): 651-669.

[160] Ibid., 655. See also Robert E. Goodin, "Democratic Deliberation Within," *Philosophy and Public Affairs* 29, no. 1 (2000): 81-109.

deliberative democrats), this solution leaves much to be desired outside so-called "constitutional moments." Finally, this line of reasoning is subject to criticism on the grounds of its internal inconsistency. If we want deliberative democratic procedures and reasoning to guide us in our *most* important decisions (around constitutional questions, for example), how can it be the case that we would not want it around all important questions?

The second (and most commonly offered solution) proves problematic in different ways, by Dryzek's estimation, depending on whether the individuals chosen to represent the population during the course of deliberation are selected via popular election or via random selection. Though one might be tempted to think that direct election would ameliorate the obvious principal-agent accountability problem described above, Dryzek argues that the fact that *the elections themselves* are not deliberative affairs undermines the legitimacy of the process itself. The electoral process, he maintains, is imbued with the very kinds of political speechmaking and interest-group jostling that deliberative democracy seeks to combat. On a more practical level, it may also be the case that should representatives need to be elected for every committee and advisory group on every imaginable issue, the space for public deliberation might very well become saturated and the quality of the deliberative endeavor weakened.

An obvious solution to this problem may be to select individuals for committee or citizens' jury service randomly, much as is done for jury service in criminal and civil courts.[161] But Dryzek rightly points out that random sampling does little to solve the accountability problems insofar as there is no robust mechanism through which those outside the deliberative process should have reason to confer authority to those within the

[161] Such an approach is advocated prominently by James Fishkin in his research on deliberative polling. See James Fishkin, *Democracy and Deliberation: New Directions for Democratic Reform* (New Haven, CT: Yale University Press, 1995).

process. Of course, the public might very well come to understand the logic of a system of random sampling, but two additional problems remain. First, what is to be done if the majority of the public actually disagrees with the outcome of the deliberation? When high profile issues are concerned, we might want to use some kind of deliberative forum or poll to extract reasoned debate from public sentiment, but it does not necessarily follow that the outcomes of such deliberation will align with public preferences. [162] And if and when it does not, unlike in the realm of parliamentary decisions, the public does not have a means to express their displeasure through the ballot box since the individuals accountable to them were not selected through popular means.

The second problem with random selection arises with regard to the scope of issues being discussed. Citizens' juries and deliberative polls almost always require that those deliberating restrict their conversation to a discrete and narrowly bound set of issues. Perhaps on certain "yes/no" policy questions (e.g. should the drinking or voting age be raised or lowered), such limitations on scope are possible, but on many of the most vexing public policy questions that might raise public concern, they are not. Particularly in the realm of health care, it is rare that we find policy questions that might reasonably be limited to such simple yes/no considerations.

A third solution proposed to the accountability problem is that of Robert Goodin, who suggests that those participating in the deliberation engage in "internal-reflective" thinking in which they actively consider the preferences of those outside the deliberation.

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[162] Take, for instance, the late 1990's example of Australian deliberation over whether or not to remain under the British monarchy. Randomly selected deliberators debated and discussed the issue, ultimately arriving at the opposite conclusion regarding remaining under the monarchy as did the voters in a subsequent referendum. See John Uhr, "Testing Deliberative Democracy: The 1999 Australian Republic Referendum," *Government and Opposition* 35, no. 2 (April 2000): 189-210; and James Fishkin, Robert Luskin, and Roger Jowell, "Deliberative Polling and Public Consultation," *Parliamentary Affairs* 53, no. 4 (2000): 657-666.

This, he argues, solves the problem of scale by rendering the population at large "imaginatively present" rather than "conversationally present" during the deliberation.[163] This kind of deliberation represents a conceptual shift the first two solutions described above. For Goodin, the deliberation occurs not just between individuals, but (perhaps most?) importantly, in the mind of each individual deliberator. In its simplest sense, Goodin would have deliberators "put themselves in the shoes" of those outside the process, calling to mind both the concerns and the means of reasoning through those concerns that might be present amongst all of those who are affected by the decision.

Though perhaps theoretically appealing, there is little sense in which Goodin's theory, applied to PPI in practice, would address the accountability concerns I have outlined above. First, Goodin's solution presupposes that there are certain individuals selected for deliberation to represent the population at large. That presupposition does not allow us to avoid confronting all of the aforementioned problems related to either direct election or selection by random lottery. Furthermore, Goodin places a remarkable amount of faith in the selected deliberators, focusing little to not at all on expanding the transparency of the process. This exacerbates the legitimacy problem insofar as deliberative democracy's account of legitimacy is linked heavily to its reason-giving requirement. Put another way, for deliberative democrats legitimacy may not require that everyone be able to deliberate in public en masse, but it does require that all those affected by a decision have access to both the reasons why decisions are made and the process through which they are made. Because Goodin's theory places so much emphasis on *internal* – that is to say, cognitively internal – deliberation, it may actually serve to create a

[163] Robert E. Goodin, "Democratic Deliberation Within," at note 160.

process that is in fact more opaque and by deliberative democrats' own standards, less accountable.

In rejecting these various proposals, Dryzek proposes his own solution, which he describes as "deliberation as a contest of discourses."[164] He suggests "detaching the idea of legitimacy from a head count (real or imaginary) of reflectively consenting individuals," and instead "build[ing] on a conception of discursive democracy that emphasizes the contestation of discourses in the public square."[165] In invoking a Rawlsian conception of public reason, Dryzek maintains further that the process' legitimacy is "achieved when a collective decision is consistent with the constellation of discourses present in the public sphere, in the degree to which this constellation is subject to the reflective control of competent actors."[166] In that sense, Dryzek conceives of the policy legitimation process as a dynamic, iterative one that occurs in the interaction between members of the public and between the public and policymakers.

But his account is also relatively amorphous insofar as legitimacy seems to emerge as sound reasoning bubbles up to the surface. "Sound reasoning carries the day" appears to be the mantra, and yet it is entirely unclear how this concept would manifest in practice. Indeed, our contemporary politics are replete with examples where "emotion," "passion," and "faith"– concepts often derided by deliberative democrats – carry the day. Dryzek also seems to ignore the ways in which powerful institutional interests (political parties, pressure groups, lobbying groups, the media, etc.) affect the way in which his almost Athenian concept of political debate proceeds. Even if we accepted the premise that political legitimacy should be completely de-linked from participatory headcounts (itself a

[164] Dryzek, "Legitimacy and Economy," 657.
[165] Ibid.
[166] Ibid., 660.

highly contentious assumption), there is little (or perhaps no) evidence that the kind of "contest of discourses" envisaged by Dryzek should be considered even remotely possible.

5.5.2 Reflections on Accountability and Representation in Patient and Public Involvement

If none of these solutions can comprehensively address PPI's (and deliberative democracy's) scale problem, are we simply left with the conclusion that policy-making outside the parliamentary realm is necessarily unaccountable? My arguments surrounding deliberative democracy's accountability problem should neither be seen as an argument that the answer to this question is yes nor that representative government writ large is unaccountable. Indeed, as I shall argue later, there are a number of actions (outside the realm of PPI) that governments (or indeed, private organizations administering health care plans) might take in order to foster greater transparency and accountability.

Nonetheless, my arguments here do suggest that current solutions to the scale problem have proven largely unsuccessful. While supporters of PPI have artfully found ways to implement deliberative democratic ideals through the use of representation (typically not by popular election), deliberative polls, and citizens' juries, they have not clearly articulated why those mechanisms of ensuring public involvement have bolstered the legitimacy of the process. In other words, the focus to this point has merely been on involving the public under the theory that it is the *involvement itself* that is the critical link to accountability rather than on the *way in which the public is involved*. A discussion of the latter, I maintain, is vital if PPI is to successfully claim to strengthen the legitimacy of the policy-making process.

Before transitioning to discuss PPI's problem with incentives to participate, I offer three broad conclusions regarding accountability and representation. First, in order for PPI

to satisfy deliberative democracy's claim to legitimacy and if representatives are chosen to deliberate, lines of accountability must be clearly delineated. A natural response to this argument is to look at all of the instances in which government bureaucrats and technocrats make decisions in spite of the fact that they themselves are not directly elected by the population. But in all of those instances, *someone* directly elected can be held accountable, even if that individual held accountable was not personally responsible for the decision at hand. Discursive theories of legitimacy have some conceptual appeal in dealing with the scale problem, but in effect they sidestep the issue since at the end of the day, a smaller subset of individuals is still making decisions on behalf of the population. And that, in and of itself, necessitates an inquiry into how those individuals are selected and how they might be held accountable.

Second, though selection by lot (otherwise known as stratified random sampling) has gained momentum amongst scholars for use in deliberative polls and citizens' juries, we should only allow the use of such random selection where information gathering is concerned.[167] Just as technocrats and expert witnesses might be useful to elected officials making decisions, so too might "lay citizens" in the course of deliberation provide useful information or testimony to decision-makers. Parkinson notes that careful attention must be paid to the way in which an information gathering forum is constructed in that "the relationship between organizers and participants is often a hierarchical one" where "the participants are subordinate, providing information rather than being active citizens in self-

[167] This point is made explicitly by Parkinson as well. See Parkinson, *Deliberating in the Real World*, 35 and 74-84.

government."[168] Though the tenor and structure of the forum may very well be a cause for concern, average citizens should nonetheless not be dismissed out of hand.

Finally, I argue that though election of representatives to a deliberative forum might strengthen the bonds of accountability, in practice, this solution is likely to prove unworkable. As was noted, the environment of campaigns is not conducive to the kind dispassionate reasoning and careful consideration that remain the hallmarks of deliberative democracy.[169] Because campaigns rely little on deliberative reasoning and more on speechmaking, persuasion, and promise-making, denigration of one's opponent, there is little evidence to suggest that elections for representatives in place of PPI would result in a process which honours the foundational principles of deliberative democracy. All that said, I maintain that elements of deliberative democracy can be infused into our already existing systems of parliamentary/congressional and administrative/agency decision-making. I will engage in a more thorough exposition of those ideas and their potential practical application in chapter 7.

5.6 Show of Hands: Who Wants to Deliberate?

The second major issue confronting patient and public involvement is that of the motivation to deliberate. Deliberation in almost any setting (citizens' jury, deliberative poll, micro-deliberative committee) requires time, effort, and in certain instances, money. If we assume that deliberating in any of these contexts is unlike jury duty in that it is not considered a compulsory element of citizenship, it is worth asking why individuals would

[168] Ibid., 34.
[169] This point is made widely by a number of theorists. See, for example, Joohan Kim, Robert O. Wyatt, and Elihu Katz, "News, Talk, Opinion, Participation: The Part Played by Conversation in Deliberative Democracy," *Political Communication* 16, no. 4 (1999): 361-385; Adam E. Simon, *The Winning Message: Candidate Behavior, Campaign Discourse, and Democracy* (Cambridge, UK: Cambridge University Press, 2002), esp. Ch. 1-3; and Fishkin, *When the People Speak*, Ch. 3.

choose to deliberate and whether their motivations have any bearing on the legitimacy of the process.

I divide my discussion of motivational concerns into two broad sub-categories. The first motivational issue facing deliberation is that of political equality. Deliberative democracy, as Cohen suggests, requires participants to be "both formally and substantively *equal*" (emphasis original).[170] But as I shall argue, deliberative forums and those related to PPI in particular have a strong tendency to favor participation by men, those with higher levels of education, and the wealthy. The second concerns the non-monetary reasons that most individuals might choose to be part of a deliberative scheme. As has been discussed already at length, deliberative democracy requires of its participants a willingness to leave all prior prejudices and opinions at the door and allow themselves to enter into the deliberation as unbiased as possible in an effort to, as Cohen writes, "arrive at a rationally motivated consensus."[171] But for most individuals drawn to deliberation, it is their passion around a given issue (in our case, health care) that brings them to the deliberation in the first place.

5.6.1 The Challenge of Political Equality

One problem facing supporters of PPI is that PPI as a particular example of deliberative democracy requires that political equality be preserved. As Cohen observes, participants in a just deliberative forum must be "formally equal in that the rules defining the procedure do not single out individuals for advantage or disadvantage" but also "substantively equal in that the existing distribution of power and resources does not shape their chances to contribute at any stage of the deliberative process, nor does that

[170] Ibid.
[171] Joshua Cohen, "Economic Basis of Deliberative Democracy," *Social Philosophy and Policy* 6, no. 2 (1989): 25-50, at 33.

distribution play an authoritative role in their deliberation."[172] My concern here is not with the formal procedures (the solutions to their potential problems being ostensibly more readily available) but with what Cohen calls "substantive equality." How does (or can) PPI ensure that all those individuals coming to the table be treated in the course of debate as substantive equals?

5.6.1.1 What is Political Equality?

Before attempting to understand the ways in which PPI might affirm or undercut political equality amongst citizens, it is important that we stop briefly to consider what political equality requires in the context of deliberative democracy. To be clear, this section is not an effort to understand the relationship between political equality and democracy writ large; indeed, that would not only be an entirely different dissertation altogether, but it is a subject broad enough to fill several stacks in most university libraries. In addressing this distinction, Jack Knight and James Johnson write that "democratic deliberation requires *equal opportunity of access to political influence*. Influence is more than mere voting"[173] Dworkin, in attempting to elucidate the difference between influence and voting, argues: "The intuitive difference is this: someone's impact in politics is the difference he can make, just on his own, by voting for, or choosing, one decision rather than another. Someone's influence, on the other hand, is the difference he can make not just on his own, but also by leading or inducing others to believe or vote or choose as he does."[174] For Knight and Johnson, the central question concerning political equality is

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[172] Ibid.
[173] Jack Knight and James Johnson, "What sort of political equality does deliberative democracy require?" in James Bohman and William Rehg (eds.), *Deliberative Democracy: Essays on Reason and Politics* (Cambridge, MA: MIT Press, 1997).
[174] Ronald Dworkin, *Sovereign Virtue: The Theory and Practice of Equality* (Cambridge, Mass.: Harvard University Press, 2002), 191.

whether deliberative democracy advances *both* procedural and substantive equality. In that sense, "equality of opportunity" must both concern the access that individuals have to deliberative forums independent of any demographic features (procedural equality) and the relative abilities of individuals to participate substantively in political discussion (substantive equality).

To be fair, a number of critiques may respond to this notion of political equality. Some may object to the notion that democracy can function if one of its prerequisites is that all citizens are endowed with equal capacities to contribute to democratic debate and decision-making. Others might suggest that this articulation of political equality in the realm of deliberative democracy is in reality, little more than a broad-based critique of liberal democracy. After all, is it not the case that in most (if not all) representative democracies, certain individuals (by virtue of education, socio-economic status, and natural skills) are more capable than others at participating actively in the political process? We might very well think of the right to vote as a manifestation of political equality while all the while recognizing that other elements of the political process (campaigning, lobbying, interest group participation, fundraising, etc.) are distributed unequally in society.

Because this dissertation is not concerned with the overall justness of democracy (or even deliberative democracy) but rather with the account of legitimacy proffered by deliberative democracy, equality is important *at the very least* because of its contribution to process legitimacy. As Cohen explains, "free deliberation among equals is the basis of legitimacy."[175] Indeed, Gutmann and Thompson also spend a significant portion of time explaining that both the procedures governing deliberative democracy and the outcomes it

[175] Cohen, "The Economic Basis for Deliberative Democracy," *Social Philosophy and Policy* 6, no. 2 (1989): 31.

produces must honour principles of fair opportunity. While their concern (and that of Knight and Johnson) relates to deliberative democracy's claim to *moral* legitimacy, my interest in its *political* legitimacy cannot so easily be de-linked from moral considerations. Though we may accept that not all elements of a liberal democratic system are moral,[176] we are nonetheless concerned in particular with the ways in which particular moral shortcomings of the system serve to undermine its claim to broader moral and political legitimacy. We move now to discuss the ways in which PPI undermines political equality in ways that are detrimental to the legitimacy of the political process.

5.6.1.2 Political Equality and PPI

The first element of this problem concerns the ways in which deliberative democracy incorporates (or excludes) the voices and opinions of historically oppressed and marginalized groups – women, ethnic minorities, etc. As I have emphasized, deliberative democrats are steadfast in their assertion that deliberation take place in a formal, often dispassionate way. But individuals from some of these minority backgrounds are often thought to not abide by the same "rules," so to speak, as their majority counterparts. Women, for example, responding to a long history of being shut out of policy-making forums and high-level business environments, may be more hesitant to assert themselves strongly and therefore feel as if they have less access to these kinds of deliberative forums. The motivation to deliberate, then, should be conceived of as intimately connected to the

[176] Consider, for example, the moral tensions that arise between liberal democracy and capitalist economics. Though capitalism is not *necessarily* an intrinsic element of liberal democracy, the two are seemingly inextricably linked in contemporary society. But, the moral tensions that arise between the two have been the subject of considerable debate amongst scholars. See, for example Samuel Bowles and Herbert Gintis, *Democracy and Capitalism: Property, Community, and the Contradictions of Modern Social Thought* (Basic Books/Routledge: New York, 1986); and Joshua Cohen, "Deliberation and Democratic Legitimacy" in *Debates in Contemporary Political Philosophy: An Anthology*, (ed.) Derek Matravers and Jon Pike (Routledge: New York, 2003).

beliefs that participants have (rightly or wrongly) that their participation, in some basic way, *matters*.

While some may remain unconvinced that there are such things as "minority speech cultures" that are dissonant with Western modes of reasoning and deliberation, it would be difficult to contest the notion that deliberative forums are more "open," as it were, to those with stronger educational backgrounds (and by correlation, if not causation, socioeconomic statuses). As many observers of actual deliberation have noted, those with stronger educational backgrounds are more likely to (1) be capable of deliberating according to the vision of deliberation described above and (2) have the resources needed to deliberate (e.g. additional available time).[177]

A different – but related – problem arises due to the division between lay people and experts in the realm of PPI. There is strong evidence to suggest that when PPI involves not just lay people deliberating amongst themselves (e.g. a citizens' jury) but instead interaction between so-called experts and members of the public, that those participants frequently complain that they feel (or have evidence to believe) that the impact they have on the actual policy making process is negligible. In discussing the impact of patient involvement on various policy planning committees in the UK, for example, Coulter explains that "Many of the current NHS initiatives that go under the banner of patient and public involvement are little more than window dressing. Including a few token patients on committees is relatively easy, but it does little to tackle the heart of the problem."[178]

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[177] See Knight and Johnson, "What sort of political equality does deliberative democracy require?" at note 173.

[178] Angela Coulter, "The NHS Revolution: Health Care in the Market Place. What do Patients and the Public Want from Primary Care?" *British Medical Journal* 331 (2005): 1199.

The problem, however, is hardly unique to the UK. Though PPI has much less robust support in the United States, there have been some efforts to increase public involvement, particularly within the National Institutes of Health (N.I.H.). The Director's Council of Public Representatives (COPR), created by then NIH Director Harold Varmus, was tasked with advising the NIH director on a variety of matters drawing on the experiences of the lay public. But when interviewed, participants on that committee voiced many of the exact same concerns that were voiced by patients in the UK National PCT survey discussed above. As Eileen Burgin explains (citing such interviews): "'COPR is window dressing, a good-will group to bridge the chasm between NIH and the public.' Another informant concurred: ''they [NIH administrators] saw us as a buffer, as a shield, as a spearcatcher. ... COPR was an audience, not a participant. We were just dummies being briefed.'"[179] Though the belief that one's involvement in PPI is unlikely to yield influence is substantively different than the idea that minorities *by their very nature* are more likely to be excluded from the policy process, they present a similar problem: if PPI is to create a more democratic (and importantly, *democratically equal*) process, how can it overcome these critical barriers to egalitarian participation?

The (seemingly) obvious answer to this question is to somehow widen the kinds of arguments and types of arguing that might be accepted in deliberative forums. If minority speech styles are marginalized, then efforts might be made to ensure that a diversity of viewpoints and means of expressing those viewpoints are accepted and considered. The same argument might very well be made in the realm of lay interaction with experts. The question of "lay knowledge" being marginalized and excluded by experts has been well

[179] Eileen Burgin, "Dollars, Disease, and Democracy: Has the Director's Council of Public Representatives improved the National Institutes of Health," *Politics and the Life Sciences* 24 (2006): 43-63; 48.

covered within the literature.[180] The question, however, of how to persuade experts to see lay individuals as possessing valuable contributions worthy of consideration is much more complex. Indeed, as we will soon see from the empirical case study investigations, the forces at work preserving the autonomy of experts are extremely strong, and it would be naïve (at best) to assert that one might simply "fiat from on high" any of these reforms. As a result, the political inequality that, as an empirical matter, appears to be intrinsic to PPI and other forms of democratic deliberation raises serious questions about whether PPI can truly lay claim to fostering egalitarian democratic flourishing.

5.6.2 Passion for Issues

Some might be inclined to accept the notion that some measure of inequality (be it economic, educational, etc.) is inevitable in a democratic capitalist society. We should strive to reduce that inequality, they might argue, but its very existence should not be seen as an impediment to democratic deliberation. But while questions of inequality bring *external* problems to theories of democratic deliberation, a passion for issues – what Parkinson calls "pre-deliberative commitments"[181] – pose an *internal* challenge to the process of deliberative democracy. That is to say – PPI, as an espoused iteration of deliberative democracy, relies fundamentally on dispassionate, reason-based decision-making, and yet it draws simultaneously on citizens' passion for the issues at hand to bring them to the table in the first place.

Why individuals choose to participate in various kinds of deliberations remains a subject of continued research, but at least with regard to PPI, current evidence suggests that when individuals choose to commit the time necessary to sit regularly on a committee, it is

[180] For what is perhaps the most comprehensive and lucid work addressing this matter, see Harry Collins and Robert Evans, *Rethinking Expertise* (Chicago: University of Chicago Press, 2007).
[181] Parkinson, *Deliberating in the Real World*, Ch. 2.

because they care passionately about the issue.[182] And, it would seem to follow, those willing to put forth that time commitment are more likely than their peers to have (a) an invested stake in the outcome of the decision and (b) pre-formed opinions on the question(s) being discussed.[183] In her work examining the relationship between political activism and democratic deliberation, Iris Young highlights the fundamental tension between the two:

> Besides being motivated by a passion for justice, the activist is often also propelled by anger or frustration at what he judges is the intransigence of people in power in existing institutions, who behave with arrogance and indifference toward the injustices the activist finds they perpetuate or flatly deny them and rationalize their decisions and the institutions they serve as beneficent.[184]

Though Young's point is slightly different (her argument being that activists are shut out of the deliberative discussion), the thrust of her argument remains relevant. Despite the fact that most members of the general public care about how, for example, priorities are set with regard to health care, the vast majority simply do not have additional time to devote to the kind of committee work advocated by PPI supporters. As a review of England's 2005 national patient survey found: "Including patients in planning developments to the service has had some positive results, but direct involvement is likely to remain a minority activity. Most people are not members of organised patients' groups, and only a minority want to sit on policy committees."[185] The survey found further that of those who do want to sit on

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[182] For extensive interview/focus group evidence on this question, see Andrea Litva, Joanna Coast, Jenny Donovan, and John Eyles, et al., "'The public is too subjective': public involvement at different levels of health-care decision making," *Social Science and Medicine* 54 (2002): 1825-1837.
[183] Iris Young, "Activist Challenges to Deliberative Democracy," *Political Theory* 29 (Oct. 2001): 670-690.
[184] Ibid, 673.
[185] Coulter, "The NHS Revolution: Health Care in the Market Place?" at note 178.

policy committees, a plurality were members of organised interest groups or were themselves in the midst of dealing with a serious health condition.

The problem here is not just that it might be logistically difficult to find individuals to deliberate who are completely unattached or dispassionate regarding very real and often deeply personal questions concerning resource allocation or medical research. It is also that an aversion to incorporating the views of those who have experience or interests at stake wrongly presupposes that impartiality is the articulated aspirational ideal in policymaking according to deliberative democrats. We might very well accept in the realm of criminal justice, for example, impartiality and an ability to apply the law without prejudice is a cornerstone of a fair system. But as Ian Young argues, the level of political debate is sometimes heightened when infused with the kind of passion and emotion that activists bring to the table. This is not to say that those activists should be exempt from the need to engage in civil and rational discourse; rather, that in matters that concern our families, communities, and country, we might have very good reason to be partial to one position or another *entering the discussion*.

5.6.3 The (Problematic?) Question of Passion

But why exactly should we be concerned with individuals entering the discussion with pre-formed beliefs (aside from the fact that deliberative democracy insists on dispassionate reasoning)? Is it not naturally the case that on almost any issue of public policy, members of an informed citizenry come to the table with at least *some* already existing thoughts? And more specifically, does this concern with these "pre-deliberative commitments" pose a particularly vexing problem in the realm of PPI?

First, there may be good reason to think that we want individuals to come to the table with their prior beliefs and experiences, very much unlike a jury in criminal court. And, moreover, it may very well be the case that powerful political and business interests are an inevitable force in participating in the resolution of moral disputes. Like Young, Ian Shapiro is skeptical that such pre-deliberative opinions can simply be cast aside. But Shapiro's argument extends further, arguing that deliberative democrats' narrow focus on reason carrying the day ignores larger institutions of power that serve to structure the way our politics proceed. This focus on reason and rationality in micro-deliberative forums, he maintains, "attends too little to the degree to which moral disagreements in politics are shaped by the differences of interest and power."[186]

This argument seems to be particularly salient in the realm of health care where powerful interests representing clinicians, patients, hospitals and pharmaceutical companies all have strong financial and moral incentives to speak passionately on any number of topical issues. One need not look very far to understand that even where attempts to foster deliberation of the Gutmann/Thompson variety were present, interest groups representing any number of constituencies ultimately were able to use considerable force to co-opt the process. Indeed, both health care reform efforts in the United States in 1994 and 2010 and in the state of Oregon in 1993 relied heavily (at least in theory) on extensive "community forum" and "town hall meetings" and yet there is little empirical evidence to suggest that those meetings had but a fraction of the influence of the aforementioned interest groups in the policy process.[187] There may be reason to believe that the kind of deliberation

[186] Ian Shapiro, "Enough of Deliberation" at note 157, 29.
[187] Jonathan Oberlander, Theodore Marmor, and Lawrence Jacobs, "Rationing medical care: rhetoric and reality in the Oregon Health Plan," *Canadian Medical Association Journal* 164, no. 11 (2001): 1583-1587.

envisaged by deliberative democrats is simply more appropriate when dealing with smaller-scale and less politically charged issues, though that concession would assuredly call into the question the broader utility of PPI as a policy formulation strategy.

If the first problem of deliberative democracy's insistence on dispassionate reasoning invokes charges of political naiveté, the second critique approaches pre-deliberative commitments from the perspective of deliberative democracy's own enunciated standards. That is to say – if, for deliberative democrats, policy formulation is centrally about reason-giving and that such reason-giving demands that individuals are willing to persuaded by new arguments, then it follows that individuals need enter the deliberative space without deeply held or strongly formed opinions on given topics. The problem for PPI, therefore, is that the individuals who are most likely to want to participate in deliberation about health care issues (from an empirical perspective) are those individuals who have personal experiences that have catalyzed that particular interest. It is for this reason that policy-makers often talk about the "patient" in "patient and public involvement." For them, PPI is not just a means to arrive at more just or publically reflective policies, but rather a *mechanism of empowerment* for individuals who, as lay people, feel shut out of decision-making in the health care system. The central problem, then, is that PPI's dual goals of fulfilling deliberative democracy's desire for more just policymaking and empowering the disempowered stand in conflict with one another.

Thus, my critique of deliberative democracy's dispassionate reasoning requirement comes from two perspectives. The first suggests that such an ideal is not attainable (indeed, perhaps not even necessarily desirable) from the perspective of political realities. The second, accepting the premise that such external pressures were not insurmountable, posits

that given individual motivations to participate in the kind of deliberations envisaged by PPI supporters, the kind of dispassionate reasoning required by deliberative democrats is not achievable. And, indeed, if at least a part of PPI's espoused goal is to empower citizens and patients, requiring that those who deliberate bear no relation to the issue at hand would seem at least partially counterproductive. Perhaps the more fundamental point is that given the sheer pervasiveness of health care in contemporary society, finding a person who brings no opinions about resource allocation issues to the table but is nonetheless a capable and engaged deliberator may constitute a tall order.

5.7 Conclusion

The central goal of this chapter was to understand the relationship between PPI and deliberative democracy and the extent to which PPI is responsible for strengthening the legitimacy of policy-making in the realm of resource allocation. I argued that while some might consider direct public participation a constitutive element of deliberative democracy, the extent to which it is a decisive factor in creating a more legitimate forum for policy-making is limited. Three main conclusions arise from my analysis here.

First, deliberative democracy must be understood as an assemblage of different ideals and practices, rather than as a single, all-encompassing concept. Deliberative democrats espouse support for a range of practices and ideals – transparency, a focus on reason-giving, public participation in decision-making, pursuit of substantive goals involving equal opportunity, liberty, etc. As such, we should devote a greater amount of time to understanding the particular ways in which these individual ideals are themselves important and the ways in which they might be affirmed and furthered. In other words – deliberative democracy should not be thought of as a recipe whereby the ingredients in the

final product cannot be distinguished and are all equally essential to produce the final outcome. Certain parts of the "recipe," if you will, may very well be more important than others in producing the eventual outcome. My contention here has been that public involvement (as articulated by proponents of PPI) is much less significant than other policies we might consider implementing vis-à-vis deliberative democracy's reason-giving, transparency, and accountability requirements.

Second, where PPI involves not just information gathering but actual decision-making and implementation, lack of explicit lines of accountability serve to undermine the legitimacy of public involvement. PPI, in relying on the misguided notion that there is a singular "public" that needs to be represented in decisions about healthcare rather than a diverse set of beliefs in the population, errs in assigning responsibility for decision-making to individuals who stand answerable to no one. In effect, implementation of public involvement in this way could undercut other reforms to the resource allocation system that strengthen transparency and reason-giving. The key failure here is the assumption that in matters of technocratic complexity, the "public" can simply be understood as a monolithic group of people who approach these sorts of problems in a singular way. That mode of thinking is both fundamentally flawed, and potentially dangerous from the perspective of democratic accountability.

Finally, a debate about PPI must not ignore the fact that policy-making takes place under very specific socio-economic, cultural, and political conditions. It would be at best naïve to ignore the fact that where greater responsibility for decision-making is vested in the hands of the public writ large, that certain segments of that population will necessarily

enjoy more empowerment than others. This, as has been discussed, is not necessarily a unique criticism of deliberative democracy, but it must be taken into account nonetheless.

The central thrust of my argument, then, is not that the principles that deliberative democracy seeks to uphold are themselves flawed; rather, it is that a narrow focus on increasing public involvement ignores the fact that other reforms to the process of resource allocation may be more effective at furthering the underlying ideals of deliberative democracy. A more thorough elucidation of those potential policy reforms will follow in chapter 7. Finally, it is worth noting that the criticisms discussed here do not exist in a theoretical vacuum. Though this chapter did not rely heavily on empirical analysis, we will turn now to a series of case studies that help to show how these problems with PPI manifest "on the ground."

6
Case Studies in Patient and Public Involvement

6.1 Introduction

To this point, my discussion of patient and public involvement has remained largely in the realm of theory – in discussions about deliberative democracy, the value and constitution of so-called "lay expertise" and in theoretical debates about the ways in which outcome-centred thinking can provide a framework for understanding the value of PPI. PPI, however, is not just a theoretical construct, but a set of ideas that have been implemented in practice in a variety of schemes and iterations over the past several decades. Though in chapter 2 I argued that PPI should be understood as the heterogeneous concept that it is, there nonetheless exists a class of activities that might reasonably be considered under the umbrella of the term "PPI."

In this chapter we turn to review some of the practical experiences that nations, states, provinces, localities, and individual hospitals and health care systems have had in implementing practices in accordance with PPI. My goal here is not simply to provide a catalog of historical examples, but to critically examine the ways in which PPI – *in practice* – has both succeeded and failed to accomplish its own objectives. I have attempted to draw on case studies that reflect the diversity of ways in which involvement takes place, the settings in which that involvement takes place, and the types of issue on which the public's input is sought. Given the fact that PPI has been used within the literature to refer to an extremely broad spectrum of activities, the case studies studied here will inevitably remain only partially representative as a whole. That said, investigating both what has worked and

what has not with regard to patient and public involvement not only serves to test the theoretical framework I have developed in this dissertation, but also helps point the way forward in terms of understanding what practices should be replicated and what practices improved upon in this area.

Ultimately, the case studies that are discussed in this chapter serve two primary functions in the overall architecture of this thesis. First, they connect the theoretical arguments that have been throughout the preceding chapters to the real-world ways in which PPI advocates have sought to implement their ideas. Second, they provide a framework through which we can evaluate and critique the ways in which PPI actually works in practice and to suggest ways in which certain manifestations of PPI have been more or less successful than others.. In this way, the case studies enable us to understand the ways in which PPI – as it has been currently implemented – lives up to and falls short of the deliberative ideal.

This chapter proceeds in two main sections. I have elected to separate my analysis of individual case studies into those that concern involving the public in research design and governance and those that concern resource allocation. As I have already argued earlier in this dissertation, there are far more compelling reasons to directly involve the public in research design (particularly when such research is of the clinical or applied variety) and less compelling reasons to directly involve the public in decisions about resource allocation, priority setting, or the approval of certain treatments and therapies for coverage. This fact, I believe, is made even clearer in an evaluation of the case studies that are to follow in this chapter. I conclude, ultimately, that PPI is a subtly complicated set of

practices, and that researchers and practitioners would do well to disaggregate the concept into its distinct component parts.

First, I examine two examples of user/patient involvement in the design of medical research and the governance of research protocols. These examples are drawn from both the United States and the United Kingdom. I then turn briefly to consider PPI in the context of allocation of funds for medical research, a subject which to some extent exists on the border between the concepts of medical research and resource allocation. And finally, I look at public involvement in the realm of resource allocation, drawing on the Oregon Medicaid experiment (U.S.) and the NHS Plan (U.K.).

It is also worth noting that this chapter spends significantly more time devoted to understanding PPI in the context of resource allocation and priority setting than it does to PPI in the realm of medical research. The reasons for this are twofold: first, in large measure, PPI in research is technically, logistically, and even politically less complicated. The examples in research are not typically particularly controversial, and the means by which we can measure their success or failure are far more straightforward. Second, as I have argued already, PPI presents far more normative challenges in the realm of resource allocation where issues of political accountability and equality abound. As a result, I have elected to devote more attention to understanding the way in which these theoretical issues manifest in practice.

Finally, I want to emphasize that though these case studies cannot be said to be wholly representative of the range of activities under the PPI umbrella, there is good reason to think that that they do represent at least a large cross-section of the activities that take place under the rubric of PPI. To be sure, they do come exclusively from the developed

world; but, as I have argued earlier, patient engagement in research in the developing world raises a series of separate questions regarding the relationship between the researchers and the research subjects that are less salient in developed world settings.[188]

Methodology for Case Study Selection

Meta-analyses of PPI reveal dozens of studies of PPI being implemented in practice[189] and as a result, the decision of which examples to include and exclude is a complicated one. Readers of this thesis might very reasonably ask to main questions of the case studies selected in this thesis: (1) why were *these* case studies selected?; and (2) why were the case studies selected only from the United States and the United Kingdom?

Given the broad nature of the types of involvement that have been discussed in this thesis, I have selected case studies that represent a relatively wide swath of activities. Keeping in mind that the overall reason to include the case studies in the first place is to highlight the ways in which PPI in practice has succeeded and failed to live up to the deliberative ideal, I sought to include examples that covered a breadth of *ways* in which involvement takes place. The process of selection occurred as follows: I first divided my

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[188] The difference between involvement of the public in developing countries vs. that in developed countries has been the subject of considerable debate and research. See E.S. Nilsen, H.T. Myrhaug, M. Johansen, S. Oliver, and A.D. Oxman, "Methods of consumer involvement in developing healthcare policy and research, clinical practice guidelines and patient information material (Review)," Cochrane *Database of Systematic Reviews* 3 (2006) Art. No.: CD004563. DOI: 10.1002/14651858.CD004563.pub2; S.R. Benatar, " Reflections and Recommendations on research ethics in developing countries," *Social Science & Medicine* 54, no. 7 (2002): 1131-1141; C.S. Molyneux, D.R. Wassenaar, N. Peshu, and K. Marsh, "'Even if they ask you to stand by a tree all day, you will have to do it (laughter)…!': Community voices on the notion and practice of informed consent for biomedical research in developing countries," *Social Science & Medicine* 61 (2005): 443-454; Paulina Tindana, et al., "Grand Challenges in Global Health: Community Engagement in Research in Developing Countries," *PLOS Medicine* 4 (2007): e273; Emanuel, Wendler, Killen, and Grady, "What Makes Clinical Research in Developing Countries Ethical?" at note 65.

[189] See Carole Mockford, Sophie Staniszewska, Frances Griffiths, and Sandra Herron-Marx, "The impact of patient and public involvement on UK NHS health care: a systematic review," *International Journal for Quality in Health Care* 24, no. 1 (2012): 28-38; and Jill Murie and Gerrie Douglas-Scott, "Developing an evidence base for patient and public involvement," *Clinical Governance: An International Journal* 9, no. 3 (2004): 147-154.

search into examples around involvement in research and involvement in funding allocation/public health policy. A review of dozens of examples within the literature revealed that the ways in which patients are involved in crafting or refining research are actually highly similar to one another. In most cases, researchers determine an overall area of research or a particular research question around a disease or condition and then bring in patients afflicted with that condition to help either refine or focus the research. In some cases, collaboration with patients is used to find the initial research question at the outset, though that is decidedly more unusual given the reticence of researchers, clinicians, and scientists to cede authority to patients. More often, these patients are helping researchers refine the research question or focus on certain outcome variables that patients might consider important but that have traditionally gone overlooked by the research community. The case example of Ataxia at the University College Hospital in London was therefore selected because it represented a large number of other examples of patient collaboration in research in which patients are consulted to help define or refine the research to make it more relevant/applicable to patients. The case study of Informed Consent at the VA Hospitals in the US was selected in large measure because it is one of the only randomized trials on PPI in existence today. It too sought advice from patients affected in an attempt to improve the effectiveness of a clinical protocol, but the study was also able to measure the effectiveness of that intervention more systematically than others given the nature of the study.

Examples concerning PPI in the context of resource allocation and public health policy are less numerous than those in research, but also more heterogeneous in terms of context, type of involvement, and level of decision-making (e.g. local, regional, national).

The case studies selected here are meant to capture some of that breadth while also focusing on examples that were relatively high profile (and therefore around which there is more publically available information). Public participation in NIH funding allocation decisions is discussed largely because it is the most significant example of PPI in the realm of funding allocation for research as the NIH is – by far – the world's largest funder of biomedical research. The case studies of the NHS Plan and the Oregon Medicaid Experiment were selected because they are two of the largest and most significant examples of PPI in the realm of public health planning to date. Not only were they considered significant in terms of size and scope, but as we will see, they were implemented with the express purpose of trying to foster greater public debate and attention on matters of broad government policy decisions. In that sense, they serve as useful examples in testing PPI's ability to create more legitimate forums for government decision-making.

Finally, I selected the case example of NICE and the ways in which it has implemented patient and public involvement because, to my knowledge, it is the best example of PPI "living up," as it were, to the deliberative ideal. This example sits in contrast to many of the other examples that are discussed earlier in the chapter and highlights ways in which PPI policy can be consonant with the principles of deliberation that have been discussed extensively throughout this thesis. Though, as we will see, the NICE example does not abide completely by the prescriptions of deliberative democratic theory, it does serve as a good working test case of how PPI can foster more deliberative, accountable, and transparent government decision-making. It is also a vital example in that it shows that PPI can further the deliberative ideal particularly well when it sits within a

broader framework of transparent and accountable decision-making – in that sense, the steps that NICE has taken beyond just involvement prove important in my analysis.

The case studies here come primarily from the United States and the United Kingdom, two countries that sit not on opposite sides, but certainly far apart on the PPI spectrum. I have elected to draw from these two countries for two main reasons: first, they represent two relatively different orientations towards the broad philosophical approach supporting greater involvement. The UK, like much of the rest of Europe, has used PPI as a framework to guide some important decisions around both health care research and resource allocation. In the United States, patient autonomy and empowerment remains a powerful social and cultural force in health care, but the push for greater citizen involvement has remained less robust. The root of these differences is not my most pressing concern here, but it has been examined elsewhere.[190] And secondly, these are the countries with which I am most personally familiar and thus I am able to comment in a more informed way on the political, social, and economic factors that have influenced user involvement. Still, in reviewing the literature on patient and public involvement, there is little reason to believe that the kinds of PPI implemented in other European countries (or in Canada or Australia) differ substantially from the examples that are discussed here. In that sense, these examples should be seen as – at least to some degree – representative of the whole.

6.2 Patient and Public Involvement in Medical Research Design

I have already outlined the ways in which patients and members of the public can be involved in research conception, design, and implementation, but a brief review is

[190] Antoine Boivin, et al., "Patient and public involvement in clinical guidelines: international experiences and future perspectives," *Qual Saf Health Care* 19 (2010): 1-4.

worthwhile. INVOLVE, for example, advocates for a greater public role in "working with research funders to prioritize research, offering advice as members of a project steering group, commenting on and developing research materials, undertaking interviews with research participants."[191] The vast majority of these efforts occur, therefore, at what we might call the "local level" – that is to say, in hospitals, research centres, and medical clinics. As a result, the case studies that follow represent small-scale efforts to involve the public, rather than national or state/province-level decisions about the structure of the health care system. Finally, it should be noted that the goal of this review is not to be comprehensive. Several other studies have engaged in systematic reviews of studies of patient and public involvement,[192] but my goal here is instead to locate individual case studies within the context of the theoretical debate that has been outlined and developed throughout the course of this thesis.

6.2.1 Case Study #1 – Treatments for Ataxia at the University College Hospital and University College London (UK)

Our first case study for investigation concerning user involvement in research comes from a collaboration between physicians, scientists, and patients at the University College Hospital and University College London intended to develop a more holistic approach to treating the neurodegenerative set of illnesses known as ataxia. Ataxia, broadly speaking, is a group of more than 100 neurodegenerative conditions that come

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[191] "What is public involvement in research?" *INVOLVE, UK National Institute for Health Research,* accessed January 22, 2014, http://www.invo.org.uk/posttypefaq/what-is-public-involvement-in-research/.

[192] Jonathan Boote, Wendy Baird, and Claire Beecroft, "Public involvement at the design state of primary health research: A narrative review of case examples," *Health Policy* 95 (2010): 10-23. See also Crawford et al., "Systematic review of involving patients in the planning and development of health care" at note 75; Boote, Telford, and Cooper, "Consumer involvement in health research: a review and research agenda" at note 59.

about as the result of defective genes.[193] As a result of ataxia, individuals often develop various tremors, debilitating muscle spasms, and lose facility with both vision and speech. The disease(s) is associated with a variety of other co-morbidities as well, including heart complications, diabetes, blindness, and general loss of neurological function.[194]

In conjunction with the charity Ataxia UK, a specialized centre for the treatment of ataxia was established in 2005 at the University College Hospital's National Hospital for Neurology and Neurosurgery in London.[195] Because much of the funding for the establishment of the centre came from Ataxia UK, a charity with significant patient involvement, patients were heavily involved "from helping develop protocols and design of the trials, through to writing patient information leaflets to make sure information is relevant, understandable by all and appropriate."[196] For example, whereas many researchers are concerned primarily with collecting standardized quantitative data regarding a range of commonly studied health metrics around a disease, one of the ataxia researchers noted that in one pharmaceutical trial, "we not only recorded the required information but we also recorded the patients' experiences. At the end of the trial the information provided by patients was instrumental in the design of a sub-study within an extension phase."[197] The Ataxia Centre remains committed, in their own words, to a "holistic" approach to

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[193] See "Friedrich's ataxia," *Ataxia UK Online*, accessed January 22, 2014 online, <http://www.ataxia.org.uk/pages/friedreichs-ataxia.html>. See also "Spinocerebrellar ataxias," *Ataxia UK Online*, accessed January 22, 2014 online, http://www.ataxia.org.uk/pages/other-types-of-ataxia.html.
[194] See "Acute Cerebrellar Ataxia," *Medline Plus, US National Library of Medicine*, accessed January 22, 2014 online, http://www.nlm.nih.gov/medlineplus/ency/article/001397.htm.
[195] "Ataxia Service," *University College London*, accessed January 22, 2014 online, http://www.ucl.ac.uk/ion/departments/molecular/themes/neurodegeneration/ataxia.
[196] "Patients help to make sure research into rare neurodegenerative disease is effective," *UCL/UCL Hospitals/Royal Free Joint Research Office*, accessed January 22, 2014 online, http://www.ucl.ac.uk/jro/patient-public-involvement/PPIcasestudies/ataxiaresearchppi.
[197] Ibid.

treatment of the disease, and notes further that patient empowerment (facilitated at least partially through direct user involvement) has encouraged patients to be more active in their own care, particularly given the feelings of social isolation that can result from having a rare and poorly understood disease.

This focus on extending the analysis of a pharmaceutical or therapeutic trial to include a discussion and examination of qualitative metrics of patient satisfaction is a common theme running through patient and public involvement in medical research. Patients in other studies have noted that while researchers are concerned primarily (or sometimes even exclusively) with standard "health outcomes," they may be likely to deprioritize or even ignore elements of the research that might be relatively important to patients such as side effects or quality of life. This theme has been particularly prevalent in research on cancer, where the known effects of treatments like radiation and chemotherapy are negative in terms of quality of life, but where quality of life has generally been deprioritized in comparison to metrics like years of life gained and remission rates.[198]

6.2.2 Case Study #2: Informed Consent Development in VA Hospitals (USA)

Though in some cases, researchers have used patient and public involvement as a mechanism to either develop or refine research aims and overall design, PPI has also been used in numerous cases to help protect potential study participants in the process of the

[198] Several studies have examined the ways in which patients have refocused the agenda for cancer research in both Europe and the United States. See, for example, David Wright, Jessica Corner, Jane Hopkinson, and Claire Foster, "Listening to the views of people affected by cancer about cancer research: an example of participatory research in setting the cancer research agenda," *Heath Expectations* 9, no. 1 (2006): 3-12; J. Hanley, M. Barnes, and J. Bradburn, et al., *Involving the Public in NHS, Public Health, and Social Care Research: Briefing Notes for Researchers 2nd edition* (Eastleigh, UK: INVOLVE), 2003; R.E. Gray, M. Fitch, C. Davis, and C. Phillips, "Challenges of participatory research: reflections on a study with breast cancer self-help groups," *Expectations* 3, no. 4 (2000): 243-252.

study and in the process of obtaining informed consent. Our next case study is but one such example.

Obtaining proper informed consent is one of the cornerstones of conducting ethical medical research.[199] Nonetheless, there remains a significant amount of disagreement amongst scholars, researchers, and physicians as to what standards need be applied for informed consent to truly be "informed" and additional controversy over what information should and should not be disclosed. The challenge of how to design informed consent procedures that are readily understandable to average patients serves as the jumping off point for this case study.

This case study comes from the United States, where researchers engaged in a multi-centre study of informed consent in Veterans Affairs (VA) hospitals across the country between 1999 and 2001.[200] Broadly speaking, researchers were trying to understand the degree to which user involvement in the design of informed consent procedures produced a document that was more readily understandable by average study participants than a document that was produced exclusively by the study investigators. The study, which was embedded in a "parent study" evaluating the impact of cognitive and behavioral therapy on Gulf War veterans, used a randomized control trial and participants were either assigned to the participant-designed informed consent document, or the investigator-designed document. The study's authors summarize the main changes made to the investigator-designed document by the lay participants as follows:

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[199] T.L. Beauchamp and J.F. Childress, *Principles of biomedical ethics*, seventh edition (Oxford: Oxford University Press, 2013).; E.J. Emanuel, D. Wendler, and C. Grady, "What makes clinical research ethical?" *Journal of the American Medical Association* 283, no. 20 (2000): 2701-11.
[200] Peter Guarino, Diana Elbourne, James Carpenter, and Peter Peduzzi, "Consumer involvement in consent document: a multicenter cluster randomized trial to assess study participants' understanding." *Clinical Trials* 3, no. 1 (2006): 19-30.

"1. Referring to the theatre of operations as the southwest Asian region instead of the Gulf War to more accurately identify those who served in the combat zone.
2. Revising the procedures section with shorter paragraphs and lists to make the document easier to read and comprehend.
3. Revising the description of treatment regimens to include all information about each treatment in the same paragraph with bolded side-heads for ease of reference.
4. Specifying that veterans will not be paid for treatment visits, although they will be remunerated for the three follow-up visits.
5. Eliminating the enumeration of the risks of aerobic exercise. The focus group believed that this was not necessary since the exercise training in the military was more strenuous than that being proposed in the study.
6. Inserting the following statement in the benefits section: 'However, if you participate, you will receive direct access to the study personnel for care related to your Gulf War Illnesses.' The focus group strongly believed that having direct access to study personnel was an important aspect of the study and would help veterans bypass the 'usual health system.'
7. Emphasizing that all veterans will be eligible for care at all VA medical centres if they choose not to participate in the study, instead of just at their VA medical center participating in the study."[201]

These changes did not alter any of the fundamental tenets of the informed consent document, but sought instead to make the document more understandable for the average study participant. Finally, it is worth noting that an institutional review board (IRB) approved both documents as suitable for fulfilling the requirements of informed consent.

Though several other studies have found that user-involvement *does* increase study participant understanding of the informed consent document,[202] researchers in this case found that "the revisions made to the informed consent document had little overall effect on participants' understanding, on their satisfaction with participation, or on recruitment to or

[201] Ibid, 20.
[202] See Elizabeth Cohn and Elaine Larson, "Improving Participant Comprehension in the Informed Consent Process," *Journal of Nursing Scholarship* 39, no. 3 (2007): 273-280; Y. Andejeski et al., "Quantitative impact of including consumers in the scientific review of breast cancer research proposals," *Journal of Women's Health & Gender-Based Medicine* 11, no. 4 (2002): 379-388; Ronald P. Strauss et al., "The Role of Community Advisory Boards: Involving Communities in the Informed Consent Process," *American Journal of Public Health* 91, no. 12 (2001): 1938-1943.

compliance with the parent clinical trial."[203] Though a number of factors may explain the lack of difference in understanding between the two documents (e.g. the investigators' extensive prior experience in designing informed consent documents, the relatively low risks that accompanied participation in the study, the fact that the lay users made only minor changes to the investigator-generated document, etc.), the researchers ultimately found that user participation added only very marginal benefit.

A range of studies have found that study participant understanding of informed consent procedures remains at unacceptably low levels.[204] But in many ways, the debate that exists within the literature around whether or not consumer involvement substantially improves the understandability of informed consent documents serves to contradict the widely held assumption within the PPI literature that patient and public involvement *necessarily* improves the degree to which study participants understand informed consent documents. To be sure, there may perhaps be good *intuitive* reason to believe that involving the individuals who are going to read the informed consent document in its design would increase the document's readability. But that assumption, along with others that underlie the broader philosophy of patient and public involvement, should be supported by rigorous empirical evidence.

The choice of this case study, as opposed to any one of the many others dealing with informed consent and patient and public involvement, comes not simply from a desire to show that the literature does not express unequivocal support for user involvement in

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[203] Guarino et al., "Consumer involvement in consent document," at note 200, 26.
[204] S. Joffe et al., "Quality of informed consent in cancer clinical trials: a cross-sectional survey," *Lancet* 358, no. 9295 (2001): 1772-1777; J. Flory and E. Emanuel, "Interventions to Improve Research Participants' Understanding of Informed Consent for Research," *Journal of the American Medical Association* 292, no. 13 (2004): 1593-1601; Jeremy Sugarman et al., "Evaluating the Quality of Informed Consent," *Clinical Trials* 2, no. 1 (2005): 34-41.

research. Rather, what distinguishes the above study from most others within the literature is its use of a randomized control trial rather than either the single-case study approach, or systematic review approach (which often draws heavily, if not exclusively, on single case studies). With that said, we proceed now to a more extensive discussion around the evidence base concerning PPI and research.

6.2.3 The Need for an Expanded Evidence Base in PPI and Research Quality

It should be noted that though we have reviewed some evidence that suggests that patient and members of the public *can* make a valuable contribution to the direction and implementation of health services and even clinical research, there remains a need for more systematic and rigorous analysis of the quality of their contributions and the cost effectiveness of those contributions. Several studies have sought to somewhat systematically aggregate and analyze the range of studies that have, to this point, evaluated the efficacy of PPI.[205] But, while most can report back various types of qualitative evidence in support of greater user involvement, few (if any) have been able to rigorously describe those benefits in any quantifiable way nor have they factored into consideration the financial costs associated with user involvement. As White maintains, "the vast and eclectic literature on participation displays a common feature: a singular lack of concern with outcomes, or the effectiveness of participation."[206]

But my concern with measuring effectiveness must extend to also measuring cost, a factor that has long been neglected within the literature on involvement. As one systematic

[205] See, e.g. Sophie Staniszewska, "The GRIPP checklist: Strengthening the quality of patient and public involvement in research," *International Journal of Technology Assessment in Health Care* 27, no. 4 (2011): 391-399.
[206] Deena White, "Consumer and Community Participation: A Reassessment of Process, Impact, and Value," in G.L. Albrecht, R. Fitzpatrick, and S.C. Scrimshaw (ed.), *The Handbook of Social Studies in Health and Medicine* (Thousand Oaks: Sage Publications, 2000), 466.

review notes: "In…systematic reviews [analyzed], there was no evidence of any economic modeling of costs or benefits, with only a very small number of papers mentioning costs of particular patient and public involvement activities."[207] And, while many would be likely to believe that involvement's cost is negligible – after all, involvement often requires just a minimal amount of time by members of the lay public – limited evidence suggests that it can be quite costly. Indeed, one study of the use of citizens' juries in Canada which involved just twelve sessions and fewer than 500 participants cost the health care system $C1.3 million. If PPI is to remain a staple element of public health policy in the UK, Canada, and other countries, it would seem only reasonable for policymakers to develop a system of cost-effectiveness analysis for PPI, much as they do for the evaluation of pharmaceuticals, procedures, and other therapies.[208]

To do so, of course, would require that the "effectiveness" element of that equation be quantified in some consistent and systematic way. If, according to the case studies above, PPI does in fact make health and clinical research "better" while empowering patients to feel more engaged in the functioning of the health care system, the natural questions to ask are: how much better? How much is that added quality worth? And how can we assess whether PPI is actually improving the quality of health care delivery? As Staniszewska et al. assert, "Such evidence may be vital in times of fiscal constraint where philosophical arguments that support PPI based on societal good are harder to defend. The strengthened PPI evidence base will also provide policymakers with an important recognition of the validity and relevance of PPI as an activity that strengthens the quality of

[207] Ibid, 396.

[208] A more complete discussion of cost-effectiveness and its current impact on health care spending globally is well outside the bounds of this dissertation. For a brief introduction, see Louise B. Russell et al., "The Role of Cost-effectiveness Analysis in Health and Medicine," *Journal of the American Medical Association* 276, no. 14 (1996): 1172-1177.

research and so ultimately underpins evidence-based policy-making."[209] Though some would (and have) argued, that patient involvement in research constitutes not merely a way to increase the quality of research but rather a *categorical* imperative, for those concerned with quality, a more rigorous base of evidence is sorely needed.

6.2.4 PPI in Medical Research – Qualified Support

Most systematic reviews[210] and extensive surveys of available case studies suggest that the experiences of both researchers and patients with regard to patient and public involvement in research have been positive. To be sure, most of that evidence, as I have pointed out, shows qualitatively that researchers were either able to create more relevant research or use patient input in order to more successfully implement research protocols. But, if PPI is to be implemented in an efficient and rigorous way going forward, it is crucial that objective measures of quality are introduced. The vast majority of existing studies are single case studies without results from which we might draw broad extrapolations. Without those and without more careful attention to the costs incurred by user involvement, health system administrators and providers will not be able to draw on the past experiences of other PPI initiatives in any systematic or reliable manner.

Finally, it should be noted that the pervasiveness of qualitative case studies (and the lack of more rigorous studies, including randomized control trials) within the PPI literature base is concerning not just because it reflects less analytical rigor, but because it presents a potential selection bias problem. As has been noted previously, the chorus of voices proclaiming the necessity of greater user involvement has only continued to grow in the last decade, but systematic and rigorous evaluations of the efficacy of PPI are still missing.

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[209] Staniszewska et al., "The GRIPP Checklist," at note 205, 397.
[210] See Crawford, "Systematic Review" at note 57.

Indeed, it seems that articles proclaiming the need for a more rigorous evidence base within PPI have appeared like clockwork every 3-4 years in the recent past.[211] While we should not ignore or discard the evidence that appears from isolated case studies, it is difficult to draw strong and generalizable conclusions from such studies given the particularities of the circumstances involved. Though I express my qualified support here for user involvement in research design and implementation, researchers going forward would do well to focus not just on *whether* PPI enhances the quality of research produced, but on elucidating precisely how and under what circumstances such involvement has succeeded in accomplishing its enunciated goals.

6.3 PPI in Resource Allocation and Priority Setting

As I have argued elsewhere in this dissertation, there are strong reasons to think that our conceptualization of patient and public involvement in the realm of research should be different than in the realm of resource allocation (in either research or health services). First, quality and utility, concepts essential to a utilitarian analysis, are (for the most part) readily available in discussions of research. Most researchers can agree, at least in theory, on what makes research "better"; we can, for example, rely on metrics that have historically and commonly been used to understand the quality of research such as the research's overall impact on health and its ability to address the population's needs. But the same,

[211] See Rosemary Barber et al., "Can the impact of public involvement on research be evaluated? A mixed methods study," *Health Expectations* 15, no. 3 (2012): 229-241; Sophie Staniszewska et al., "Developing the evidence base of patient and public involvement in health and social care research: the case for measuring impact," *International Journal of Consumer Studies* 35 (2011): 628-632; Sophie Staniszewska, Sandy Herron-Marx, and Carole Mockford, "Measuring the impact of patient and public involvement: the need for an evidence base," *International Journal for Quality in Health Care* 20 (2008): 373-374; Jill Murie and Gerrie Douglas-Scott, "Developing an evidence base for patient and public involvement," *Clinical Governance: An International Journal* 9 (2004): 147-154; Boote, Telford, and Cooper, "Consumer involvement in health research: a review and research agenda" at note 59.

unfortunately, cannot often be said in the realm of resource allocation where the debate over how to allocate resources is often, if not always, a debate that is *itself* about what we mean by quality or utility.[212]

Second, the concerns articulated in this dissertation with political representation, accountability, and political equality are much less salient with regard to patient and public involvement in research than they are with regard to resource allocation. But why is that the case? Perhaps most importantly, my concern with regard to resource allocation centres around the idea that there is not some universal, definable, or generalizable "public" that can be represented by a single opinion when it comes to how we allocate scarce resources; reasonable people are likely to disagree about whether to spend the £100,000 on childhood nutrition, cancer treatment, or geriatric palliative care. But in research, because we have agreed upon goals and because patients *generally* desire most of the same things (prolonged life, increased quality of life, ethical treatment during research), patient "representatives," as it were, may in fact serve as legitimate (in the normative sense) and accountable agents. As a result, patient and public involvement in resource allocation and priority setting constitutes a significantly more contentious normative dilemma and is therefore the central focus of this dissertation.

With that said, we turn now to evaluate case studies in resource allocation that look at patient and public involvement in both the allocation of health care funding and the allocation of funding more generally for health services.

6.3.1 Case Study #3 – Allocating Resources in Medical Research: The National Institutes of Health

[212] A more thorough exposition of this idea can be found in Chapter 3, which addresses the cost-benefit framework analysis in greater depth.

6.3.1.1 Part I – Context for Greater Involvement

Calls for greater patient and public involvement have, to be sure, been much less vociferous and widespread in the United States than they have been in Europe and certainly than the U.K. Though one can only speculate as to why this is the case, we can at least surmise that it might have something to do with the fact that the majority of U.S. health care is funded through private, market-based mechanisms and that in some substantial way, that fact has created a culture of focus on the individual with little attention paid to the concept of health care as a scarce and public resource.[213] Indeed, one need only look to the vitriolic rhetoric of rationing and "death panels" surrounding the debate about health care reform in 2010 to understand the polarized nature of discourse around health care in the United States.[214]

Nonetheless, there have been limited cases of efforts to increase patient and public involvement in priority setting in the United States, particularly in the late 1990's and early 2000's as patient advocacy and interest groups took on more active roles in lobbying the government for additional funds for biomedical research.[215] Though over the last several

[213] See Ruth M. Parker, Scott C. Ratzan, and Nicole Lurie, "Health Literacy: A Policy Challenge For Advancing High-Quality Health Care," *Health Affairs* 22, no. 4 (2003): 147-153; and Kenneth W. Kizer, "Establishing Health Care Performance Standards in an Era of Consumerism," *Journal of the American Medical Association* 286, no. 10 (2001): 1213-1217.

[214] See Jacob S. Hacker, "The Road to Somewhere: Why Health Reform Happened," *Perspectives on Politics* 8, no. 3 (2010): 861-876; Brendan Nyhan, "Why the 'Death Panel' Myth Wouldn't Die: Misinformation in the Health Care Reform Debate," *The Forum* 8, no. 1 (2010): online.

[215] In particular, sociologists and historians have paid particularly close attention to the efforts of breast cancer and AIDS activists in the 1990's. These groups were enormously successful in obtaining increased funds for AIDS and breast cancer research, while expanding the public dialogue surrounding research on long-neglected diseases. For a more thorough exposition of this subject, please see Epstein, *Impure Science*, at note 12; Elizabeth Armstrong, Daniel P. Carpenter, and Marie Hojnacki, "Whose Deaths Matter? Advocacy and Attention to Disease in the Mass Media," *Journal of Health Politics, Policy, and Law* 31, no. 4 (2006): 729-772; K. Kedrowski and M. Sarow, *Cancer Activism: Gender, Media, and Public Policy* (Urbana: University of Illinois Press, 2007); and Christopher H. Foreman, Jr., "Grassroots Victim Organizations: Mobilizing for Personal

decades the National Institutes of Health (NIH) has by far constituted the largest public spender on biomedical research globally, it has historically been able to fund fewer than 30% of grant applications, leading disease advocates, health policy researchers, and NIH administrators alike to debate about the means by which funding is and should be allocated.[216] As the fight to increase the overall size of the pie has increased, so have the battles between interest groups representing various disease constituencies to claim a larger slice of that pie for themselves.

In the early 1990's, disease advocacy underwent rapid professionalization as advocates representing diseases like breast cancer and AIDS hired full-time professional staffs and assembled massive lobbying infrastructures aimed at securing more funding for projects related to their diseases from the U.S. Congress (the body responsible for appropriating funds to the NIH).[217] These advocates asserted that although the NIH had offered public statements endorsing the theory of public input in priority setting, that in reality scientists and technocrats were in full control of budgetary allocation.[218]

As a result, the U.S. Congress convened public hearings on priority setting in the context of biomedical research and asked the federally controlled Institute of Medicine (IOM) to "conduct a comprehensive study of the policies and processes used by the NIH to determine funding allocations for biomedical research."[219] In the late 1990's, members of Congress could not agree on what was the appropriate response to the trend towards narrow

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and Public Health" in *Interest Group Politics*, ed. Allan J. Cigler and Burdett A. Loomis (Washington, D.C.: CQ Press, 1995).

[216] Cary P. Gross, Gerard F. Anderson, and Neil R. Powe, "The Relation between Funding by the National Institutes of Health and the Burden of Disease," *New England Journal of Medicine* 340 (1999): 1881-1887.

[217] Kedrowski and Sarow, *Cancer Activism* at note 215; Epstein, *Impure Science* at note 12.

[218] E. Marshall, "Lobbyists Seek to Reslice NIH's Pie," *Science* 276, no. 5311 (1997): 344-346.

[219] Institute of Medicine, *Scientific Opportunities and Public Needs*, p. 13.

lobbying and so-called "earmarking" of funds for particular diseases. At Congressional hearings in 1997, then NIH Director Harold Varmus argued against specific disease earmarks, contending that such a framework would violate the essential nature of scientific research:

> Because science attempts to discover what is unknown, it is inherently unpredictable… History has repeatedly shown the benefits of allowing a significant portion of our research activity to be governed by the imagination and productivity of individual scientists, not by a regimented plan for alleviating diseases we do not yet fully understand.[220]

Some, like then House Appropriations Subcommittee Chair John Porter sided with Varmus, arguing for a more limited role amongst interest groups. He proclaimed that "the worst thing that could ever happen for biomedical research would be amendments on the floor of the Senate or House that start moving money from one place to another in response to interest groups."[221] Others, however, chastised the NIH director, claiming that the NIH priority-setting process was both opaque and fundamentally anti-democratic. Notably, Representative Ernest Istook charged that "The jealousy with which you [Varmus] try to say the purse strings should be under the control of persons who know better than the rest of us is an attitude that is not healthy in our society."[222]

Following the 1997 hearings, Congress asked the IOM to provide additional guidance on priority setting and in 1998, the IOM issued its report, "Scientific Opportunities and Public Needs: Improving Priority Setting and Public Input at the

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[220] Harold Varmus, "Testimony on Setting Research Priorities at NIH," *The House Committee on Appropriations, Subcommittee on Labor, HHS, Education,* 1997, accessed online January 30, 2014 at < http://www.hhs.gov/asl/testify/t970610a.html>.
[221] Bruce Agnew, "Two in a Row: A Whopping Budget Boost for NIH," *Journal of NIH Research* 8 (1996): 19.
[222] Rebecca Dresser, *When Science Offers Salvation,* Oxford: Oxford University Press, 2001:96.

National Institutes of Health" The report unambiguously endorsed a greater role for the public in the process of priority-setting:

> It is clear that broader involvement of the public in discussions about NIH priority setting can result in positive outcomes by enhancing the relevancy of research programs, improving the design and conduct of research, particularly patient-oriented studies, and assuring all those with an interest in NIH research that there is an opportunity to be heard.[223]

Ultimately, the IOM committee recommended that the NIH take two specific steps to improve the quality of public input into the NIH decision-making process. First, it said that the NIH should "establish an Office of Public Liaison in the Office of the Director" that could act as a conduit for feedback from the public. Second, the committee instructed the NIH director to create a Council of Public Representatives (COPR) made up of individuals from "a broad range of public constituencies (e.g., disease-specific interest groups, ethnic groups, public health advocates, and health care providers).[224] In elucidating the new role of the COPR, the committee was clear to point out that it "will not set priorities regarding the NIH budget or its research program" and that "it is not intended to serve as a forum for advocacy groups to lobby the NIH director for research dollars."[225] Rather, it saw the COPR as "a mechanism for NIH to receive valuable and thoughtful perspectives on its research programs from those who are in some way affected by disease and disability and who are therefore advocates for a healthy NIH and for NIH to provide information about its research and priority-setting process as part of a two-way exchange of information."[226]

6.3.1.2 Part II: Evaluating the Impact of Involvement

[223] Institute of Medicine, *Scientific Opportunities and Public Needs,* 57.
[224] Ibid, 66.
[225] Ibid, 8.
[226] Ibid.

Discerning what exactly the impact of the COPR has been remains a difficult task. Though the committee releases periodic reports attesting to its activities, those reports provide little – if any – insight into the practical impact that the representatives have had on the course of NIH policy around resource allocation and the way in which research takes place at the NIH.

A 2010 article written by two former COPR members sheds some light on some of the activities undertaken by the body and some of the changes that the NIH has made independently with regard to community engagement in research. According to Ahmed and Palermo, "Many of NIH's 27 institutes and centers encourage some investigators to engage the public in their research. For example, NIH sponsored the Partners in Research Program, which supports partnerships between academic or scientific institutions and community organizations to study methods for improving public understanding of research and enhance outreach to the public by scientists."[227] Ahmed and Palermo also note that the COPR has devoted a substantial amount of time and energy into developing a robust "community engagement framework" that can be harnessed and replicated by research institutions across the country that are interested in expanding the patient and public involvement efforts. But notably, they treat (as many other within the PPI literature do), community engagement as a necessary good, failing to distinguish between kinds of involvement that improve the quality or responsiveness of research and involvement that does not.

Very few studies have actually conducted an in-depth external examination of the COPR and its effect on policy, but the little evidence that does exist suggests that the

[227] Syed M. Ahmed and Ann-Gel S. Palermo, "Community Engagement in Research: Frameworks for Education," *American Journal of Public Health* 100, no. 8 (2010): 1380-1387.

members have largely seen their participation as little more than symbolic. In what is, to date, the most extensive study of the COPR, Burgin found that "all evidence demonstrates that COPR's intended goals remain unaccomplished goals."[228] She notes that according to meeting records, the COPR rarely if ever discusses apportionment choices and that none of the commissioned COPR reports have dealt directly with apportionment. Statements made by several of Burgin's interviewees (all former COPR members themselves) provide strong support for this claim. One, for instance, stated that "COPR didn't have any influence on where research dollars go. We just provided political cover for difficult decisions."[229] Still another charged that "COPR is window dressing, a good-will group to bridge the chasm between NIH and the public… They [NIH administrators] saw us as a buffer, as a shield, as a spearcatcher. ... COPR was an audience, not a participant. We were just dummies being briefed."[230]

Some of these concerns, to be sure, are what we might call "practical" concerns – in other words, they indict not the fundamental normative or ethical basis for involvement but rather the nature of a particular effort of implementation. I would argue, however, that insofar as patient and public involvement cannot be understood entirely in a theoretical context, the fact that this "window dressing" argument has appeared and reappeared in a range of involvement contexts suggests something more fundamental about the nature of the activity. Finally, after the following case studies surrounding PPI in health care services in resource allocation, we will return to connect these case studies to the larger theoretical framework established earlier. But, it is at least worth noting here that this case study does serve to concretize my earlier concerns with political accountability and political

[228] Burgin, "Dollars, Disease, and Democracy" at note 179, 48.
[229] Ibid.
[230] Ibid.

equality. Indeed, because the type of deliberation and decision-making necessitated by COPR appointment requires a number of resources (notably time) and experiences (education, experience in health care, etc.), the individuals chosen to serve cannot reasonably be said to even descriptively – that is, demographically – represent the individuals to whom they are ostensibly accountable.[231] We will return to this point later in the chapter.

6.3.2 Case Study #4 – Priority Setting in Public Health Planning: The NHS Plan

6.3.2.1 History of The NHS Plan

The NHS plan, created in 2000, was a white paper produced by the UK's Secretary of State for Health that sought to outline the future of health care delivery and priority setting for the first decade of the 21st century.[232] From the perspective of patient and public involvement, the plan was notable primarily because it placed heavy emphasis on the value of direct citizen involvement and because it utilized a range of deliberative techniques in order to generate input from the general public.

Broadly speaking, the plan called for direct public input into the process of priority setting in four main ways. First, it conducted a series of focus groups with individual patients in an effort to create a list of the main health needs in the population that deserved attention over the next 10 years. Then, the Department of Health (DoH) held larger focus groups intended to deal directly with the problem of priority setting. These larger focus

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[231] All of the individuals currently represented on the COPR would easily be considered to have above average levels of education, professional status (and one can infer), income. The current membership of the council consists of a senior media consultant focused on health issues, two members of patient-advocacy groups, two CEO's of public health organizations, two professors, the CEO of a community health centre, and an administrator at a major professional association of physicians.

[232] John Parkinson, *Deliberating in the Real World*, Ch. 1.

groups consisted of two-day-long meetings with approximately 200 participants each,[233] and at the end of the meetings (which included expert-led presentations) participants were asked to prioritize a list of treatments for the NHS. The third element of the plan was, as Parkinson notes, "not obviously deliberative in itself but had the broadest reach."[234] In an effort to both increase publicity around the patient and public engagement while soliciting public input, the Department of Health sent out postcards to hospitals, GP's surgeries, and a range of retail stores, with the question "What are the top three things which you think would make the NHS better for you and your family?"[235] In total, the DoH received just 151,999 responses from the general public, and 48,961 from NHS staff and providers, which reflected a very low response rate, particularly given how prevalent the issue was in public discourse at the time.[236] In the final part of the public engagement process, the DoH created a series of working groups that included individuals representing medical and nursing colleges around the country, staff members of the NHS, and individuals representing patient advocacy groups.[237] Finally, the DoH set up a series of teams focused on monitoring and evaluation to ensure that the recommendations created from this deliberative process were effectively implemented in the decade to follow.[238]

6.3.2.2 Evaluating The NHS Plan – Did it Work?

Evaluating whether the NHS Plan "worked" is a task that is much more difficult than it may appear initially. Ostensibly, the goal of the NHS plan was to involve the public

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[233] Ibid.
[234] Ibid.
[235] Parkinson, "Why Deliberate?" at note 147, 389.
[236] Ibid.
[237] Ibid.
[238] Zoe Radnor and Bill Lovell, "Success factors in implementation of the balanced scorecard in a NHS multi-agency setting," *International Journal of Health Care Quality Assurance* 16, no. 2-3 (2003): 99-108.

– that is to say, to create an NHS that was more responsive to the overall needs and desires of the public and to prioritize future public health planning in response to the generated feedback. But in another (perhaps more cynical) sense, it also seems clear that one of the primary goals of the overall plan (and in particular, the mass postcard mailing element of the campaign) was to legitimate the NHS during a period of time when it was under enormous scrutiny. Despite the fact that only a statistically insignificant fraction of the 21 million households in England, Wales, and Scotland ultimately returned their postcards to the DoH, as Parkinson explains, "the publicity surrounding the cards ensured that the message 'we're listening' was transmitted loud and clear."[239] Parkinson notes further that the "primary aim" of the postcards – by far the largest and most visible element of the NHS plan – "was to show the British people that something was being done, to make the whole process more 'public' in a way that could not be achieved by micro-deliberative processes alone."[240]

It is worth noting that the NHS plan faced little to no opposition within the general public – within the broader bureaucracy of the NHS and the DoH there was skepticism that the plan would actually accomplish anything resembling robust reform, but the plan itself was almost universally popular.[241] With that said, it is difficult to know whether the NHS plan actually accomplished its enunciated goals of creating more patient-centered, patient-driven care. First, it is difficult to isolate the effects of the NHS plan from any of the other reforms taking place within the NHS over the coming years; indeed, public consultation was but one element of what the government used in its efforts to reform the NHS over the course of the early 2000's. But perhaps more importantly (and as we have seen elsewhere

[239] Parkinson, "Why Deliberate" at note 147, 389.
[240] Ibid.
[241] Rudolf Forster and Jonathan Gabe, "Voice or Choice?" at note 82.

in case studies of public deliberation), involving the public is often treated *in and of itself* as the objective to be accomplished. In the case of the NHS plan, the government did not devote any resources to specifically evaluating what the effect of involvement was on overall policy changes, system performance, or patient satisfaction. This, at the very least, must lead us to ask the question: is involvement seen as an end in and of itself or instrumental towards achieving a more measurable and identifiable policy outcome? And if the former, should involvement be characterized as a tool to generate greater transparency or accountability or merely a technology of policy legitimation?

6.3.3 Case Study #5 – Priority Setting in Public Health Insurance: the Case of Oregon

Our final case study comes from Oregon, an American state which implemented an initiative in line with the principles of public involvement on one of the largest scales to date. But understanding the importance of Oregon's story requires a brief digression into the historical context that shaped its decision, and the broader social, political, and economic context of the U.S. health care system.

6.3.3.1 Background: Health Reforms in Oregon, 1989 – 1994

Discussions about rationing – then and now a dirty word in American health care[242] – revolved not around health care allocation generally, but around health care rationing with respect to Medicaid, a partnership program between the federal government and the individual states that provides health care to (for the most part) indigent patients. From the beginning Medicaid was a classic federalist enterprise – the federal government has always provided the majority of funds, but states are required to devote substantial funds themselves to the effort while remaining within the federally established minimum and

[242] David Mechanic, "The Managed Care Backlash: Perceptions and Rhetoric in Health Care Policy and the Potential for Health Care Reform" *Milbank Quarterly* 79, no. 1 (2001): 35-54.

maximum guidelines for eligibility.[243] The federal government also requires that states provide certain basic health care services, but states are given relatively significant flexibility in determining what additional services to offer beyond the minimum.

In the late 1980's and early 1990's, policymakers in Oregon confronted exponentially rising health care costs and ultimately, insufficient funds for Medicaid. To respond, the legislature denied coverage for highly expensive organ transplants, and the issue became a political disaster when a 7-year old boy was denied coverage for a life-saving bone marrow transplant under the state's policy.[244] The case was the subject of intense media attention and though significant private funds were raised for an operation, he ultimately died waiting. Deciding to revisit the issue, the legislature began debates on reinstating coverage for organ transplants, but opposition to the measure found support from John Kitzhaber, an emergency-room physician, president of the state's senate, and the state's future governor. Kitzhaber argued that it was morally irresponsible to pay for costly operations like transplants when a significant percentage of the state remained completely uninsured, unable to access even the most basic health care services.[245] He advocated a system of universal health insurance – then a novel idea in American health care – but argued that the only way to accomplish it within fiscal limits was to explicitly ration services through prioritization.[246]

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[243] For a more comprehensive and robust history of Medicaid and its federal financing system, see John D. Klemm, "Medicaid Spending: A Brief History," *Health Care Financing Review* 22, no. 1 (2000): 105-113; and Richard P. Nathan, "Federalism and Health Policy," *Health Affairs* 24, no. 6 (2005): 1458-1466.

[244] James F. Blumstein, "The Oregon Experiment: the Role of Cost-Benefit Analysis in the Allocation of Medicaid Funds," *Social Science and Medicine* 45, no. 4 (1997): 546.

[245] J.A. Kitzhaber, "Prioritising health services in an era of limits: the Oregon experience," *British Medical Journal* 307 (1993): 373-377.

[246] D.M. Fox, H.M. Leichter, "Rationing care in Oregon: the new accountability," *Health Affairs (Millwood)* 10, no. 2 (1991): 7-27.

In 1989, the Oregon legislature enacted a bill that called for the implementation of the "Oregon Health Plan" (OHP) that fundamentally took two courses of action. First, it mandated that employers provide their employees with health insurance[247] and second, it expanded Medicaid eligibility to include all those under the federal poverty line, whereas previously only those up to 66% of the poverty line had been included. Expanding eligibility would increase access to health care, but the state was to rely on a systematic method of rationing health care services covered in order to pay for the program. How exactly that list would be generated was the subject of considerable public debate.

The legislature ultimately appointed a "Health Services Commission" tasked with condensing more than 10,000 medical procedures into 709 discrete medical conditions and associated treatments (referred to as "condition/treatment pairs"). The Commission then convened dozens of public meetings across the state in an effort to garner public input into the process of prioritizing that list of treatments. It used these public meetings, in conjunction with survey data from physicians regarding the value of certain clinical treatments, and outside research on health outcomes to create the definitive list of priorities. Condition/treatment pairs at the top of the list are deemed essential services – pairs like pregnancy/maternity care, preventive services, obesity, major depression, HIV, and diabetes are routinely "ranked" in the top 15 in the priority list. Conversely, condition/treatment pairs at the margins are generally those with either minimal impact or those that are purely evaluative and little evidence exists supporting the effectiveness of treatment. In the most recent list, for example, the last three approved conditions were (1)

[247] Due to a range of political factors (including the election of a conservative legislative majority), the employer mandate was never fully implemented. As a result, though Medicaid eligibility and coverage expanded substantially, the state was never able to achieve its desired goal of 100% coverage, something that was not accomplished by any U.S. state until health reform in Massachusetts the following decade.

genitourinary conditions, (2) musculoskeletal conditions, and (3) gastrointestinal conditions with "no or minimally effective treatments or no treatment necessary."[248]

The plan, then, was that each year the Oregon legislature would allocate a certain amount of money for the OHP and then approve all of the treatments above a certain number based on that overall budget. And, while the experiment at the time (and even today) has garnered enormous national and international attention[249] around the ethics of rationing, little attention has been paid to either (1) whether the efforts have "worked," so to speak in accomplishing Oregon's goals and (2) what the normative implications are not just of rationing, but in using public deliberation in this specific way to ration. I explore of these in greater detail next.

6.3.3.2 Evaluating Oregon: What is the Value of Public Deliberation?

At the outset, it is worth emphasizing that the rationing decisions in Oregon were not made exclusively using the results of public deliberation; as I noted above, those results were simply one of several variables that Oregon's health commission input into its model for prioritizing services. Though an examination of the exact details of its formulary are beyond the scope of my discussion here, suffice it to say that an examination of clinical impact was also deemed critically important.

6.3.3.3 Has the Oregon Health Plan Worked?

Of course, for the reasons I have already listed, determining whether or not the Oregon Health Plan has "worked," so to speak, is a conceptually challenging question.

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[248] "Prioritized List of Health Services," Oregon Governmental Website, accessed 27 May 2014 at <http://www.oregon.gov/oha/herc/PrioritizedList/10-1-2013%20Prioritized%20List%20of%20Health%20Services.pdf>.

[249] See J. Dixon and H.G. Welch, "Priority Setting: Lessons from Oregon," *The Lancet* 337, no. 8746 (1991): 891-894; and Thomas Bodenheimer, "The Oregon Health Plan – Lessons for the Nation," *New England Journal of Medicine* 337, no. 10 (1997): 651 – 655.

Was the goal of the plan to provide comparable health care at similar cost? At reduced cost? Was the goal to improve overall health? Or perhaps the health of a particularly marginalized and previously ignored segment of the population? These sorts of prior questions were not answered during the course of the debates about the Oregon Health Plan, nor are they the sort of conceptual debates that policymakers and legislatures engage in with regularity. Nonetheless, a review of the literature suggests at least a few conclusions that might reasonably be drawn about the efficacy of Oregon's Health Plan.

First, it is not clear that the plan was at all successful in forcing the public to grapple with the difficult decisions required by rationing in an era of scarce public resources. Recall that the initial catalyst for the OHP was a public controversy surrounding the coverage of organ transplants. Today, those same organ transplants are all found within the top 100 prioritized treatments, and treatments found at the bottom of the list are nearly all either those marked "with no or minimally effective treatments or no treatment necessary" or elective procedures, such as #675 for "dental conditions where treatment is chosen primarily for aesthetic considerations."[250] Across most metrics, the coverage under the current plan is significantly more generous than the initial OHP, and according to at least one account, for some services like mental health, the OHP "is considered superior to commercial insurance in Oregon."[251]

Secondly, a consequence of not actually engaging in true prioritization is that Oregon appears to have not saved any significant amount of money through the OHP. Administrators in Oregon have maintained that in the first five years of implementation, the plan saved only 2% of the overall budget, but massive increases in spending over the next

[250] Ibid.
[251] Oberlander, Marmor, and Jacobs, "Rationing medical care: rhetoric and reality in the Oregon Health Plan" at note 187.

decade caused a near 100% increase in total health care costs and widely controversial cuts to essential services, particularly those in mental health, in the early 2000's.[252]

Finally, there is little evidence that – at least in the case of Oregon – public deliberation enhanced the likelihood that the public would, as a result of their own participation, be more likely to accept the results of the rationing decisions. This is what Oberlander et al. call the "political paradox of rationing": "the more public the decisions about priority setting and rationing, the harder it is to ration services to control costs."[253] In Oregon, as discussions about rationing services became more prominent in public discourse, public reticence at cutting funding for the services actually increased. As Oberlander et al. note, "the OHP moved debates over Medicaid policy and service coverage from the quiescence of legislative corridors to the front pages of the state's newspapers."[254] To be sure, this is to some extent an American phenomenon – indeed, discussions about rationing health care resources play much more prominent roles in public discourse across most of Europe,[255] but the paradox is worthy of note nonetheless.

6.3.3.4 Ethics and the Oregon Health Plan

The principal objective of this dissertation, however, is not to evaluate the efficacy of public involvement so much as the ethics of involving. Though an examination of whether or not the OHP improved health, lowered cost, and elevated public discourse around rationing may be valuable, my main concern is in understanding the nature of public

[252] Jonathan Oberlander, "Health Reform Interrupted: The Unraveling of the Oregon Health Plan," *Health Affairs* 26, no. 1 (2007): w96-w105.
[253] Oberlander et al., "Rationing medical care," at note 187, 230.
[254] Ibid.
[255] Donald W. Light and David Hughes, "Introduction: A sociological perspective on rationing: power, rhetoric, and situated practices," *Sociology of Health and Illness* 23, no. 5 (2001): 551-569.

deliberation and the place of the Oregon example (and that of our two previous case studies) within the theoretical framework that has been developed to this point.

With that said, it is important to emphasize that the normative considerations examined here are rooted in the process of Oregon's use of public deliberation rather than in the substance of the ultimate outcomes. Numerous scholars have devoted their attention to evaluating whether the outcome of the OHP has been "fair" or comports with particular frameworks of distributive justice.[256] Questions about whether Oregon's plan created a system more consonant with various conceptions of distributive justice are important, but less attention has been focused on the process by which Oregon sought public input and the way in which that public input was used to generate policy decisions for a subset of the population. I turn now to consider not just the Oregon case, but indeed all three resource allocation case studies in broader theoretical context.

6.4 The Case of NICE: the National Institute for Health and Clinical Excellence

6.4.1 NICE History, in brief

As part of major Labour government reforms to the NHS in the late 1990's, the National Institute for Clinical Excellence (now the National Institute for Health and Clinical Excellence) (NICE) was established in April of 1999 with the express purpose of advising the National Health Service in Wales and England on questions of clinical effectiveness and cost effectiveness for medicines and other health technologies. NICE was charged with the responsibility to produce guidelines for a host of conditions and to

[256] See, e.g., Norman Daniels, "Is the Oregon Rationing Plan Fair?" *Journal of the American Medical Association* 265, no. 17 (1991): 2232-2235; Michael J. Garland, "Justice, Politics and Community: Expanding Access and Rationing Health Services in Oregon," *Journal of Law, Medicine, and Ethics* 20, no. 1-2 (1992): 67-81; and Robert M. Nelson and Theresa Drought, "Justice and the Moral Acceptability of Rationing Medical Care: The Oregon Experiment," *Journal of Medicine and Philosophy* 17, no. 1 (1992): 97-117.

systematize the practice of medicine and use of medicines and technologies throughout the NHS.[257] NICE was not, however, given carte blanche in terms of how to think about prioritizing certain technologies or medicines over others. Indeed, it is explicitly guided by three main principles: "(1) that all guidance should be based on the best available evidence; (2) that the process of creating that guidance should be as open and transparent as possible; (3) that is should be inclusive: 'any stakeholder likely to be affected by its guidance should be part of the development of that guidance, either by being a member of one of the independent advisory bodies, or though participating in open consultations'."[258]

By 2005, NICE's overall portfolio expanded to include policy guidance on questions of disease prevention and public health promotion. Ultimately, this resulted in the creation of four additional programmes within NICE: the clinical guidelines programme, the interventional procedures programme, the technology appraisal programme, and the public health guidance programme. As part of the clinical guidelines programme, NICE convened so-called "Guideline Development Groups" which consisted of patients, carers, researchers, and healthcare professionals. The GDG's are tasked with meeting regularly and assessing all quantitative evidence from the literature while incorporating qualitative feedback from patients and carers about quality of life. In practice, NICE has become a relatively powerful entity – the NHS almost always will not provide medicines or technologies unless they are first approved by NICE.[259]

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[257] Kalipso Chalkidou, "Comparative Effectiveness Review Within the U.K.'s National Institute for Health and Clinical Excellence," *The Commonwealth Fund* 59, no. 1296 (July 2009): http://www.commonwealthfund.org/~/media/Files/Publications/Issue%20Brief/2009/Jul/Chalkidou/1296_Chalkidou_UK_CER_issue_brief_717.pdf.

[258] Peter Littlejohns, "The Establishment of NICE" in P. Littlejohns and Michael Rawlins (eds.), *Patients, the Public and Priorities in Healthcare,* (Oxford: Radcliffe Publishing, 2009), p.1.

[259] Robert Steinbrook, "Saying No Isn't NICE – The Travails of Britain's National Institute for Health and Clinical Excellence," *New England Journal of Medicine* 359 (2008): 1977-1981.

It is worth emphasizing at the outset, however, that NICE has not been an uncontroversial entity within the politics of British health and the NHS. In certain instances, NICE has been criticized for being too slow in its evaluation of certain treatments or drugs, leaving patients in limbo while evaluations proceed.[260] In other cases, NICE has been criticized for its rigorous commitment to a cost effectiveness framework, not approving very expensive cancer drugs that may only prolong life by a few months.[261]And, in addition, the agency has come under scrutiny for the particular cost-effectiveness thresholds (in cost/QALYs) that it uses for appraisals. This is a subject to which we will return later in this chapter.

6.4.2 The NICE Citizens' Council: Introduction

In both appraising medicines and technologies and issuing guidance on clinical and public health questions, NICE has involved members of the public in different ways. As was pointed out earlier, one way is by directly involving members of the public on the committees issuing the clinical and public health guidance. But perhaps the highest profile manifestation of patient and public involvement is in the NICE Citizens' Council, a body that was created by NICE in 2002 to advise on a range of questions and in many ways, was designed to reflect the deliberative ideal that has been described throughout this thesis. The idea to form a Citizens' Council in the first instance emerged out of the NHS Plan (see earlier in this chapter) and, as Davies et al., explain, it was seen as a real experiment in the viability of true deliberation and lay participation in decision-making: "Those involved have seen themselves as engaged in a pioneering social experiment and have wanted to

[260] House of Commons Health Committee. First report of session 2007-8. London: Stationery Office, January 10, 2008. Accessed at
[261] Steinbrook, at note 259.

convey the lessons learned to an audience that went beyond the confines of a single organisation."[262]

The Council is composed of 30 individuals from the general public and the individuals are chosen to reflect the diversity of perspectives within the general public.[263] The group meets twice per year for three day sessions during which it discusses an issue that is put before it by NICE. The group hears testimony from independent experts and the feedback from the group is captured by an independent reporter who then circulates the summary of the group's discussion for final approval. The ultimate report is made available for public comment and then submitted to NICE's board for discussion. According to NICE, the overall point of the Citizens' Council is to "provides NICE with a public perspective on overarching moral and ethical issues that NICE has to take account of when producing guidance."[264]

Importantly, though, there is no requirement that the Citizens' Council come to any kind of consensus or majority decision on an issue – the forum only serves as a mechanism to reflect back to NICE what is believed to be the general public's perspective on an important issue. Indeed, NICE makes this point explicitly: "The Citizens Council does not produce NICE's guidance (such as for health, local government or social care services), nor does it input directly into any individual pieces of guidance that NICE produces."[265] It

[262] C. Davies, M. Wetherell, E. Barnett, and S. Seymour-Smith, *Opening the Box: Evaluating the Citizens Council of NICE*. Nottingham: Open University Press, 2005, p. 8.
[263] Ela Pathak-Sen, "Ordinary People, extraordinary wisdom," in P. Littlejohns and Michael Rawlins (eds.), *Patients the Public and Priorities in Healthcare* (Oxford: Radcliffe Publishing, 2009), p. 81.
[264] NICE, "Citizens Council," accessed 1/7/15 at https://www.nice.org.uk/get-involved/citizens-council.
[265] Ibid.

notes further that "there are other mechanisms NICE uses for doing this [incorporating feedback into guidance]"[266] but it does not specify how that takes place.

The goal of this case study is not to engage in a full history of the Citizens Council and the particular reports it has issued over the last dozen years. Nor, on the other hand, is it to evaluate the precise degree to which the Citizens Council has lived up to (or not lived up to) the particular principles of deliberation that have been articulated earlier in this thesis. That task is one that has been taken up extensively by scholars elsewhere.[267] Instead, my goal is locate the Citizens Council within the broader apparatus of decision-making within NICE and to suggest that it is the *other* steps that NICE has taken in the name of transparency and accountability that should render it a more legitimate decision-making body in the eyes of members of the general public.

6.4.3 The Citizens' Council: Moral Debates and Principles of Deliberation

It is worth pausing briefly to examine the structure of the Citizens' Council and the ways in which its deliberations relate to the broader policymaking authority of NICE. It is important to emphasize that the Citizens Council does not answer "just any" question that NICE is considering, but rather specifically questions that invoke moral or normative questions. Consider, for example, the titles of the last four reports issued by the Citizens Council:[268]

Report 17: Trade-offs between equity and efficiency
What are the societal values that need to be considered when making decisions about trade-offs between equity and efficiency?
Report 16: Social care values

[266] Ibid.
[267] Davies et al., *Opening the Box* at note 262.
[268] NICE, "Citizens Council" at note 264.

What aspect of benefit, cost and need should NICE take into account when developing social care guidelines?
Report 15: Discounting
How should NICE assess future costs and benefits?
Report 14: Incentives
In what circumstances are incentives to promote individual behavior change an acceptable way of promoting the health of the public?

In general, the Citizens Council is consulted to not provide a specific decision on an issue (should the cost/QALY ratio be at £20,000 or £25,000) or should X drug or treatment be approved for NHS use, but more general criteria that guide NICE decisions. In the report, for example, on social care, the final recommendations that emerged from the Citizens Council meeting were as follows:

- NICE should approach the development of quality standards and guidance for social care with 'fresh eyes' – those of the service user.
- NICE should produce new and original quality standards for social care that are authoritative and they must have 'teeth'.
- NICE standards and guidance should enable care to be built around each person's individual needs.
- NICE should consider integrating health and social care better to the point of producing joint health and social care guidance, and
- NICE standards and guidance should advocate that unpaid and informal carers are properly supported from an early stage and that these costs and benefits are taken account of in any calculations.[269]

The guidance, as can be clearly seen, is at a very high level and intended to simply provide NICE with the general public's thinking around a set of issues.

In designing the Citizens Council, NICE essentially had three main problems that often face institutions trying to involve members of the lay public in public policy decisions: (1) how would it ensure that the members were representative but not biased (i.e.

[269] NICE Citizens Council, "Citizens Council Meeting Report: 24 and 25 January 2013," accessed online 8/6/15 at https://www.nice.org.uk/Media/Default/Get-involved/Citizens-Council/Reports/CCReport16SocialCareValues.pdf.

representing interested stakeholders like certain pressure groups)?; (2) what could it do to foster genuine deliberation? and (3) how would it combat the notion that this was just a group to provide window dressing for an organization that simply existed to ration care for the population?

In attempting to address the first concern, NICE contracted with an independent organization that would recruit individuals and screen for potential biases. For the initial Citizens Council (members serve three year terms), NICE received over 35,000 "expressions of interest" and more than 4,000 actual applications.[270] Though precisely how the external organization was able to screen out individuals with significant pre-existing biases, other researchers who have examined the applications note that individuals were selected whose applications focused on wanting to make a contribution to the public health rather than those whose applications centered on a particular issue or problem within the NHS.[271]

Inasmuch as the facilitators worked to create a "truly" unbiased council of citizens, they operated with the knowledge that all members of the council (as patients with the NHS) would approach the issues with *some* bias. As a result, facilitators worked meticulously to foster deliberation of the Gutmann and Thompson variety. Consider, for example, this description of the evolution of the facilitation over the course of the first four Council meetings by Davies et al.:

> A great deal changed over the first four meetings, as hosts and facilitators worked to find ways that would engage citizens more effectively. Different styles of presenting and of assimilating information were tried as well as ways to explore the members' positions on values. Role plays, and teasing out priorities by allocating paper money

[270] Celia Davies, Margaret Wetherell and Elizabeth Barnett, "A Citizens Council in the Making: Dilemmas for Citizens and Their Hosts" in P. Littlejohns and Michael Rawlins (eds.), *Patients, the Public and Priorities in Healthcare,* (Oxford: Radcliffe Publishing, 2009), p. 130.
[271] Ibid.

> to photographed individuals, for example, were devices that were light hearted and fun. These were also safe devices for starting to name and explore differences of values. The facilitators made efforts to redesign sessions, incorporating feedback from Council members and moving away from a sole reliance on the formal witness presentations, small groups and plenary debates on which the initial session had relied… Less visible was a considerable amount of behind- the- scenes support by facilitators for members, both during the meetings and between them. We tracked differences in emotional tone as this paid off.[272]

The picture, to be sure, is not entirely rosy. Davies et al. note that the group still encountered difficulties in bringing forward truly oppositional ideas and that "A lack of clarity about the grounds on which citizens could legitimately speak, and pressures to not generate conflict, meant that while differences of class, ethnicity, gender, disability and age were visible to all, these identities were not able to be explored with regard to the topic under discussion."[273] That notwithstanding, evidence of attempts to foster genuine deliberation and discussion between participants is stronger in the case of the Citizens Council than any other case study (of the dozens) that I examined in the course of writing this thesis. In short, it would be difficult to make the case that this wasn't in some sense driving towards what many deliberative theorists would call the deliberative ideal.

Finally, we return once again to the question of relevance and policy importance: put simply, is there evidence that – unlike the NIH COPR – the Citizens Council had a measurable impact on actual policy? Because the conclusions that the Citizens Council comes to are not binding on NICE or the NHS, it is difficult, if not impossible, to come to the conclusion that in the absence of Citizens Council guidance, NICE would have arrived at the same conclusion on a given issue. With that said, there is limited evidence that on broad policy statements related to social values, NICE has incorporated conclusions that emerge from Citizens Council Reports. Norm Daniels, for example, notes that "In the

[272] Ibid., p. 133.
[273] Ibid.

document *Social Value Judgments: principles for the development of NICE guidance,* NICE articulates principles that should govern its advice for the NHS and these principles embody conclusions, where available, from Citizens Council deliberations about specific issues."[274] In another more recent development, NICE has "recently required decision-making committees to demonstrate how they have taken account of the social value judgments generated by the counsel and endorsed by the Board."[275]

6.4.4 NICE, Transparency, and Accountability

As we have seen to this point, in many ways the construction and operation of the Citizens Council is consonant with the principles of deliberation highlighted in chapter 4 of this thesis. Is NICE, then, a template for how to proceed with more effective and legitimate patient and public involvement? Is NICE the paradigmatic example of how to foster patient and public involvement that actually does incorporate important public feedback while creating a more representative and legitimate apparatus of government decision-making on critical moral questions of resource allocation and public health?

In many ways, I have argued that though consulting members of the public on matters of public importance is without question important, that patient and public involvement does little to further strengthen the transparency or accountability where decisions about how to allocate scarce resources are concerned. In certain ways, we might think that the Citizens Council is increasing democratic accountability: decisions rendered

[274] Norman Daniels, "Accountability for reasonableness and the Citizens Council" in P. Littlejohns and Michael Rawlins (eds.), *Patients, the Public and Priorities in Healthcare,* (Oxford: Radcliffe Publishing, 2009), p. 146.
[275] Annabelle Lever, "Democracy, deliberation and public service reform: The Case of NICE," *Economic and Social Research Council Publications* (July 2010), accessed online at http://clients.squareeye.net/uploads/2020/documents/0921TWE_ESRC_democracy_050730%20C.pdf, p. 16-17.

by NICE often cite feedback from the Council and the Citizens Council appears to have drawn attention to important moral questions in the realm of public health.

At several points throughout this thesis, I have argued that if our primary concern with allocating scarce resources is the transparency of the decisions and the ability of the public to hold policy-makers accountable, then we should try to implement reforms that make the decision-making process more transparent in an effort to foster vigorous debate about those issues in the public square. Knowledge about *how* NICE makes it decisions and *why* it makes it decisions (to approve drug X but not drug Y, etc.) is what empowers members of the general public to engage in a public debate about these moral questions on a larger scale and to vote for representatives who will implement public policies more consonant with the public's moral view. In this sense, it would reasonable to argue that the Citizens Council implemented by nice does take steps to further the principles of transparency and accountability that I have discussed earlier.

I want to pause, however, to emphasize that I do not see the Citizens Council as sufficient – or even as the most important factor – in rendering NICE a transparent and accountable organization. Empirical evidence on whether the Council's work has actually strengthened broader public debate on important moral issues in health care is limited to non-existent. What we do know, however, is that despite the fact that some of NICE's decisions have been controversial,[276] the vast majority are completely public and many of them are also available for public comment. Importantly, NICE's criteria for things like technology appraisal, clinical guidance, and public health guidance are both specific and

[276] See Steinbrook, "Saying No Isn't NICE" at note ___; Peter Littlejohns, Sarah Garner, and Nick Doyle et al., "10 years of NICE: still growing and still controversial," *The Lancet Oncology* 10, no. 4 (April 2009): 417-424; and Steven Pearson and Michael Rawlins, "Quality, Innovation, and Value for Money: NICE and the British National Health Service," *JAMA* 294, no. 20 (2005): 2619-2620.

publically available, and when it renders a decision about a particular case, drug, or treatment, it does so most often with reference to a specific provision of its value statements. This type of transparency is more exception than rule in the United States, and does more, I would argue, to advance a system of democratic accountability than simply convening a council of lay citizens. In short, true deliberation requires openness and honesty about moral decision-making and a willingness to try and push debates about those issues forward in the public square. In this case, the NICE Citizens Council appears to be contributing positively to that endeavor, but we must understand it in the broader context of how decisions are rendered within NICE and the NHS.

6.4.5 Appeals and Revisability – the NICE Appeals Process

We will recall that the primary tenets of a deliberative democratic process, as articulated in chapter 4, were relevance, publicity, revisability, and enforcement. To this point, one of the key deficiencies with the case studies that we have examined is the lack of a mechanism for appeal and revision. For deliberative democrats, one of the core features of a system of ideal deliberation is a mechanism through which the system can review and, if need be, change a decision that was unjust (for either procedural or substantive reasons). In none of the three resource allocation case studies to this point have we seen a true appeals process by which individuals affected by a rationing or resource-limiting decision could appeal to justness of that decision. NICE stands as a counter-example to this trend.

In many ways, NICE's appeals process renders it unique amongst its resource-rationing partners internationally. As Raftery notes, "Stakeholders, including companies and clinical organisations, can appeal against its findings on the grounds of process (due process), perversity (given the evidence), or powers (exceeding its powers). Appeals are

heard by a panel composed largely of non-executive members of NICE and industry and patient representatives."[277] Though other regulatory bodies (like, for example, the American Food and Drug Administration) open certain policy decisions and approvals for public comment, a standardized process of appeal with particular standards of review and evidence is a rarity in the international community.

With that said, NICE's appeals process has nonetheless come under criticism for not sufficiently living up to Daniels and Sabin's "Accountability for Reasonableness" framework. Schlander, for example, argues that the appeals process is overly restrictive and does not provide true accountability for unjust decisions:

> Appeals are narrowly limited to specific grounds and do not permit the debate to reopen. New evidence or simply disagreement with an appraisal will "almost certainly" not be accepted. Although understandable from a pragmatic perspective, these limitations are not adequately compensated for by opportunities for (invited) consultees and commentators to provide inputs during the appraisal process. Only relatively short windows of opportunity are provided, with a massive amount of data to be reviewed under limited transparency.[278]

Other have similarly criticized the appeals process for the extremely tight window of appeal, noting that appeals must be submitted "within 15 working days of the date of issue of the final recommendation."[279] In addition, anecdotal evidence suggests that there may be some political blowback that has entered the review process. As Mitton et al. report, "Manufacturers in the UK may also seek a judicial review of a NICE decision, although this is seldom pursued: 'People are concerned that if they take NICE to judicial review, the

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[277] James Raftery, "Review of NICE's recommendations, 1999-2005," *BMJ* 332, no. 7552 (2006): 1266-1268.
[278] M. Schlander,"The Use of Cost-Effectiveness by the National Institute for Health and Clinical Excellence (NICE): No(t yet An) Exemplar of a Deliberative Process," *Journal of Medical Ethics* 34, no. 7 (July 1, 2008): 534–39. doi:10.1136/jme.2007.021683.
[279] Craig R. Mitton, Meghan McMahon, Steve Morgan, and Jennifer Gibson, "Centralized drug review processes: Are they fair?" *Social Sciences and Medicine* 63, no. 1 (2006): p. 206.

next time they have to go to NICE, they're likely to get a much less friendly welcoming reception and possible outcome.'"[280]

Though NICE must strive to strike a balance between an open appeals process that is readily available to all and not prohibitively expensive to pursue, it must also ensure that the wheels of its bureaucracy do not grind to a halt in the management of appeals. With that said, its appeals process represents an important step forward in seeking to full the mandates of deliberative democracy through means outside of mere patient and public involvement. Though perhaps imperfect, it would be difficult to characterize the process as mere window dressing on an otherwise unaccountable and undemocratic system.

6.5 Connecting Practice with Theory: Resource Allocation

This chapter is interested not only with cataloguing the experiences of different countries, regions, or health care systems with patient and public involvement, but in analyzing the relationship between those practical experiences and the arguments articulated in this dissertation. Broadly speaking, my philosophical critiques of patient and public involvement in resource allocation fell into three main theoretical categories: I argued that (1) outcome-based decision-making provided an insufficient basis for evaluating these efforts insofar as it invoked certain assumptions about what outcomes are to be preferred; (2) that public involvement (in this context) violated important norms of political accountability and representation; and (3) that the motivation to become involved would leave us with a representative/represented relationship that threatened norms of political equality and rendered the process of deliberating (from the deliberative democrats' perspective) more difficult. I move now to analyze the extent to which each of these theoretical concerns manifested in practice in the case studies described above.

[280] Ibid.

6.5.1 Revisiting Outcome-Based Decision-making

At many different points in this dissertation, I have argued that a key deficiency of an outcome-based framework in the context of resource allocation is that it assumes that there exists some common agreement on what constitutes "desirable outcomes", and that the goal of policy is to maximize that agreed upon concept. But in the realm of resource allocation (as opposed to that of research governance), we may have good reason to believe that the debate about how to allocate resources is itself a debate about what constitutes a good outcome in the first instance.

This fundamental component of my arguments against the value of an outcome-centered framework in the realm of resource allocation becomes even clearer when examining the case studies examined above. In the case of the NIH, for example, outcome-centered theory relies on the (false) assumption that all (or indeed, any) of the individuals chosen to represent the public come to the table with a common understanding of what constitutes "welfare" in the realm of biomedical research. Should, for example, the NIH invest greater funds in diseases based on the burden of disease, the likelihood that funding will produce a successful deliverable, or take into account other social factors like whether or not a population subset has been historically marginalized or neglected? If it is to take into account multiple variables, how precisely does an "accurate" understanding of utility optimize and balance those variables?

With regard to the NHS plan and the deliberations in Oregon, similar concerns abound. In the U.K., for example, input from the public vis-à-vis focus groups, questionnaires, and postcard surveys are only useful insofar as there is an agreed upon concept of "utility" that policymakers understood that they are trying to maximize. In the

case of Oregon, town halls were also not held with these prior assumptions put on the table; in other words, individuals attending those meetings were not told that in rationing the Medicaid budget, the government was seeking to maximize utility in X, Y, and Z ways. Rather, they were asked – in an open ended fashion – how they thought health services should be rationed. In both cases, policymakers may or may not have had a set of organizing assumptions about utility and health outcomes in mind, but the precise *point* of involving the public is to solicit advice from external, blank-slate, and theoretically independent individuals.

The case of NICE departs slightly from this experience in an important and powerful way. Rather than asking its Citizens Council to try and answer the question of precisely *what* to do with a particular issue (fund X or Y, approve drug A or B), it relied on the Council to answer precisely the kind of questions that should be entrusted to average citizens: questions about *social values* and what constitutes welfare and desirable outcomes in the first place? In asking the Council to deliberate over what values should be important in social care or how NICE should account for future costs and benefits, NICE did not assume a prior determination about what constituted desirable outcomes – it instead asked the Council to make those kinds of determinations. This, to be sure, does not address all of the concerns that I've lain out (see, for example, below regarding political accountability) but it does demonstrate that where lay deliberation is concerned, challenges with outcome-centered decision-making are surmountable.

6.5.2 Political Accountability in Practice

Not all four cases raise the same questions of political accountability, and in a certain way, their differences prove informative as we seek to determine which elements of

PPI are worth refining and replicating going forward. In the case of the NIH, individuals are selected through an "open application process, with the advice of external and internal reviewers."[281] But importantly, in no way are the individuals who are ultimately selected through the NIH's bureaucratic process accountable to the public directly or even accountable to any member of the NIH who is accountable directly to the public. Should, for example, the COPR choose to act in a way that is entirely dissonant with the actual preferences of the general public, the public would have no recourse to remove or replace those individuals. That said, as a practical matter, the accountability – or lack thereof – within the COPR system may be of little more than academic significance. For, as I have argued already (and will again shortly), the activities of the COPR do not in reality represent true involvement but serve instead to simply appease those within the general public calling for a more democratic process. With that said, comparably situated committees – such as the National Institute for Clinical Excellence's (NICE) Citizens Council – are (at least theoretically) endowed with greater decision-making authority, and confront similar questions of political accountability.[282]

In both the Oregon case and that of the NHS plan, problems of accountability are less salient. In Oregon, though unaccountable members of the general public did participate in deliberations over rationing decisions in Medicaid, ultimate decision-making authority remained with the state legislature and its members – and to their credit, the

[281] National Institutes of Health, "COPR Fact Sheet," Director's Council of Public Representatives Page, accessed 17/02/14 online at < http://www.nih.gov/about/copr/about/factsheet.htm>.
[282] Though the NHS (and greater public participation in the NHS) remain extremely popular, the efficacy and viability of the NICE Citizens Council have been the subjects of considerable debate. See, e.g. Anne Gulland, "NICE proposals for citizens council condemned by patients," *British Medical Journal* 325 (2002): 406; Michael D. Rawlins, "Pharmacopolitics and Deliberative Democracy," *Clinical Medicine* 5, no. 5 (2005): 471-475; M. Schandler, "The Use of Cost-Effectiveness by the National Institute for Health and Clinical Excellence (NICE): no(t yet) an exemplar of a deliberative process," *Journal of Medical Ethics* 34, no. 7 (2008): 534- 539.

decision remained highly public, transparent, and subject to both media and public scrutiny. The same can be said of the NHS plan. As part of that plan, substantial feedback and input was sought from members of the general public, but decision-making authority rested with the centralized Department of Health that was ultimately overseen by an elected body in Parliament.

The case of the NICE Citizens Council does not, unfortunately, solve the problems of political accountability that arise at the NIH but the case falls closer to both the Oregon and NHS plan cases. Though the members of the Citizens Council are not elected, great care was taken to ensure both that they were descriptively representative of the country as a whole and that they were able to come to the deliberative space with the ability to set aside personal biases. Finally, it should be noted that NICE was able to strike something of a "sweet spot" – it did not entrust full decision-making authority to the Council but it took steps to ensure that the feedback was indeed taken seriously, at least in very broad terms.

6.5.3 Addressing the Motivation to Deliberate

Recall from chapters 4 and 5 that my concern with an individual's motivation to become involved in public deliberations manifested in two separate considerations: (1) that a system of public involvement could exacerbate problems of substantive equality and (2) that those who were highly passionate about a given issue were less likely to come to the process with an open mind and willingness to engage in true debate and deliberation. Examples of both concerns can be found in the case studies discussed here.

A brief survey of both current and former members of the NIH's COPR reveal that the individuals who were either externally nominated or self-nominated were both significantly more educated than an average member of the general public, and

significantly more well versed in the intricacies and complexities of public health and biomedical research. The current committee, for example, consists of a senior media consultant focused on health issues, two members of patient-advocacy groups, two CEO's of public health organizations, two professors, the CEO of a community health centre, and an administrator at a major professional association of physicians.[283] Though it is difficult, of course, to generalize as to what constitutes an "average" member of the lay public, the academic and professional backgrounds of the individuals on the COPR suggest at minimum that they are represent those with higher educations and socio-economic advantages. The NIH might counter that the nomination process is open, which is to say that it is not simply a matter of "elites" selecting other "elites." But where resources (financial, educational, etc.) play a role – either directly or indirectly – in determining one's ability to participate, substantive equality is implicated. In addition, despite the fact that the NIH claims that participating members all agree "to represent the interests of the public at large putting aside our individual affiliations and personal interests,"[284] there is little reason to believe that this is necessarily the case. Over the course of its history, the COPR has always had members of both physician-organizations and patient-advocacy groups within its ranks, and nearly all of its members have (perhaps unexpectedly) a connection to a particular health constituency.

Questions of substantive equality and a passion for issues played a smaller role in the implementation of the NHS plan, perhaps again because the ultimate locus of decision-making still rested with those in a position of accountability. In addition, the NHS was deliberate in its efforts to draw a racially, geographically, and socio-economically diverse

[283] National Institutes of Health, "Current Member Biographies," *Director's Council of Public Representatives Page*, accessed 17/2/14 at < http://www.nih.gov/about/copr/members/bios.htm>.
[284] National Institutes of Health, "COPR Fact Sheet."

group of individuals to its focus groups. Though there was some evidence that of the individuals who sent back postcards, a disproportionate percentage were from those who worked within the health care field, that fact was, at least theoretically, taken into account by policymakers attempting to sift through their mounds of data.

Oregon presents a slightly more complicated case than either of the first two. Like the case of the NHS plan, Oregon's process was "open," meaning that any individual throughout the state could attend the town meetings at which members of the general public could voice their opinions. And, like the NHS plan, ultimate decision-making authority remained with a body that was directly accountable to the general public. With that said, the process does implicate an element of substantive equality and political accountability not yet discussed to this point. Notably, the Oregon experiment dealt only with rationing policy as it related to Medicaid, the health insurance program used primarily for the indigent, despite the fact that the public deliberations were open to the entire population, most of whom would remain unaffected by these decisions. As Ian Shapiro observes, "In countries like Britain and Canada, where the great majority of the population use collectively rationed medical services, their participation in democratic decision-making through the political process lends legitimacy to the resulting policies. By contrast, in Oregon, more than 80 percent of the population is unaffected by the rationing program."[285] And, indeed, there is evidence that those who participated in the public forums were disproportionately wealthy, well educated, and had careers as either physicians or health professionals.[286] Though we might have expected that the individuals most likely to participate in open public deliberations were those most likely to be affected (Medicaid

[285] Ian Shapiro, "Enough of Deliberation" at note 157, 33.
[286] Jack H. Nagel, "Combining Deliberation and Fair Representation," *University of Pennsylvania Law Review* 140, no. 5 (1992): 1965-1985.

beneficiaries), that hypothesis would fail to account for the fact that the ability to take the time to participate in such a forum requires a surplus of resources – time, money, and a belief that one's participation in such a setting is likely to be influential or taken seriously.

I do not mean to suggest here that Oregon illustrates the need for some kind of categorical imperative: that in some sense *only* those affected by a decision should be allowed to participate in decision-making. In this case, surely the taxpayers whose taxes were funding Medicaid and the physicians responsible for providing care had a compelling (if not overriding) stake in the outcome of the rationing process. With that said, deliberative democratic theory is built on the essential premise that decisions made in deliberative forums should be justifiable to those who are ultimately bound by those decisions. And, as Shapiro argues, because "different people are bound by collective decisions[,] when there is a great variation in the impact of a decision, then interests diverge in ways that are relevant to assessing the decision's legitimacy."[287]

Finally, as I have already documented, the NICE Citizens Council is composed of 30 individuals who are heavily screened by an independent agency to ensure that they can approach the process of moral decision-making in an unbiased manner (much as jurors would be selected for a civil or criminal trial). We should not, of course, be naïve in thinking that the participants are completely unbiased or apathetic – after all, they care enough about the future of the NHS to give up valuable time that they could be spending other ways to volunteer to serve. With that said, volunteers were selected primarily on the basis of their desire to see the NHS succeed as a whole rather than see an individual "pet project" succeed. Lastly, unlike the Oregon case, all of the members of the Citizens Council were British citizens who, by virtue of being citizens, ostensibly were also NHS

[287] Shapiro, "Enough of Deliberation" at note 157.

patients. This avoids some of the problems that were associated with non-Medicaid patients making decisions for Medicaid patients in the Oregon case.

6.5.4 Window Dressing as a Tool of Policy Legitimation

Though I have not explicitly addressed the idea of PPI as a tool of policy legitimation to this point, it is worth pausing to examine the ways in which the various case studies illustrate how involvement can be used to pacify critics without making more vigorous reforms in the name of transparency and accountability. In the case of the NIH, the only robust study to date of COPR activity cites numerous former COPR members who all saw their roles as fundamentally symbolic in nature. In the case of the NHS plan, the public nature of the plan lent itself to a similar dynamic – media coverage around the postcard mailing was intense, and DoH staff were able to portray themselves as vigorously engaging with the preferences of the general public. In Oregon, the same type of media coverage was intensified by the fact that (at least at that point in time) Oregon was the only state in the country actively engaging in the business of rationing in a transparent and public way.

With that said, there is little evidence from any of the cases that the process of resource allocation became more transparent, accountable, or consonant with stated public preferences. In the case of Oregon, for example, bringing rationing to the forefront of public discussion ironically had the opposite of the intended effect: over the next 20 years, the number of items funded by legislature increased steadily as the public was forced to directly confront with the implications of true rationing, something it found distinctly unappealing.

The exception to this rule is the case of NICE. As I documented earlier, guidance produced by the Citizens Council has been cited in many NICE policy statements and appraisal decisions and committees within NICE are now required to show how their decisions are consonant with the Council's reports on social values. With that said, it is still difficult to know the extent to which the Council has actively changed the decisions that would have been made by NICE in the Council's absence. This is, of course, a counterfactual that will never come to pass, but we should be cautious in over-ascribing power to the Citizens Council in decisions that have ultimately been made by NICE. Finally, as I have argued, NICE's appeals process (though perhaps imperfect) lends greater legitimacy to the decisions is ultimately renders and helps to rebuff the notion that its actions are merely meant to provide political cover for otherwise unjust decisions.

PPI as window dressing is, of course, less of a theoretical or philosophical challenge to PPI itself and instead a criticism of the way in which it has been used in practice. Obviously involving patients in the aforementioned ways is not mutually exclusive with engaging in other efforts that reinforce transparency and accountability, but it is important to be aware of the way in which political realities play out in practice. Proponents of greater user involvement should remain mindful of the underlying reasons for involvement (transparency, accountability, etc.) and be open to the fact that other mechanisms might well further those goals more strongly.

6.6 Conclusion

This chapter sought not to provide a comprehensive review of patient and public involvement broadly, but to isolate individual case studies in an effort to highlight the ways in which the theoretical concerns elucidated here manifest in practice. In examining

instances of patient involvement in medical research design, I found not serious normative problems, but an overall dearth of evidence concerning the effectiveness and cost-effectiveness of these programs. Though calls for more rigorous evidence surrounding patient involvement and research are not new, there appears to be very little sustained effort by either patient advocacy organizations or public institutions to gather such evidence. Because these involvement efforts are not cost-free, it is incumbent upon governments who seek to foster greater user involvement to develop means of ascertaining which types of involvement are cost-effective and which are not.

In the realm of resource allocation, the question – as it has been elsewhere in this dissertation – is much more complicated. Concerns around accountability, substantive equality, and the motivation to deliberate abound within the case studies discussed here, but the degree to which they raise concerns varies heavily based on the type of involvement, the individuals involved, and the issues on which they are involved. In many ways, this analysis simply reinforces the idea established in chapter 2 that patient and public involvement is a category that needs to be disaggregated and dissected in a more conceptually useful manner.

I also attempted to show that those interested in the ethics of patient and public involvement cannot summarily dismiss the so-called "practical questions" out of hand. Though we should perhaps distinguish between those issues that are theoretical and those that are practical, how and whether to involve is an issue that confronts policymakers, health systems administrators, health care providers, and patients on a daily basis around the world. If, for example, certain PPI efforts are both ineffectual and merely serving as window dressing, the question naturally arises: in what other ways might transparency and

accountability in the allocation process be advanced? This is one of the exploratory questions to which I turn in the conclusion.

Finally, it is worth emphasizing that the example of NICE serves as a useful counterpoint to the other case studies in this chapter and may perhaps provide a template for more effective patient and public involvement going forward. First, the citizens' council is well integrated into the broader apparatus of decision-making and citizens are consulted on questions of high social importance. In addition, there is strong evidence that their beliefs are actually taken into account during the course of actual policy decision-making. Finally, NICE does not rely exclusively on the Citizens Council as its only (or even primary) tool of policy legitimation – its social values framework and appeals process resonate with other elements of deliberative decision-making and constitute a more holistic approach to accountable and transparent government.

7
Conclusion

7.1 Introduction

In large measure, as the trend towards greater patient and public involvement has grown, scholars have increasingly focused their attention almost exclusively on understanding *when* and *how* to involve members of the public in decisions about research or priority setting, rather than *whether* to involve in the first place. As a result, this thesis sought to take a step back and ask what should be considered the primary question: what is the normative justification for involving patients and members of the public in decisions about medical research and health services?

Broadly speaking, a review of the literature found two prominent justifications given for involvement: one based on the idea that greater patient and public involvement improved the overall health of the population through better, more applied, and patient-centered research and policy decisions (the outcomes-centred justification) and another rooted in the notion that participation enhances accountability and transparency in the health care system, thereby strengthening bonds of democratic legitimacy. I engaged in an examination of these two justifications in order to better understand whether broad-based policies supporting patient and public involvement were warranted. My goal was not simply to understand whether or not compulsory PPI policies (such as those instituted in the UK) were justifiable, but to ask more broadly whether there is a generally strong argument in support of patient and public involvement. More specifically, my goal was to engage with the arguments in favor of PPI *as they are articulated* by PPI's advocates. In that sense, I sought not to attack marginal or fringe arguments in this field, but to find the

strongest arguments that are made by supporters of PPI and then critically engage with them.

In this final chapter, I first review the main conclusions of this thesis, and then consider the ways in which those conclusions apply to the case studies that were examined in chapter 6. My goal here is not simply to reiterate the ideas put forward earlier in this thesis, but to highlight the ways in which the theoretical conclusions here have practical implications. Then, I move to discussing avenues for future research while highlighting aspects of the debate over PPI that remain unanswered. Finally, I transition to a discussion of alternative solutions, examining the types of steps that health care providers and payers can take in order to foster a more transparent and morally accountable system. I conclude by arguing that accountable and transparent systems are defined more by certain deliberative characteristics than they are by procedural commitments to involve lay citizens directly in policy-making.

7.2 Broad Takeaways

7.2.1 Conclusion #1: PPI represents a diverse set of practices, many of which may be subject to different types of policy and ethical analyses

If nothing else, this dissertation sought to clarify the conversation around patient and public involvement by highlighting the ways in which different kinds of involvement are not just practically different, but philosophically distinct. Since patient and public involvement became a subject of considerable scholarly discussion, it has been discussed in relatively broad and general terms without attention to the *meaningful* ways in which different kinds of involvement raise different kinds of ethical considerations. Policy action to increase patient and public involvement has similarly understood all types of

involvement as falling under one conceptual umbrella.[288] And though different types of involvement are, to be sure, united by certain features, in many ways, I have tried to show how they must be understood as fundamentally separate ideas.

In chapter 2, I argued that different types of involvement could be understood as falling along three separate axes: (1) who was involved, (2) on what issue were they involved, and (3) how were they involved. I maintained further that the nature of the obligation to involve (or not involve) differed substantially depending on variables associated with all three of those different axes. Whether to involve individual patients, for example, in medical research, raises a set of questions that are entirely different (e.g. does such involvement generate research that improves health care quality, responsiveness, patient-centeredness, etc.) from those associated with whether to involve general members of the public in a citizens' jury on fundamental structural forms to health care delivery in a particular primary care trust in the UK (e.g. do such reforms foster a more accountable or transparent system of governance?). Similarly, if we involve patients or members of the public in a purely consultative capacity, the nature of our concerns around accountability is markedly different than if we authorize those individuals to render binding decisions. Though it is not possible to simply construct a 3-D model of these axes and deem certain areas justifiable and others unjustifiable, greater attention to the ways in which PPI is an assemblage of related – yet in many ways distinct – concepts is necessary within the broader literature on citizen participation and deliberative democracy.

[288] See, for example, the UK Health and Social Care Act, which mandates patient and public involvement at all levels of the UK National Health Service. See UK Health and Social Care Act, 2001, at <http://www.legislation.gov.uk/ukpga/2001/15/contents>.

7.2.2 Conclusion #2: Outcome-based arguments are powerful – to a point

Much of the discussion around "improving" patient and public involvement necessarily operates under the assumption that the things PPI is trying to improve (medical research, health system functioning, resource allocation, etc.) can be measured easily. Though this seems plausible with certain facets of PPI – for example, the relevance and quality of medical research – it is much more difficult when questions surrounding resource allocation or priority setting are concerned. To the extent that the question of how to allocate scarce resources to various health needs is a debate *itself* about what should be optimized, outcomes-centred arguments are of only limited utility. Put simply: it is difficult to know whether PPI produces better "outcomes" when the desirability of the kinds of outcomes PPI may produce is the subject of the debate.

It should be emphasized, however, that this is not a sweeping critique of all types of outcomes-centred evaluation of patient and public involvement. In certain areas, like medical research, health system functioning, etc. – outcomes are critical *and* well agreed upon. As the literature on PPI is growing, the number of cases where PPI has been implemented has grown as well. But because PPI imposes real financial costs on the health care system, it would be naïve to approach questions of efficacy and effectiveness without a consideration of cost as well. Just as health care systems have developed cost-effectiveness frameworks (cost/QALY, etc.) for procedures, therapies, and pharmaceuticals, so too should they begin to develop cost-effectiveness frameworks for evaluating whether to pursue (or mandate) PPI in a particular context. As I will argue later in this chapter, research that rigorously determines how effective PPI is at improving the quality and/or

applicability of medical research should be high on the agenda for scholars in general and those supporting greater involvement in particular.

With that said, the case studies in this chapter demonstrated in real and tangible terms the ways in which patient involvement can improve things like the relevance of certain kinds of research and the strength of patient protection in informed consent. In these realms, where the objectives are clear and around which there is relative consensus, it would be a mistake to deny the notion that outcomes hold powerful policy value.

7.2.3 Conclusion #3: Direct involvement does not guarantee a more legitimate or transparent process

One of the things that struck me most in researching this thesis was the overwhelming sense in the literature that patient and public involvement, *because it constituted greater direct citizen involvement in decision-making*, would *automatically* produce a more accountable and transparent system. In this sense, much of the literature that was referenced earlier in chapter 1 and again in chapter 5 understands there to be a direct line between citizen involvement and greater accountability and transparency. One of the fundamental goals of this thesis has been to question and probe that assumption.

Indeed, if there is one critical normative conclusion to be drawn from this dissertation, it is that both transparency and accountability are critical virtues in any democracy, but the mechanisms through which those virtues can be strengthened and/or achieved is profoundly complicated and not well suited to "quick-fix" solutions. The democratic intuition, in many cases, is to believe that the closer people are to the decisions made by government, the more responsive that government is likely to be to the will of the people. This is a lesson that many of us are taught in primary school civics classes and a

sentiment that is very often bandied about in the political sphere on both sides of the Atlantic. In the US, for example, it is common to decry national politicians as being "out of touch" with real America because we believe that our local and state governments, by virtue of being closer to us, are necessarily more accountable. But is this really so?

This thesis sought to delve into a much more granular understanding of the *mechanism* by which PPI can serve to strengthen norms of accountability and transparency. While an empirical analysis evaluating that claim was beyond the scope here, my discussion in chapters 4 and 5 (in addition to the case study analysis in chapter 6) revealed that in many instances, there was no evidence that the health care system became more accountable to as a result of patient and public involvement (e.g. Oregon, the NIH). In other cases, I showed that where the system was potentially accountable, there remained an outstanding question as to *whom* the system was accountable to. Simply involving members of the public directly in decision-making and assuming that those members of the public represent either the "general public" or are descriptively representative of certain sub-populations is a risky endeavor that I contend papers over many of the nuanced complexities of transparent, accountable, and representative government.

7.2.4 PPI is not <u>the</u> problem – it is part of a <u>systemic</u> problem of democratic accountability

At various points throughout this dissertation, I have made the case that PPI can do more harm than good in the realm of political accountability and transparency. Recall, for example, that in chapter 5 I contended that PPI can create an unjust system that actually reifies certain social and political divisions based on privilege. I also maintained that deliberative forums frequently lack strong mechanisms for appeal and recall, casting doubt

on PPI's claim to be a mechanism for asserting citizen control over processes that affect their well-being.

This critique could be understood as primarily one that isolates PPI as the culprit in a system that doesn't adequately protect and promote accountability or transparency. In reality, however, my critique is instead one of a broader system in which PPI has been seen in certain cases as a quick-fix solution to the "democratic deficit." While I do argue that PPI has largely been an ineffective way to safeguard these core democratic values, the fundamental take-away from my argument is not that PPI has caused damage to an otherwise working system but rather that the system itself has failed to reckon with the very real challenges of how to foster greater accountability around often-technical and complicated questions that have major downstream effects on social welfare. In a world of representative democracy where the notion of billions of people participating in Greek-style direct democracy is simply not feasible, what does modern democratic governance require from the perspective of transparency and accountability?

It is for this reason that the rest of this conclusion deals not just with major questions for future research around PPI but extends more broadly to the question of how to create a more transparent, accountable, and deliberate system of decision-making, particularly around questions of how to allocate scarce resources. The conclusions that I draw here have implications not just for how to reform our existing structures of decision-making in health care and biomedical research, but indeed for the broader social policy space as well. Indeed, if we establish high standards for these core democratic virtues in health care, there is little reason to believe we should not maintain them in other critical policy realms like education, housing policy, or economic policy.

7.3 Future Opportunities for Research

This dissertation sought, first and foremost, to examine whether or not a strong normative justification existed for patient and public involvement, as it is presently constituted. Though I ultimately conclude that insufficient reasons exist to support the sort of broad-based policies favouring involvement that are currently in place in the United Kingdom, several gaps in the research remain, many of which are brought to light by the work of this dissertation. I turn now to explore some of these unanswered questions and to discuss the impact that future research might have on the way in which PPI is practiced going forward.

7.4.4 Is PPI "effective" from an outcomes-centred perspective?

Recall that in chapter 3 I found outcomes-centred arguments were of only limited value. Two overarching concerns were elucidated there. First, I argued that these arguments missed the point insofar as where priority setting and resource allocation questions are concerned, the entire reason behind involving patients or members of the public is because the question of which outcome to maximize is itself a contested one.

But where involvement in medical research is concerned, I argued that outcomes-centred frameworks may be of enormous value. The problem, however, is that scholars fundamentally do not know which types of involvement and in what research contexts involvement actually improves the quality, applicability, or other outcomes of medical research. In medical research, we should be much less concerned with the problems of representative accountability that were discussed in the context of deliberative democratic theory. We should, however, be concerned with whether the funds that are being spent to promote PPI in research are actually changing the research in significant and measurable

ways. Though several others have also pointed to the need to research the efficacy and effectiveness of PPI in a more scientifically robust way,[289] little progress has been made in this regard, while momentum towards greater patient and public involvement continues unabated.

The literature is replete with individual case studies and increasingly, systematic reviews evaluating those case studies. But lacking are more rigorous studies which can isolate the reasons why PPI is effective in certain research contexts but not in others. Ultimately, when asked if patient and public involvement is net beneficial for society, this dissertation answers "sometimes." But given the state of the current literature, we have little ability to know when it is and when it is not.

7.4.5 What kinds of reasons should be considered "acceptable," "reasonable," or "legitimate" in debates around health care?

Throughout the course of this dissertation, I have referenced at several points deliberative democracy's concern with "reason-giving." Indeed, many deliberative democrats in their focus on both decisions made in the deliberative space and the decisions rendered from non-deliberative entities, place substantive constraints on the kinds of reasons that should be considered acceptable. Gutmann and Thompson, for example, note that decisions should not be considered legitimate unless they "appeal to principles that individuals who are trying to find fair terms of cooperation cannot reasonably reject…They

[289] See Rosemary Barber et al., "Can the impact of public involvement on research be evaluated? A mixed methods study," *Health Expectations* 15, no. 3 (2012): 229-241; Sophie Staniszewska et al., "Developing the evidence base of patient and public involvement in health and social care research: the case for measuring impact," *International Journal of Consumer Studies* 35, no. 6 (2011): 628-632; Sophie Staniszewska, Sandy Herron-Marx, and Carole Mockford, "Measuring the impact of patient and public involvement: the need for an evidence base," *International Journal for Quality in Health Care* 20, no. 6 (2008): 373-374; Jill Murie and Gerrie Douglas-Scott, "Developing an evidence base for patient and public involvement," *Clinical Governance: An International Journal* 9, no. 3 (2004): 147-154.

are reasons that should be accepted by free and equal persons seeking fair terms of cooperation."[290] They further place substantive constraints on these reasons, extolling the virtue of broad principles like "basic liberty, basic opportunity, and fair opportunity."[291]

But what should those reason-constraints look like on the ground in health care? If part of the goal of creating a health care system that is more transparent, accountable, and open to appeals of citizens is to foster greater legitimacy, surely a more robust conversation is needed around the kinds of ideals and ideas that should legitimately govern our public reason. With greater academic focus on procedural justice and attempting to elucidate the precise mechanisms by which just decisions can be rendered, the need to identify the kinds of reasons that should be considered legitimate only rises in importance. Frameworks like Gutmann and Thompson's serve as a potentially useful starting point, but they are undoubtedly only the very beginning of an important conversation going forward.

7.4.6 How far does the "right" to involvement extend (or not extend)?

Though this dissertation is concerned with *whether* a democratic "right" to involvement exists, future scholarship should also address the *extent* to which such individuals have a right to participate in decisions made at the national, regional, and local levels. In many ways, the effort to understand where to draw the line between involvement to which the public is entitled and involvement which is not would prove useful for both supporters and opponents of greater involvement.

For those who support PPI, the question of where to draw the line is not often even recognized. If individuals should participate directly in decisions about the fundamental restructuring of a hospital or health care system, should they also be directly involved in

[290] Gutmann and Thompson, *Why Deliberative Democracy*, 3.
[291] Ibid., 133.

decisions about drug regulation, national security, or national education policy? Undoubtedly, many would respond that in those areas, certain technical levels of expertise are needed. But in important ways, decisions about drug regulation, national security, and national education policy involve moral considerations of value that are similar to those required in health care services. Supporters of PPI must consider the practical limits of citizen involvement in policy-decisions, and explain why citizens have the democratic right to participate in resource allocating or priority setting decisions in crucial area of human services but not in any (or all) of the others.

Conversely, those opposed to greater citizen involvement must deal with the opposite question. If there is no inherent right in a liberal democracy to participate *directly* in decisions about health care or medical research, do any such rights exist, and in what political contexts? Even most opponents of PPI would be reticent to argue that citizens *never* have the right to participate directly in decisions made by the government, though such an argument in favor of a purely representative system is of course conceivable.

Despite the fact that line-drawing of this nature can often devolve into fruitless debates over cases at the margins, the exercise should nonetheless prove valuable in isolating the relevant variables at hand. Is the right to involvement mediated by the "distance," so to speak, of the governing body (e.g. local, regional, federal) from the citizen? By the magnitude of the issue and its impact on human flourishing? Or, perhaps, there exists a compelling reason to distinguish between involvement in health and involvement in other issues of national importance? In any case, identifying these variables is a philosophically challenging but important task.

7.3.4 Who <u>should</u> make decisions about resource allocation? What does "expertise" in resource allocation mean?

Readers at the conclusion of thesis may thus justifiably ask: "if lay people are not to be involved directly in decision-making around priority setting or resource allocation, who should be?"

This is a legitimate and difficult question, particularly given the history of medical paternalism that looms large over the health care system as a whole. In many ways, patient and public involvement was a natural outgrowth of the reaction against paternalism in the clinical setting. Once patients (rightly, I would argue) began to take greater control over decisions about their own care in the clinical context, it made sense for lay individuals to push back against the dominion of control scientists and technocrats held over health care systems, national drug regulation regimes, and systems of biomedical research.[292]

I do not dispute the idea that in certain instances, lay members of the public may bring to the table a valuable perspective that is absent amongst experts, scientists, and technocrats. But just as I maintain that it is overly simplistic to argue that there is such a thing as "the public perspective" that can be embodied by a representative of "the public," I similarly think it is myopic to characterize all so-called "experts" as evincing little to no understanding of "the common person's" perspective. Resource allocating committees should unquestionably seek to incorporate a diversity of perspectives into their decision-

[292] The history of patient activism with regard to the health care system, drug regulation regimes, and biomedical research has been extensively chronicled by other scholars in numerous different countries. For a brief history on these activities in the UK, see Rob Baggott, "A Funny Thing Happened on the Way to the Forum? at note 28; and Rudolf Forster and Jonathan Gabe, "Voice or Choice?" at note 82. The history of public involvement in various levels of the health care system has been much more widely studied in the US. See, e.g. Daniel L. Kleinman (ed.), *Science, Technology, and Democracy* (Albany: State University of New York Press, 2000), particularly Chapter 1.

making processes, but they should also not shy away from relying on experts to guide them. This, naturally, begs the question of what constitutes expertise in resource allocation, fundamentally an exercise in moral reasoning as much as it is one in economics, health policy, or medicine. Who, therefore, are the moral experts?

This remains today a highly controversial topic within the literature on moral expertise, and specifically, bioethical expertise.[293] Unlike some of the other areas of future research highlighted here, there can be no definitive answer to the questions of "are there moral experts?" and "who are they?" Nonetheless, organizations and agencies attempting to make sound ethical decisions on-the-ground should seek to involve individuals in the resource allocating process who embody the principles of deliberative thinking that have been discussed here. Insofar as there can be no guarantee that resource allocators arrive at the "right" decision (as principles of distributive justice would deem "right"), they can craft processes that are in accordance with widely agreed upon principles of deliberation. To be sure, a focus on process and on constructing a morally deliberative process does not immediately answer the question "who to involve," but it does serve to reorient the debate around moral expertise.

In some sense, debates about whether moral experts exist and if so, who they are distract attention away from the more fundamental goal of crafting a just *process* rather

[293] Debates about moral expertise have been the subject of considerable conversation within the literature for more than 30 years. See, e.g. Peter Singer, "Moral Experts," *Analysis* 32, no. 4 (1972): 115-117; David Archard, "Why Moral Philosophers Are Not and Should Not Be Moral Experts," *Bioethics* 25, no. 3 (2011): 119-127; H. Tristam Engelhardt Jr., "The Ordination of Bioethicists as Secular Moral Experts," *Social Philosophy and Policy* 19, no. 2 (2002): 59-82; and Loretta M. Kopelman, "Bioethics as a Second-Order Discipline: Who is Not a Bioethicist?" *Journal of Medicine and Philosophy* 31, no. 6 (2006): 601-628.

than arriving at the right outcome.[294] In short, then, my answer to the question of "who should deliberate" is that individuals should be chosen to deliberate not based on whether they are experts or lay-people, but based on whether they possess sufficient knowledge and appropriate disposition to participate in active moral deliberation in a considered and reasoned fashion. How precisely to implement those ideals in practice is a difficult, but significant question for future applied research.

7.4 The Path Forward: How can research governance health system priority setting be made more accountable, transparent, and deliberative?

As I have argued at many points throughout this thesis, the principles undergirding deliberative democracy are, in and of themselves worthy of pursuit. Few would dispute that accountability, transparency, and reciprocity – in many ways the cornerstones of deliberative democratic theory – are virtuous ideals within a liberal democracy. And, while in certain instances, patient and public involvement may advance those ideals, there is little evidence that categorically, that is the case. At this point, I turn to discuss other options available to health care systems and government agents that might foster greater accountability, transparency, and reciprocity in decision-making about health care. My focus here is in trying to understand what makes a process deliberative in the first place and how those characteristics can be incorporated into health care organizations responsible for allocating scarce resources.

It should be emphasized at this point that deliberative democracy, above all else, proposes a system of reason giving and decision-making that abides by certain principles.

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[294] See Norman Daniels, "Accountability for Reasonableness: Establishing a fair process for priority setting is easier than agreeing on principles," *British Medical Journal* 321 (2000): 1300-1301; and Sofia Gruskin and Norman Daniels, "Process is the Point," *American Journal of Public Health* 98, no. 9 (2008): 1573-1577.

But, in no way does it require direct participation in the decision-making *process* by those who stand to be affected by the decision. As Daniels and Sabin explain:

> We should not be misled into thinking that only large, public votes are at issue, or that the deliberative process requires direct, grass-roots participation, a la town-meeting democracy. Much of our democratic process takes place in decentralized procedures in which those affected by decision-making often do not participate. This is true not only of representative legislative bodies, but in executive and legislative branch agencies. What is crucial is that the heart of that process involve [sic] democratic deliberation.[295]

To that end, the focus of my analysis in this final chapter is in highlighting the ways in which government agencies (and even private payers) can create processes more in line with the principles of democratic deliberation.

7.4.1 Advancing Transparency – Making Priority-Setting and Resource-Limiting Decisions Public

At the core of a just system of resource allocation is the idea that where decisions are made affecting the health or quality of life of individuals, those individuals retain the ability to directly challenge the legitimacy or fairness of those decisions. A prerequisite to that idea is the guarantee that individuals affected by resource-limiting decisions have access to information about both the content of the decision and the justification for it. As Daniels and Sabin note, "Regardless of the mechanism for organizing and reimbursing these services, justice requires that they be distributed fairly, and *there is no way to assure that outcome without requiring that limit-setting decisions and their rationales be public*

[295] Norman Daniels and James Sabin, "Limits to Health Care: Fair Procedures, Democratic Deliberation, and the Legitimacy Problem for Insurers" at note 46.

and be challengeable by those affected by them [emphasis not added]."[296] But while most countries articulate broad principles that govern resource allocation and priority-setting decisions and subsequently release specific guidance to hospitals, providers, and patients as to *whether* a particular therapy, treatment, or physician consultation will be covered, few explain in moral terms *why* they have chosen to cover some of those treatments or therapies as opposed to others. There is a difference, in other words, between having a general public debate about values and explaining to beneficiaries, enrollees, or taxpayers why a certain treatment, therapy, or line of research has been denied or rejected.

Consider, for example, some of the case studies that were discussed in chapter 6. In Oregon, rationing decisions with regard to Medicaid were made with significant input by public bodies, though the ultimate decisions were eventually rendered by the legislature. But, the legislature did not take the next step further in explaining why it made the moral distinctions that are inherent in priority setting (e.g. on what basis were decisions made about how to list the various procedures within the list?) This provided those affected by the decisions with little moral recourse insofar as the legitimacy of the decisions could not be substantively challenged from the perspective of distributive justice. Instead, the legislature could have explained in concrete moral terms why it had elected to fund certain treatments rather than others. Though involving members of the public might have fulfilled certain espoused principles of procedural justice, it allowed the legislature to avoid a substantive public conversation around the moral principles that govern a difficult problem of resource allocation.

The same can be said of our case study of resource allocation of biomedical research at the National Institutes of Health (NIH). The NIH has been willing, in broad

[296] Ibid, p. 312.

terms, to explain the general criteria that govern its decisions around priority setting. In 1997, it published a document which explained the procedural details of the priority-setting process and noted the following as criteria that were "both influential and continuous" in priority setting: "public health needs, scientific quality of the research, potential for scientific progress (the existence of promising pathways and qualified investigators), portfolio diversification along the broad and expanding frontiers of research, and adequate support of infrastructure (human capital, equipment and instrumentation, and facilities)."[297] But it has been reticent to explain in concrete terms (a) how it measures or defines those criteria and (b) how its actions in allocating funds satisfy them. Since the early 1990's, for example, the NIH has continued to fund breast cancer research at roughly 2-3 times the amount of prostate cancer research, despite strong similarity in overall burden of disease between the two. Though obvious political factors are at play due to the power of the breast cancer lobby,[298] in a more transparent and publically accountable system, the NIH would be willing to justify its decisions on a more specific level, rather than simply referring back to general principles of public health and scientific progress.

To be sure, there has been some progress in this direction in the United Kingdom. With the advent of the National Institute of Clinical Effectiveness (NICE) came greater openness and transparency around the approval of individual treatments and therapies. To a significant extent, the entire system of therapy approval via NICE operates under a set of assumptions that support cost-effectiveness research and implementation. But, as a body sensitive to various exigencies of health care and the imperfections of the science of cost-effectiveness, NICE evaluates each technology or treatment on a case by case basis and

[297] Institute of Medicine, *Scientific Opportunities and Public Needs*, at note 25.
[298] The influence of the breast cancer lobby has been chronicles extensively within the literature. See, e.g. Emily S. Kolker, "Framing as a cultural resource in health social movements" at note 17.

releases a detailed analysis of individual technology appraisals that account for why an individual treatment was or was not approved. Though the appraisals are not framed in explicitly philosophical terms, NICE's methodology engages directly with the central ethical questions that govern technology approval.[299] It should be noted that NICE does have expert patient evidence considered in all of its technology appraisals, but that is one of many actions that it takes in concert in order to foster greater accountability.[300] It is important to emphasize that my critique here should not be construed as an attack on PPI so much as espousing skepticism that PPI is a quick-fix catch-all answer to the problems of political and moral accountability in health care.

It is worth pausing to emphasize that central to the deliberative ideal is the notion that decisions are not simply provided, but explicitly justified. Because the goal of the deliberative process is not just to create a workable system where decisions are abided by, but one where they are actively respected, justifying decisions initiates an important dialogue between the resource allocator and those who stand to be affected by the decision. Individuals may very well disagree with decisions that are rendered, but they are significantly more likely to respect the legitimacy of decisions if the decision-makers show respect for their status as reasonable moral agents. As Schauer argues, "…when decisionmakers expect voluntary compliance, or when they expect respect for decisions because the decisions are right rather than because they emanate from an authoritative

[299] M.D. Rawlins and A.J. Culyer, "National Institute for Clinical Excellent and its value judgments," *British Medical Journal* 329 (2004): 224-227.
[300] Eva Kaltenthaler, Diana Papaioiannou, Angela Boland, and Rumona Dickson, "The National Institute for Health and Clinical Excellence Single Technology Appraisal Process: Lessons from the First 4 years," *Value in Health* 14, no. 8 (December 2011): 1158-1165.

source, then giving reasons becomes a way to bring the subject of the decision into the enterprise."[301]

In short, then, we can say that resource-allocating bodies would do well to both make public their decisions *and* justify their decisions on moral (rather than simply political) grounds. As several others have noted,[302] fairness in the priority setting process requires that similarly situated individuals (and cases) are dealt with similarly. Forcing priority-setting and resource-allocating bodies to justify their decisions provides a public safeguard that citizens are treated comparably, and can find evidence that either challenges or supports that idea. Our overarching concern should not be that the "right" decision is reached within any resource allocating body; rather, we want to ensure that those bodies are grappling directly *and publically* with the basic moral questions that surround priority setting in the first place.

7.4.2 Thinking About Moral Reasoning in the Deliberative Process

It is tempting to think about deliberative democracy as espousing first and foremost, a set of procedural considerations. But it is worth noting that significant debate exists within health policy and political theory circles as to what reasons should be considered "acceptable" by members of the general public. In other words, on what basis are we to accept a decision by a resource-allocator as "fair" or respect the body's authority as being legitimate? Though these questions are perhaps the subject of a dissertation all its own, I should emphasize that the requirement on priority-setters or resource allocators to justify their decisions publically does not assume agnosticism around the various potential reasons for the decisions. For example, denial of coverage for a treatment because the disease only

[301] Frederick Schauer, "Giving Reasons," *Stanford Law Review* 47, no. 4 (1995): 658.
[302] See Gutmann and Thompson, *Democracy and Disagreement*, Chapter 2.

affects individuals of a particular race or ethnic heritage should obviously not be considered fair or legitimate simply because the decision was rendered publically and a reason was given.

At bare minimum, I argue that the reasons given should be constrained by the principles of reciprocity that are articulated by Gutmann and Thompson and described at greater length in chapter 4. Indeed, the legitimacy of the entire enterprise of the deliberative forum rests on the ideas that (a) individuals in the deliberative forum are themselves seeking terms of mutual cooperation and (b) they are therefore willing only to render decisions that are justified by reasons that other similarly motivated individuals would respect as legitimate. I do not intend at this point to delve into the details of which reasons, at the margins, should be considered legitimate and which ones should not (e.g. is cost a reasonable consideration? What is a reasonable way to arrive at a cost threshold? To what extent should age be taken into consideration at either end of the spectrum?). With that said, it is nonetheless important to highlight the fact that our discussion of the ways in which priority setters should make public their decisions and corresponding justifications must be accompanied by constraints on the types of reasons that should be considered acceptable.

7.4.3 Priority-Setters and Resource-Allocators Must Develop Mechanisms for Appeal

Recall that a central problem I highlighted with patient and public involvement was its lack of clearly delineated lines of accountability. Where individuals are simply selected to participate through an unelected process by unelected officials, there exists little reason for those outside the deliberative process to have faith that it will be an accountable one or that the interests of the general public will be well represented. Though deliberative

democrats and PPI practitioners have attempted to devise various "workarounds" (including random selection, demographic representation, participation as a consultative endeavor, etc.),[303] where PPI has been put into practice, there has been no ultimate guarantee that the general public interest would remain protected. And indeed, I have argued elsewhere that electing members of resource allocating or priority-setting bodies would do very little to increase accountability in any non-formal sense. Because these issues tend not to rise to the level of true political salience, the idea that explicit lines of accountability can be drawn between, for example, a local primary care trust and a set of citizens, is questionable. My concern in fostering accountability is thus in dealing with the implications of potentially unjust decisions rather than seeking to place in positions of control individuals likely to make perfect decisions at the outset.

Suppose a governing body – be it the National Institutes of Health, the state of Oregon, the National Institute for Health and Clinical Effectiveness, or the Oxfordshire Primary Care Trust – issues a decision that a patient or other member of the general public deems profoundly unjust. Of what options might that individual avail him or herself? To address this problem, Daniels and Sabin argue for the creation of so-called "Dispute Resolution Procedures" in order to create a process that "is made iterative in a way that broadens the input of information and argument."[304] Though they are writing in the context of private health insurers and providers, the basic principles governing Daniels and

[303] See, e.g. Mark Button and Kevin Mattson, "Deliberative Democracy in Practice: Challenges and Prospects for Civic Deliberation," *Polity* 31, no. 4 (1999): 609-637; David Ryfe, "The Practice of Deliberative Democracy: A Study of 16 Deliberative Organizations," *Political Communication* 19, no. 3 (2002): 359-377; and Julia Abelson, Pierre-Gerlier Forest, John Eyles, and Patricia Smith, et al., "Deliberations about deliberative methods: issues in the design and evaluation of public participation processes," *Social Science and Medicine* 57, no. 2 (2003): 239-251.
[304] Daniels and Sabin, "Limits to Health Care," at note 46, p. 340.

Sabin's theory of appeal and dispute resolution are applicable to any body that is tasked with responsibility to distribute scarce resources.

Individuals affected by a particular resource-limiting decision[305] should have the opportunity to bring forth an appeal to an independent body (that is to say, a set of individuals who were not necessarily responsible for making the initial decision in the first instance). Even if the ultimate decision remains unchanged, creating a system whereby individuals have recourse and access to a set of procedures that recognize the importance of nuanced moral discourse strengthens the legitimacy of the overall process and increases the probability that fair outcomes are achieved. If priority-setters and resource allocators are forthcoming in both publicizing their decisions and explaining why a given decision was reached, individuals affected can challenge a decision on the basis that it is inconsistent with prior ones. This helps to ensure that similarly situated citizens and patients are treated similarly by the health care system as a whole.

Those opposed to the creation of such a dispute-resolution system might argue that it will prove unworkable in practice. Admittedly, crafting an appeals process proves more difficult when the question at hand is a matter of national policy: how much money should be given to breast cancer research as opposed to other types of cancer research? How much should be allocated to primary and preventive care versus acute care and inpatient medical services? Can any citizen bring an appeal, or (as is the case in the American courts), does a

[305] To be sure, determining exactly who is "affected" by a resource limiting decision may prove complicated, particularly when discussing issues of resource allocation in biomedical research. A large percentage of men will eventually be diagnosed with prostate cancer, but is a young undiagnosed man eligible to challenge a decision regarding the funding of prostate cancer research? Governments will need to grapple with the challenge of who should be allowed to challenge or appeal a decision, but those difficult questions should not prove insurmountable.

citizen need to have "standing" and show that they have been personally affected adversely by a decision?

Here again, the details of precisely how to craft a dispute resolution system that is (a) workable, (b) inclusive, and (c) responsive and not simply reactive to moral disagreement are beyond the scope of my discussion. Naturally, dispute resolution procedures are much easier to devise at the local level – at the level of the hospital, insurance company, or primary care trust. With that said, national or state level organizations like NICE or Oregon's Department of Human Services could develop appeals processes that enabled not just citizens but perhaps institutions or advocacy groups to challenge the validity of a decision. The critically important factor here is not that dispute resolution procedures are perfect but that a forum exists where debate around the moral acceptability of a given policy or decision can take place and most importantly, where citizens trust that deliberation and appeals to public reason are taken seriously.

7.5 Final Thoughts – The Politics of Deliberative Reforms

It is easy – perhaps too easy – to talk in generalities about transparency, accountability, and acceptable norms of reasoning and deliberation in health care. Indeed, most liberal democracies talk about health care resource allocation in the broadest of terms with national commissions discussing the need to balance "public health" against "fiscal responsibility." Terms like "patient-centered," "efficient" and "cost-effective" are tossed about with little regard for how to implement those values on the ground, in real decisions between option A and option B. The devil, as is almost always the case, is in the details.

In that sense, the hard work of constructing a truly deliberative system of priority setting and resource allocation cannot be accomplished with the simple establishment of a

commission, issuing of a report, or pursuit of a broad-based policy of patient and public involvement. Though it need not be the case, patient and public involvement has often served to relieve pressure on public institutions to pursue more nuanced (but potentially more effective) means to improve transparency and foster greater democratic accountability.[306]

In many ways, decisions about whether to pursue more transparent and accountable policies in resource allocation and priority setting are, at their core, political ones. In the Oregon case study that was discussed earlier, for example, bringing moral questions about rationing to the forefront of public debate paradoxically resulted in public pressure being placed on the legislature, which ultimately raised the overall budget for Medicaid, sidestepping the difficult moral question of rationing altogether. Resource allocating entities may be reticent to engage in very public conversations about how decisions are made in part because resource allocation and priority-setting decisions often involve very crude realities about the value that is placed on human life and the limited lengths society is willing to go to in order to protect life and alleviate human suffering.

Above all else, one should not finish this thesis under the impression that I believe public engagement with policymaking – particularly policymaking in health care – is undesirable. On the contrary, it is my contention that patient and public involvement can and has often served as window dressing that distracts attention away from more fundamental reforms that would enhance the transparency and accountability of the priority setting process while raising the level of moral conversation in society. Given the aversion

[306] This argument regarding political window dressing has been made outside the health care realm as well. See, e.g. Graeme Cheeseman and Hugh Smith, "Public consultation or Political Choreography? The Howard Government's Quest for community views on defence policy," *Australian Journal of International Affairs* 55, no. 1 (2001): 83-100.

that citizens on both sides of the Atlantic have shown to engaging in very public conversations about rationing, cost-effectiveness, and cost/QALY ratios, politicians may be reluctant to put forth the kind of transparency reforms that I have outlined here. To do so, however, would not take political courage, but simple faith in the ability and willingness of average citizens to consider openly, reasonably, and deliberately challenging issues of moral significance.

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