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# Privatizing Biomedical Citizenship: Risk, Duty, and Potential in the Circle of Pharmaceutical Life

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## INTRODUCTION

Genomic research is at an impasse. In the decade since the completion of the first draft of the human genome, progress has been made, but few of the grandest promises of genomics have materialized. Biomedical researchers largely agree that one critical thing is essential to propel genomics into the future and maintain its legitimacy: more bodies. This Article will examine



* JD, PhD, Professor of Law, Hamline University School of Law. I would like to thank Karen-Sue Taussig and the participants at the Arizona State University Conference on Governance of Emerging Technologies: Law, Policy, and Ethics and the UCI Newkirk Center for Science & Society Conference on Science and Its Publics for helpful comments on earlier versions of portions of this article.

recent efforts at massive recruitment of subjects to participate in biomedical research and will argue that such efforts, while clearly motivated by a desire to drive biomedical research to its next stage of promised critical breakthroughs, also promote a privatized conception of citizenship that configures citizens' duties as serving the public good primarily through serving the good of private corporations—pharmaceutical manufacturers in particular. This reconfiguration of citizenship, in turn, implicates the allocation of related public resources to support drug development.

This Article explores the tacit interconnections among five major federally sponsored biomedical initiatives of the past decade in order to illuminate critical aspects of the current drive to get bodies. The initiatives are: 1) a multi-year study conducted for the National Institutes of Health (NIH) by the Genetics and Public Policy Center (GPPC) at Johns Hopkins University to examine methods of effectively recruiting subjects to a national biobank;[1] 2) the passage of the Genetic Information Nondiscrimination Act (GINA) in 2008;[2] 3) the Million Veteran Program (MVP), an initiative of the Department of Veterans Affairs to enroll one million veterans in a massive federal biobank to promote biomedical research;[3] 4) the July 2011 publication by the Department of Health and Human Services of an advanced notice of proposed rulemaking (ANPRM) to reconsider the "Common Rule" regulating the protection of human subjects in research;[4] and 5) the creation, in 2011, of the National Center for Advancing Translation Science (NCATS) at the NIH, which aims to develop collaborative relationships with industry to "de-risk" early stage drug research and bridge the "valley of death" between bench science and the actual production of valid therapeutic interventions.[5]

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1. *See infra* note 57 and accompanying text.
2. *See infra* notes 152–55 and accompanying text.
3. *See infra* notes 379–82 and accompanying text.
4. *See infra* note 413 and accompanying text.
5. Francis S. Collins, *Reengineering Translational Science: The Time Is Right*, SCI. TRANSLATIONAL MED., July 6, 2011, at 5 ("Through partnerships that capitalize on our respective strengths, NIH, academia, philanthropy, patient advocates, and the private sector can take full advantage of the promise of translational science to deliver solutions to the millions of people who await new and better ways to detect, treat, and prevent disease."); NAT'L CTR. FOR ADVANCING TRANSLATIONAL SCI., TRANSFORMING TRANSLATIONAL

Framing these initiatives are calls from prominent federal actors for citizens to participate as research subjects to serve the public good of improving health, as they might serve on a jury or in the military.[6] What these arguments elide, however, is that where jury duty directly serves the polity, participation in research directly serves corporations seeking to develop new biomedical products and only indirectly (if at all) promotes the public good. As recruitment efforts privatize citizenship to serve corporate interests, NCATS privatizes the research resources of the federal government, essentially socializing the risk of drug discovery, to serve corporate interests[7]—all in the name of serving the "public good" of health.[8] In this model, corporations become essential mediators of the public good. The model also creates a fundamental asymmetry wherein citizens bear duties, the government carries risk, and private corporations reap the commercial benefits without any concomitant duties or obligations.[9] Indeed, by law corporations have only one duty—to maximize return to their investors.[10]

Along with the proposed new duties of citizenship, this Article will also explore themes of risk and potential as they intersect, construct, and inform relations among these diverse federal initiatives. Risk, as Ulrich Beck has argued, is a key organizing concept of modernity.[11] Risk is also a central concept

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RESEARCH 2 (2013), *available at* http://www.ncats.nih.gov/files/factsheet.pdf (providing that NCATS is developing collaborations across different scientific organizations which have been traditionally distinct).

6. *See infra* notes 215–18 and accompanying text.

7. *See infra* notes 542–45 and accompanying text; s*ee also* Collins, *supra* note 5, at 2 (describing how NCATS's "new scientific approach" will "count on the scientific community to conceive highly innovative ideas" and then fund those proposed programs through the NIH grant system).

8. *See* Collins, *supra* note 5, at 5 ("[L]et us embark on this new adventure with eyes wide open . . . fixing our vision on the possibility of profound benefits for humankind."); *infra* notes 512–14 and accompanying text.

9. *See infra* notes 358–60 and accompanying text.

10. *Cf.* Amir N. Licht, *The Maximands of Corporate Governance: A Theory of Values and Cognitive Style*, 29 DEL. J. CORP. L. 649, 686–717, 705 (2004) (providing a historical view of corporate directors' fiduciary duties to investors and finding that, at least for some scholars, "[t]he traditional law and economics approach to the maximands issue holds simply that the shareholder-value-maximization rule is (1) efficient and (2) workable," but noting that this viewpoint is susceptible to criticism).

11. ULRICH BECK, RISK SOCIETY: TOWARDS A NEW MODERNITY 19 (Mark Ritter trans., SAGE Publications 1992) (1986).

in biomedicine,[12] informing NCATS's approach to translational research and providing a foundation for the ethical and regulatory guidelines structuring human subject research.[13] As political scientist Jacob Hacker has argued, risk also critically mediates current debates over the proper roles of public and private spheres in governing critical social and economic goods such as health care.[14] This is, in part, because there are basic value judgments embedded in defining what counts as risk, an act which, as Paul Slovic notes, is "an exercise in power."[15]

Potential, particularly in the domain of biobanking and drug development, has been widely invoked to make demands upon individuals and society in diverse contexts to help realize the great promise of modern biomedicine.[16] It is in many respects the flip side of risk—presenting visions of hope and expectation rather than concern or apprehension.[17] Potential is

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12. Claus Møldrup & Janine Marie Morgall, *Risk Society—Reconsidered in a Drug Context*, 3 HEALTH, RISK & SOC'Y 59, 72 (2001) ("[R]isks associated with modern drugs are . . . capable of producing risk on an objective as well as on a non-objective global level."); Bryan S. Turner, *Risks, Rights and Regulation: An Overview*, 3 HEALTH, RISK & SOC'Y 9, 9 (2001).

13. Jonathan Kimmelman, *Valuing Risk: The Ethical Review of Clinical Trial Safety*, 14 KENNEDY INST. ETHICS J. 369, 369 (2004) ("The ethical conduct of research involving human subjects demands that risks to participants and society be minimized through independent review, monitoring, and possible revision of research proposals."); Peter H. Van Ness, *The Concept of Risk in Biomedical Research Involving Human Subjects*, 15 BIOETHICS 364, 366 (2001) ("It is especially evident in the context of biomedical research involving human subjects that benefits are intended and harms are not.").

14. Jacob S. Hacker, *Privatizing Risk Without Privatizing the Welfare State: The Hidden Politics of Social Policy Retrenchment in the United States*, 98 AM. POL. SCI. REV. 243, 246 (2004) ("[T]he emergence of risk-benefit mismatches should itself be seen as a process that is highly mediated by politics."). *See generally* JACOB S. HACKER, THE GREAT RISK SHIFT 39–57 (2006) [hereinafter HACKER, THE GREAT RISK SHIFT] (describing the history of public social insurance in the United States).

15. Paul Slovic, *Trust, Emotion, Sex, Politics, and Science: Surveying the Risk-Assessment Battlefield*, 19 RISK ANALYSIS 689, 689 (1999); *see also* SHEILA JASANOFF, SCIENCE AND PUBLIC REASON 132–49, 156–60 (2012) (discussing the concept of risk as it mediates between knowledge and power and asserting a hybrid nature of risk assessment and risk management as always necessarily involving value judgments as well as technical analysis).

16. *See, e.g.*, *infra* Part X (describing how NCATS and other federally sponsored initiatives seek to realize the potential of genomic medicine).

17. MICHAEL FORTUN, PROMISING GENOMICS: ICELAND AND DECODE GENETICS IN A WORLD OF SPECULATION 10 (2008) ("Genomics *must* be analyzed in terms of the promise, because promise is an ineradicable feature

invariably connected to successive hyperbolic claims made on behalf of the progress of biomedical research.[18] This is perhaps best exemplified by the speeches made at the White House Ceremony announcing the completion of the first rough draft of the human genome in June, 2000. Here, President Clinton declared, "[i]n coming years, doctors increasingly will be able to cure diseases like Alzheimer's, Parkinson's, diabetes and cancer by attacking their genetic roots."[19] Prime Minister Blair characterized the draft as "a breakthrough that opens the way for massive advances in the treatment of cancer and hereditary diseases, and that is only the beginning."[20] Craig Venter, then of Celera Genomics, attended the ceremony and was similarly enthused that with knowledge from the genome, we now had "the potential to reduce the number of cancer deaths to zero during our lifetimes."[21]

Promise and potential are often invoked side by side in such declarations, but for the purposes of this Article, I would like to make a distinction between the two. Here I will be considering promise as relating more to the commercial aspects of biomedicine and related therapeutic interventions, while the

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of genomics."); ADAM HEDGECOE, THE POLITICS OF PERSONALISED MEDICINE: PHARMACOGENETICS IN THE CLINIC 17 (2004) ("One of the most important ways in which expectations about personalized medicine are being constructed is through the deployment of technological *visions*."); Richard Tutton, *Banking Expectations: The Promises and Problems of Biobanks*, 4 PERSONALIZED MED. 463, 463 (2007) ("Analysts of science and technology have recently paid attention to how expectations, hopes and visions of the future are central to the dynamics of innovation in emerging technologies . . . ."). For a foundational essay on the anthropology of potential and its relation to risk, see Karen-Sue Taussig, Klaus Hoeyer & Stefan Helmreich, *The Anthropology of Potentiality in Biomedicine: An Introduction to Supplement 7*, 54 CURRENT ANTHROPOLOGY S3 (2013).

18. Tutton, *supra* note 17, at 467 (providing that some epidemiologists, disease advocacy organizations and commercial companies are "overwhelmingly positive" about the potential and impact of biobanks).

19. Remarks on the Completion of the First Survey of the Human Genome, 1 PUB. PAPERS 1267, 1268 (June 26, 2000).

20. Press Release, The White House, Remarks Made by the President, Prime Minister Tony Blair of England (via satellite), Dr. Francis Collins, Director of the National Human Genome Research Institute, and Dr. Craig Venter, President and Chief Scientific Officer, Celera Genomics Corporation, on the Completion of the First Survey of the Entire Human Genome Project (June 26, 2000) [hereinafter Human Genome Project Remarks] (on file with the National Human Genome Research Institute), *available at* http://www.genome.gov/10001356.

21. *Id.*

concept of potential is more often located in the objects of scientific study themselves—whether particular molecules or entire bodies. Promise generally invokes a commitment to provide a certain good or service to a promisee, often in return for a particular action or other form of support. Potential, with the linguistic root *potentia* (Latin, meaning "power, might, force"),[22] is characterized more by a sense of latent power. In contrast to the commitments made by a promisor, those invoking potential make demands upon others in order to actualize its latent power. This is an admittedly crude and overly dichotomous characterization of the terms that in practice are often used interchangeably, but I find it heuristically useful.

This Article will consider how tropes of risk and potential are deployed in efforts to reshape existing notions of public citizenship into emergent new understandings of citizenship as "privatized"—that is, as serving not only the public good but also private interests, particularly of drug developers, hoping to bring new products to market. As recruitment efforts privatize citizenship to serve these interests, the Article will consider how NCATS may be privatizing the research resources of the federal government, essentially socializing the risk of drug discovery, similarly in the name of serving the "public good" of health.

On the one hand, it can be argued that promoting collaborative public/private research enterprises that produce innovative therapeutics is a clear good. On the other hand, where such initiatives involve the intersection of commercial interests with federal resources and new characterizations of the nature and duty of citizenship, it is imperative to consider some of the broader implications they might have, not only for biomedical innovation, but also for broader understandings of citizenship, risk, and the common good in a post-genomic age.

## I. GETTING BODIES

In 1990, the U.S. government embarked on a major long-term project to map the human genome.[23] The human genome

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22. *Latin Definition for: Potentia, Potentiae*, LATDICT LATIN DICTIONARY & GRAMMAR RESOURCES, http://www.latin-dictionary.net/definition/31066/potentia-potentiae (last visited Feb. 8, 2014).

23. *Human Genome Project,* NAT'L INST. HEALTH, http://report.nih.gov/NIHfactsheets/ViewFactSheet.aspx?csid=45&key=H#H (last updated Mar. 29,

is comprised of some three billion base pairs of the chemical nucleotides: adenine, cytosine, guanine, and thymine.[24] Among the chief aims of the Human Genome Project (HGP) were to determine the actual sequence of the base pairs and identify all the genes (portions of the genome that code for the production of proteins), in human DNA.[25] Alternately framed as reading the "book of life"[26] or cracking the "code of codes,"[27] among many other grand metaphors, the HGP soon became imbued with great hopes and promises for improving the human condition.[28] Dorothy Nelkin and Susan Lindee noted early on that DNA itself had become enveloped in a "mystique" of complex cultural meanings that deeply shaped broader social attitudes toward the HGP and related endeavors.[29]

As the original plan for the first five years of the HGP stated:

> The information generated by the human genome project is expected to be the source book for biomedical science in the 21st century and will be of immense benefit to the field of medicine. It will help us to understand and eventually treat many of the more than 4000 genetic diseases that afflict mankind, as well as the many multifactorial diseases in which genetic predisposition plays an important role.[30]

The HGP itself formally came to a close in April 2003,[31] nearly three years after the triumphant announcement by President

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2013) (providing key facts and a timeline related to the Human Genome Project).

24. Richard B. Hallick, *Introduction to DNA Structure*, U. ARIZ. (1995), http://www.blc.arizona.edu/molecular_graphics/dna_structure/dna_tutorial.html.

25. *See Human Genome Project*, *supra* note 23; *The Human Genome Project Completion: Frequently Asked Questions*, NAT'L HUM. GENOME RES. INST., https://www.genome.gov/11006943 (last visited Mar. 20, 2014).

26. *See, e.g.*, LILY E. KAY, WHO WROTE THE BOOK OF LIFE?: A HISTORY OF THE GENETIC CODE 1 (Timothy Lenoir & Hans Ulrich Gumbrecht eds., 2000).

27. *See, e.g.*, THE CODE OF CODES: SCIENTIFIC AND SOCIAL ISSUES IN THE HUMAN GENOME PROJECT (Daniel J. Kevles & Leroy E. Hood eds., 1992).

28. *See, e.g.*, *Human Genome Project*, *supra* note 23 ("[A] deeper understanding of genetics will shed light on more than just hereditary risks . . . .").

29. DOROTHY NELKIN & M. SUSAN LINDEE, THE DNA MYSTIQUE: THE GENE AS A CULTURAL ICON (1995).

30. DEP'T OF ENERGY & NAT'L INST. OF HEALTH, UNDERSTANDING OUR GENETIC INHERITANCE: THE U.S. HUMAN GENOME PROJECT: THE FIRST FIVE YEARS, FISCAL YEARS 1991–1995, at vii (1990).

31. *A Brief Guide to Genomics*, NAT'L HUM. GENOME RES. INST., http://www.genome.gov/18016863 (last updated Oct. 19, 2011).

Clinton of the completion of a "working draft" of the human genome at a much-publicized White House Ceremony in June of 2001.[32]

The problem was that, while a remarkable technical achievement, by 2003 the HGP had yet to make significant progress toward realizing its original great promise of finding new cures for disease.[33] Thus, fast on the heels of the completion of the HGP, researchers, clinicians, and prominent government actors were calling for new initiatives to continue the march toward the promised land of genomic medicine.[34] In 2004, Francis Collins, then Director of the National Human Genome Research Institute (NHGRI) (later to be elevated to Director of the NIH under President Obama),[35] reported on a December 2003 meeting at the NIH discussing the need for a massive longitudinal study of up to 200,000 people to further develop information needed to treat disease.[36] Collins noted that if the experts agreed on the need for such a population based cohort study, "then we must collectively seek ways to organize and implement it quickly and efficiently—or face the real possibility that a decade from now the promise of genetic and environmental research for reducing disease burden on a

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32. *See supra* notes 19–21 and accompanying text.

33. *See generally A Brief Guide to Genomics*, *supra* note 31 ("It is important to realize, however, that it often takes considerable time, effort, and funding to move discoveries from the scientific laboratory into the medical clinic. Most new drugs based on genome-based research are estimated to be at least 10 to 15 years away.").

34. Since the HGP, there has been a steady succession of new grand promises being made on behalf of new technologies in a march toward an ever-receding horizon of biotechnological nirvana. *See, e.g.*, Jonathan Kahn, *Synthetic Hype: A Skeptical View of the Promise of Synthetic Biology*, 45 VAL. U. L. REV. 1343, 1347 (2011) ("As the initial promises from the HGP failed to materialize, successive new rounds of hype followed: Stem cell therapies would make the blind see and the lame walk; pharmacogenomics would provide individualized therapies to tailor medicines directly to your personal genetic profile; Genome Wide Association Studies ('GWAS') would unravel the mysteries of common complex diseases such as diabetes; new initiatives, such as the Personal Genome Project would provide the sort of information we originally thought to glean from the HGP; the epigenome would provide the answers to how the genome really worked; and so on, and so on.").

35. David Brown, *Obama Picks Francis Collins as New NIH Director*, WASH. POST (July 8, 2009, 9:41 PM), http://www.washingtonpost.com/wp-dyn/content/article/2009/07/08/AR2009070802769.html.

36. Francis S. Collins, *The Case for a U.S. Prospective Cohort Study of Genes and Environment*, 429 NATURE 475, 476 (2004).

population basis will remain out of reach."[37] Collins was arguing that to truly realize the promise of genetic research, what was really needed was bodies, lots of bodies, at least 200,000 bodies for the one study he was discussing in this paper.[38] Bodies were so important that failure to get them could place the entire genomic enterprise, begun by the HGP, at risk.[39]

Here, at the outset, Collins placed a certain type of risk at the center of his call for genomic innovation: a risk of lost potential and lost hopes.[40] Collins also bound together recruitment, risk, and potential in a manner that placed the obligation for realizing continued progress on forces outside of the scientific enterprise of genomics itself, into the social and political world where responsibility for the logistics of realizing such a large-scale population cohort study would inevitably fall.[41]

Two years later, when further making the case for large-scale prospective cohort studies, Collins and others asserted that:

> The sequencing of the human genome and increased investigation of its function are providing powerful research tools for identifying genetic variants that contribute to common diseases. Recognition is growing, however, that genetic variants alone cannot account for most cases of chronic disease. It is far more likely that environmental and behavioural changes, in interaction with a genetic predisposition, have produced most of the recent increases in chronic disease, and might therefore be the key to reversing this trend.[42]

The HGP was all well and good, but it was conducted primarily in laboratories and involved deriving the complete sequence for only one prototypical genome.[43] Identifying genes alone, it

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37. *Id.* at 477.

38. *Id.* at 476 ("These shortcomings could be addressed by a longitudinal study of 200,000 people.").

39. *Id.* at 477.

40. *Id.* at 476 ("[T]he probable presence of different environmental risk factors, and the potential for limited access to data and biological materials make it unlikely that the current cohort projects will be adequate for the needs of the United States.").

41. *Id.*

42. Teri A. Manolio et al., *Genes, Environment and the Value of Prospective Cohort Studies*, 7 NATURE 812, 812 (2006) (internal citations omitted).

43. *See Human Genome Project*, *supra* note 23.

turned out, did not carry us very far down the road toward the promised land of genomic medicine.[44] The thinking now was that to fully understand the complexity of the gene-environment interactions that contributed to most common diseases, scientists would need to study large numbers of genomes in context in order to pick up the many small effects that cumulatively might play a significant role in determining health outcomes.[45]

Getting bodies is complicated. There are already multiple population cohort studies that have been ongoing in the United States for many years.[46] Prominent among these are the Framingham Heart Study[47] and the Jackson Heart Study.[48] The Framingham Study originally recruited 5209 white men and women between the ages of thirty and sixty-two from the town of Framingham, Massachusetts, and tracked them for decades to study common patterns related to the development of cardiovascular disease.[49] The study enrolled new generations of participants in 1971 and again in 2002.[50] The Jackson Study began in 1999 and recruited 5301 African Americans in and around Jackson, Mississippi.[51] It focuses on identifying factors that contribute to the much higher incidence of cardiovascular disease in African American populations.[52] These significant studies have produced valuable information but operate at a much smaller scale than that contemplated earlier by Collins.[53] Indeed, later in 2004, an NIH panel of experts recommended that a population of 500,000 would be optimal for the sort of

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44. *See* Kahn, *supra* note 34, at 1346–53.

45. Manolio et al., *supra* note 42, at 813 (summarizing the advantages of cohort studies that can better identify genetic risk factors and markers).

46. *Id.*

47. FRAMINGHAM HEART STUDY, http://www.framinghamheartstudy.org (last visited Feb. 8, 2014).

48. JACKSON HEART STUDY, https://www.jacksonheartstudy.org/jhsinfo (last visited Feb. 8, 2014).

49. *History of the Framingham Heart Study*, FRAMINGHAM HEART STUDY, http://www.framinghamheartstudy.org/about/history.html (last visited Feb. 8, 2014).

50. *Id.*

51. *For Researchers*, JACKSON HEART STUDY, https://www.jacksonheartstudy.org/jhsinfo/Researchers/tabid/122/Default.aspx (last visited Feb. 8, 2014).

52. JACKSON HEART STUDY, *supra* note 48.

53. Collins envisioned a "longitudinal study of 200,000 people." Collins, *supra* note 36, at 477.

large-scale prospective study discussed by Collins.[54] This marked an entirely different scale of research. In ambition it is more akin to one of the national DNA biobanks being developed by such countries as Britain, Japan, and Estonia, among others.[55] Accordingly, the NHGRI's plans for a prospective large population study (LPS) demanded extensive consideration of both the logistics and ethics of recruitment.[56]

Such considerations clearly animated the NHGRI's decision in 2006 to award $2 million to the Genetics and Public Policy Center (GPPC) at Johns Hopkins University to engage in a two-year cooperative Public Consultation Project (PCP) on public attitudes toward participating in a possible large-cohort study of genetic and environmental contributors to health.[57] Dubbed, "Making Every Voice Count: Public Consultation on Genetics, Environment, and Health," the project came to

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54. NAT'L HUMAN GENOME RESEARCH INST., NAT'L INST. OF HEALTH, DESIGN CONSIDERATIONS FOR A POTENTIAL UNITED STATES POPULATION-BASED COHORT TO DETERMINE THE RELATIONSHIPS AMONG GENES, ENVIRONMENT, AND HEALTH: RECOMMENDATIONS OF AN EXPERT PANEL 6–7 (2005) [hereinafter COHORT REPORT], *available at* http://www.genome.gov/Pages/About/OD/ReportsPublications/PotentialUSCohort.pdf (explaining that the panel also looked at sample sizes as large as 1,000,000 participants); *see* Manolio et al., *supra* note 42, at 818.

55. Richard Tutton, *Constructing Participation in Genetic Databases: Citizenship, Governance and Ambivalence*, 32 SCI. TECH. & HUM. VALUES 172, 172 (2007). A report from a public meeting of the U.K. Biobank Ethics and Governance Council provides a useful, succinct description of a biobank:

> Originally, and often still now, the term "biobanks" refers to collections of biospecimens which are available for some dispersive use (as compared with archival reference use). More recently the term has come to include collections of biospecimens along with related health and/or social information to be used in research. Often these biobanks are accumulated in the course of clinical care, and are often closely held by those who created the collection. The most robust contemporary definition of 'biobanks' is "rich collections of data plus biospecimens, specifically developed as resources for research".

UK BIOBANK ETHICS & GOVERNANCE COUNCIL, REPORT: PUBLIC MEETING OF THE UK BIOBANK ETHICS AND GOVERNANCE COUNCIL 1 (2007), *available at* http://www.egcukbiobank.org.uk/stellent/groups/egc/@msh_grants/documents/web_document/wtx041249.pdf.

56. COHORT REPORT, *supra* note 54, at 5 (providing that surveys and focus groups could help to obtain input on recruitment approaches which then will define expectations about the consent process and privacy protections).

57. *Making Every Voice Count: Public Consultation on Genetics, Environment, and Health*, JOHNS HOPKINS U. GENETICS & PUB. POL'Y CENTER, http://www.dnapolicy.org/policy.consult.gene.php (last visited Feb. 8, 2014).

involve focus groups, community leader interviews, and town halls in five U.S. cities, as well as a 4000-person national survey.[58] It also developed educational materials to provide background information for the various targets of engagement.[59] In the years that followed, the GPPC, under the direction of Kathy Hudson,[60] came to play a central role in furthering the federal government's efforts to get bodies for an LPS.

Increasing pressure to enroll participants throughout biomedical research has brought into being what sociologist Steven Epstein has characterized as "a new science . . . that might be called 'recruitmentology.'"[61] While applicable to a broad array of recruitment practices and actors for diverse projects (ranging from small observational studies at academic health centers to large multinational clinical trials for drug development), Epstein notes that "[p]ractitioners of recruitmentology seek to produce and disseminate knowledge about how to successfully recruit and retain participants."[62] In contrast to the science of clinical trials, which evaluates the efficacy of therapies, Epstein posits that the "science of recruitmentology evaluates the efficacy of techniques necessary to get bodies into a trial in the first place, and to keep them there throughout the life of the experiment."[63] The GPPC efforts on behalf of the NHGRI in laying the groundwork for an LPS fall squarely under the rubric of recruitmentology. Indeed, for the GPPC, identifying "the best recruitment strategies" was a central concern of its PCP.[64]

The NHGRI came to the GPPC because, prior to undertaking an initiative as massive as a 500,000-person LPS, it understandably wanted to gauge public attitudes about and

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58. *Id.*

59. *Id.*

60. *GPPC at Five*, GENETICS & PUB. POL'Y CENTER (Apr. 18, 2007), http://www.dnapolicy.org/news.enews.article.nocategory.php?action=detail&newsletter_id=21&article_id=81 (reflecting on Kathy Hudson's work at the GPPC).

61. Steven Epstein, *The Rise of "Recruitmentology": Clinical Research, Racial Knowledge, and the Politics of Inclusion and Difference*, 38 SOC. STUD. SCI. 801, 802 (2008).

62. *Id.*

63. *Id.* at 803.

64. *Making Every Voice Count: Public Consultation on Genetics, Environment, and Health*, *supra* note 57.

willingness to participate in such a project.[65] The PCP involved focus groups and "town halls" conducted in diverse locations across the country.[66] At sixteen focus groups in six cities, GPPC representatives showed participants a video explaining the proposed LPS, and then discussed whether the study should be done and what factors would influence their willingness to participate.[67] Following the focus groups, the GPPC conducted twenty-seven individual interviews about the proposed study with community leaders in the same locations.[68] The GPPC used the information derived from the focus groups and interviews to shape the subsequent town hall meetings and the design of a national survey.[69]

The GPPC held five town hall meetings in 2008 in Jackson, Mississippi; Kansas City, Missouri; Philadelphia, Pennsylvania; Phoenix, Arizona; and Portland, Oregon (the same cities where it conducted the focus groups).[70] The meetings had audiences ranging from 76 to 134 people.[71] The GPPC made efforts to have the participants roughly match the demographics of their local communities.[72] Each meeting began with a presentation by a "senior member" of the GPPC staff, who welcomed the participants and explained that the PCP was hoping to "gather feedback on a proposed large-cohort government study of genes, environment, and health."[73] The proceedings were then turned over to be moderated by Jonathan Ortmans, of the Public Forum Institute, which describes itself as "an independent, nonpartisan, not-for-profit organization committed to developing the most advanced and effective means of fostering public discourse."[74]

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65. SHAWNA WILLIAMS ET AL., JOHNS HOPKINS UNIV. GENETICS & PUB. POLICY CTR., THE GENETIC TOWN HALL: PUBLIC OPINION ABOUT RESEARCH ON GENES, ENVIRONMENT, AND HEALTH 3, 5 (2009), *available at* http://www.dnapolicy.org/images/reportpdfs/2009PCPTownHalls.pdf.

66. *Id.* at 3.

67. *Id.*

68. *Id.*

69. *Id.*

70. *Id.*

71. *Id.*

72. *Id.*

73. *Id.* at 4.

74. *About*, PUB. FORUM INST., http://publicforuminstitute.org/about/ (last visited Mar. 3, 2014).

The moderator framed the event with the following three sets of questions:

> 1. Do you think the government should create a national biobank? Why or why not?
>
> 2. Would you participate in such a biobank? Why or why not?
>
> 3. What conditions need to be in place in order for the biobank to happen?[75]

Participants were then shown a nine-minute video discussing genetic variation and its possible contribution to disease.[76] The video also described how the project planned to collect genetic samples and data about medical history, diet, lifestyle, and environmental exposures from up to 500,000 U.S. residents.[77] It informed viewers that researchers, both public and private would have access to this information to study how genes, environment, and lifestyle contribute to disease.[78] During the course of the video, a female narrator states:

> No program large enough to do this has ever been done in the United States. But other countries have begun studying gene-environment interactions. Many people in these counties have given their permission to researchers to take genetic samples. . . . including Great Britain, Iceland, Estonia, Japan, and Canada. Here in the United States, the National Institutes of Health and other federal health agencies have a similar project in mind but it has not yet been approved or funded. NIH would like to get a lot of public input before going ahead to make sure U.S. citizens are comfortable with the project, have a say in how it's run and are willing to participate in it.[79]

There are a few noteworthy aspects to this particular framing. First, in referring to existing programs in other countries, the video clearly gives the impression that this is an increasingly common practice, implying that as others have given permission, so too would it be reasonable for these participants to give their permission. Second, in the reference to other *national* projects, as opposed to private ones (for example, projects being developed at the Mayo Clinic[80] or Vanderbilt

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75. WILLIAMS ET AL., *supra* note 65, at 4.

76. *Id.*

77. *Id.* at 5.

78. *Id.*

79. Video: The Proposed Study, at 2:44–3:43 (Johns Hopkins Univ. Genetics & Pub. Policy Ctr. 2008) [hereinafter The Proposed Study], *available at* http://www.dnapolicy.org/video/tps/index.htm.

80. *Mayo Clinic Biobank Overview*, MAYO CLINIC, http://mayoresearch.mayo.edu/mayo/research/biobank (last visited Feb. 9, 2014).

University),[81] there is also perhaps an implicit call to patriotism (at best) or (less positively) to a jingoistic concern about the United States being left behind in the march of biomedical progress. Third, the stated concerns to make sure citizens are "comfortable, . . . have a say . . . and are willing to participate,"[82] while reasonable, may also be problematic. Comfort and having a say are well and good but they seem clearly geared toward actualizing the third concern (i.e., insuring a willingness to participate).

The focus groups and town halls certainly allow for a measure of citizen feedback that could shape how the project is carried out. Having a say implies a measure of power, but the town halls do not appear to have provided any ongoing mechanism for citizens to exercise any substantive control over how the project would be carried out.[83] They "have a say" in the recruitment process but not in the substance of the project itself.[84] Thus, "having a say" appears to be part of the preliminary process of making potential subjects "comfortable" so that they will be more willing to participate.[85] This fits squarely within a "sub-genre" of recruitmentology identified by Epstein as seeking "to determine the barriers that keep individuals from volunteering."[86]

NHGRI Director Francis Collins also makes an appearance in the video to declare that a big study of hundreds of thousands will "really give us answers" and serve as "a discovery engine for everything we need to know about medicine in the future."[87] Collins's enthusiasm is understandable. In many respects he was simply following up

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81. D.M. Roden et al., *Development of a Large-Scale De-identified DNA Biobank to Enable Personalized Medicine*, 84 CLINICAL PHARMACOLOGY & THERAPEUTICS 362, 362 (2008).

82. The Proposed Study, *supra* note 79, at 3:37–3:42.

83. *Cf.* WILLIAMS ET AL., *supra* note 65, at 4, 7 (discussing the town hall meeting process, which focused primarily on determining whether participants thought the study should move forward and whether the participants themselves would be willing to participate).

84. *Cf. id.* at 7 (providing that the town halls included some discussion of study benefits and burdens, as well as acceptable and unacceptable types of research).

85. *Cf. id.* (describing how the researchers sought to uncover what factors or assurances would make individuals more likely to participate in the project).

86. Epstein, *supra* note 61, at 810–11.

87. The Proposed Study, *supra* note 79, at 3:45–4:58.

on the statements made at the White House ceremony announcing the completion of the first draft of the human genome.[88] One problem, perhaps, is that those earlier statements were made at the turn of the millennium, and here, eight years later, Collins was still looking to the future and calling for another new venture to keep us on the path toward the ever-receding horizon of biomedical promise.[89]

Collins's remarks also differ from the earlier pronouncements in two distinct ways. First, Collins's statements are made to propel forward a nascent project rather than celebrate the fruition of an existing one.[90] Second, they are directed at potential research subjects.[91] Such remarks function very differently in the context of recruitment. The difference may be understood, in part, by considering the relation between invoking the "promise" of genomics and invoking its "potential."[92] In his exemplary ethnography of the ventures of deCODE Genetics in Iceland and the related creation of Iceland's biobank (alluded to in the PCP presentation), Mike Fortun notes that "[t]he language of promising is a diverse and intricate one, demanding equally diverse and intricate analyses."[93] While my consideration of promise here is far more modest than that undertaken by Fortun, I agree with him that "promising is an ineradicable feature of genomics."[94] This is so largely because the complexity

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88. *See* s*upra* notes 19–21 and accompanying text.

89. The Proposed Study, *supra* note 79, at 3:45–4:58; *cf.* Kahn, *supra* note 34, at 1346 (describing the "ever receding horizon of promise").

90. The Proposed Study, *supra* note 79, at 3:45–4:58.

91. *Id.*

92. *See, e.g.*, FORTUN, *supra* note 17, at 102–13 (highlighting the ways "promising manifests itself in genomics"); HEDGECOE, *supra* note 17, at 16–17 ("In these terms, we can see pharmacogenetics . . . as a 'promissory science', a discipline that exists more in the speculations and promises of its supporters than in terms of scientific results and marketable products."); Michael Arribas-Ayllon et al., *Promissory Accounts of Personalisation in the Commercialisation of Genomic Knowledge*, 8 COMM. & MED. 53, 53 (2011) (noting that in the context of direct to consumer genetic test marketing, "promising information that will empower prevention of common complex diseases and ensure better quality of life is conflated with promising greater access to personal information"). On the concept of potential in the life sciences, see generally Taussig, Hoeyer & Helmreich, *supra* note 17, at S3–S12 (suggesting that "anthropologists of the life sciences" should utilize and work "with the concept of potentiality").

93. FORTUN, *supra* note 17, at 9.

94. *Id.* at 10.

of contemporary genomics, involving whole genome scans of large populations and examinations of the complex interactions of genes, behavior, and environment, is full of uncertainty and contingencies so that results can only be promised, not directly forecast.[95] Making such promises, as Fortun notes, "speaking very roughly, entails a mixture of a high degree of speculation, an avowed commitment stemming from multiple insecure extrapolations, and bets or gambles placed with a combination of care and risk."[96]

Promises can be influential and do a lot of work in enlisting resources and propelling an enterprise forward. Clinton, Blair, and Venter were largely celebrating the "promise" of genomics in marking the completion of the first draft of the human genome.[97] Generally speaking, once made, a promise does not further call upon the promisee to be realized. Promise and potential may often be mixed—"if you fund us, we will have the potential to cure cancer!"—but when they are, the promise takes on different valences.[98] Potential, with its connotations of latent power, may require ongoing action from the promisee to be realized.[99] It therefore may make different sorts of demands than a simple promise. Genomic promises are often really about potential—about unlocking the latent power of information stored in the genome to enable us to cure disease.[100] In the context of developing an LPS, diverse actors invoke this potential to make demands on fellow citizens—in particular, to demand their participation in research to cure disease.[101] In this context, a decision not to participate is not

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95. *See id.* at 10–11 (discussing the necessity of analyzing genomics "in the terms of the promise" on account of the complexity and uncertainty involved).

96. *Id.* at 10.

97. *See supra* notes 19–21 and accompanying text.

98. *See, e.g.*, Tutton, *supra* note 17, at 467 (discussing the potential of biobanks to improve clinical practice and whether "investment in biobanks will yield the promised results").

99. *See, e.g.*, FORTUN, *supra* note 17, at 10–11 (arguing that genomic corporations are essentially providing promises "to produce future products" designed to live up to the potential of genomics).

100. *See, e.g.*, Human Genome Project Remarks, *supra* note 20 (highlighting the "remarkable promise of biomedical research" to cure disease).

101. *See, e.g.*, *Making Every Voice Count: Public Consultation on Genetics, Environment, and Health*, *supra* note 57 (explaining the necessity of citizen

simply turning down a proposed bargain as in a promissory contract ("if you give me this, I promise to give you that"); it is thwarting scientific progress itself ("if you do not participate, we cannot realize the potential of genomics to cure disease"). This, I believe, is evident in the PCP presentation and related endeavors to recruit subjects into a massive new federally sponsored LPS and related enterprises.

Returning to Collins's statement to potential subjects in the PCP video, it presents the idea that participating in an LPS will provide researchers with "a discovery engine for everything we need to know about medicines in the future."[102] This is not a general declaration about the importance of some abstract LPS; it is part of a specific appeal to recruit subjects to participate. It is telling them that their bodies are needed to realize this vision. In a similar vein, the GPPC's flyer describing the PCP opens with the bolded question to the prospective participant: "Would you volunteer to help solve medical mysteries?"[103] By framing the project as a call to actively "help" it becomes clear that this is not just about promising future medical advances; it is making a claim upon individuals to participate, with the unstated message being that failure to do so places the realization of the biomedical potential of the LPS at risk.[104]

"Are you," the flyer continues, "and a half-million of your fellow citizens ready and willing to volunteer . . . ? That question, as well as what incentives would encourage study participation and what concerns people might have, is at the heart of the Genetics & Public Policy Center's Public Consultation Project."[105] The invocation of citizenship is particularly striking, connoting, as it does, conceptions of duty

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participation in order to obtain the research necessary to understand and fight complex diseases).

102. The Proposed Study, *supra* note 79, at 4:45–4:58.

103. *Public Consultation Project on Genes, Environment, and Your Health*, JOHNS HOPKINS U. GENETICS & PUB. POL'Y CENTER, http://www.dnapolicy.org/resources/PCPdescription.pdf (last visited Mar. 20, 2014) [hereinafter GPPC Flyer]; *cf. Making Every Voice Count: Public Consultation on Genetics, Environment, and Health*, *supra* note 57 ("This project will help determine what Americans think . . . .").

104. *See* GPPC Flyer, *supra* note 103; *Making Every Voice Count: Public Consultation on Genetics, Environment, and Health*, *supra* note 57 (stating that without the "participation of hundreds of thousands of volunteers," the "research necessary to understand" the complexities of genetic diseases would not be possible).

105. GPPC Flyer, *supra* note 103.

and service to a public good.[106] The GPPC is quite clear, however, that it is also looking for "incentives" to encourage participation, indicating an understanding that a sort of quid pro quo might provide a useful complement to claims of civic duty.[107] More fundamentally, this and other statements about the PCP indicate a tension within its framing and goals.

The GPPC characterized the PCP as an exercise in "deliberative democracy."[108] The concept of "deliberative democracy" has been the subject of extensive study and discussion and may not be readily susceptible to one set definition.[109] But if democracy of any sort involves popular power and control, the PCP conferred little of this upon participants. The focus groups, town halls, and survey were less about seeking public input in order to determine *whether* a federally sponsored LPS should go forward, *to what ends* it might be directed, or *how* it might be pursued, than it was about gathering input on how best to frame a pitch to potential subjects in order more effectively to recruit them into participating in the project.[110] The moderator followed a set script that imposed a clear structure for discussion upon the participants.[111] The preset agenda specified limited periods of discussion on prechosen topics—including "Initial Impressions"

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106. *See id.* ("Are you and a half-million of your fellow citizens ready and willing to volunteer . . . to try to advance our understanding of how genes and environment contribute to disease?").

107. *See id.* ("[The question of] what incentives would encourage study participation . . . is at the heart of the [GPPC's] Public Consultation Project.").

108. *Public Consultation and Engagement*, JOHNS HOPKINS U. GENETICS & PUB. POL'Y CENTER, http://www.dnapolicy.org/policy.consult.php (last visited Jan. 25, 2014).

109. *See, e.g.*, Jon Elster, *Introduction* to DELIBERATIVE DEMOCRACY 8–9 (Jon Elster ed., 1998) (providing various definitions of deliberative democracy used by contributors to the book that "differ widely from one another"); JAMES S. FISHKIN, WHEN THE PEOPLE SPEAK: DELIBERATIVE DEMOCRACY AND PUBLIC CONSULTATION 80 (2009) (conceptualizing deliberative democracy as a democratic theory which "attempts to combine deliberation by the people themselves with political equality"); AMY GUTMANN & DENNIS F. THOMPSON, WHY DELIBERATIVE DEMOCRACY? 7 (2004) (defining deliberative democracy as "a form of government in which free and equal citizens . . . justify decisions in a process in which they give one another reasons that are mutually acceptable and generally accessible, with the aim of reaching conclusions that are binding in the present . . . but open to challenge in the future").

110. *See supra* text accompanying notes 83–86.

111. *See* WILLIAMS ET AL., *supra* note 65, at 4, 7 (describing the process and agenda for the town hall meetings).

(fifteen minutes); "Benefits and Burdens" (thirty minutes); "Acceptable and Unacceptable Types of Research" (ten minutes); and "Return of Results" (ten minutes).[112] One of the final sections was titled "Build your own Contract," a twenty-minute period during which participants were to list "elements that should be included in research agreements between the researchers and study participants for the proposed study."[113]

In this context, "deliberation" was not directed to coming to an informed, mutually agreed-upon course of action that empowers participants; it was being used as a tool to elicit information from subjects about what "incentives" might encourage them to participate in an LPS, which in turn would then be used to elicit even greater amounts of (genetic) information from them (or other prospective participants in an LPS).[114] The structuring frame of such discussions was not "should we do this?" or "how should we do this?", but "what do we need to do to get you to participate?" These questions, of course, are not mutually exclusive, but the process did not foster any questioning of the underlying enterprise, serving merely as a consideration of how to make recruitment to it more effective. It was, as terms such as "focus group" might indicate, more an exercise in marketing than democracy.

Such an approach is not unique to the GPPC's and NHGRI's plans for large cohort genomic studies. In his study of similar focus groups conducted as part of the UK Biobank Project, Richard Tutton discusses what he terms the "discourse of participation" in such projects, which he suggests "can be seen as a[n] . . . institutional response to public ambivalence toward science and expertise."[115] The idea of seeking "participants" in research, Tutton observes, is a distinctly recent phenomenon.[116] In the past, subjects were viewed as passive or expendable.[117] Following the aftermath of the atrocities of World War II, and with the rise of modern bioethics, subjects became vulnerable and in need of ethical

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112. *Id.* at 7.

113. *Id.*

114. *See supra* notes 83–86, 110 and accompanying text.

115. Richard Tutton, *Constructing Participation in Genetic Databases: Citizenship, Governance, and Ambivalence*, 32 SCI. TECH. HUM. VALUES 172, 172 (2007).

116. *Id.* at 175.

117. *Id.*

protection.[118] In the context of biobank recruitment, subjects are increasingly being cast as "empowered citizens"—empowered largely with information that enables them to make free, informed, and rational decisions.[119] Tutton argues, however, that in practice, the "discourse of participation is used by the institutions behind UK Biobank" to enact a constrained and impoverished model of participation that is "largely confined to providing samples and data to the project, with the likelihood of receiving some general feedback about the progress and key findings of the research in the future."[120]

Nonetheless, alternative approaches have also been tried. Researchers in Canada devoted considerable attention to developing models of deliberative democracy for engaging the public around the creation of the "BC Biolibrary," which "was established in 2007 to support biobanking and a broad range of health research applications that utilize biospecimens in British Columbia, Canada."[121] In contrast to the GPPC's town halls, which conceived of public engagement primarily as a means to overcome barriers to recruitment, researchers at the W. Maurice Young Centre for Applied Ethics, University of British Columbia, clearly stated:

> When talking about public engagement, we are not referring to unidirectional attempts to increase public awareness of certain aspects of science and technology; nor are we referring to the measurement of 'public opinion' on certain controversial issues. Rather, we are concerned with mechanisms whereby there can be meaningful and legitimate public input into policy that involves dialogue between relevant publics with scientists, policy makers, and other stakeholders.[122]

To act on this vision, the BC Biolibrary project took a very different approach to public engagement. It opted for one single group of twenty-five Canadians, chosen to represent "the

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118. *Id.*

119. *Id.* (respecting participation in biomedical research).

120. *Id.* at 188.

121. Kieran O'Doherty & Alice Hawkins, *Structuring Public Engagement for Effective Input in Policy Development on Human Tissue Biobanking*, 13 PUB. HEALTH GENOMICS 197, 200 (2010).

122. *Id.* at 198–99 (providing that similar efforts have also been undertaken by the Mayo Clinic in Rochester, Minnesota); *see also* K.C. O'Doherty & M.M. Burgess, *Engaging the Public on Biobanks: Outcomes of the BC Biobank Deliberation*, 12 PUB. HEALTH GENOMICS 203, 205 (2009) (explaining the use of deliberative democracy to foster public engagement in the BC Biolibrary project).

diversity of values, life experiences, and discursive styles of the citizens of British Columbia," and selected also to give "voice to individuals and groups that would otherwise not be heard."[123] In contrast to the PCP's nine minute introductory video, BC Biolibary prepared a workbook for participants outlining key areas of ethical concern, including: collection of biospecimens; initial contact/introducing the biobank to potential donors; linking samples to personal information; consent; and governance of biospecimens and associated data.[124] In perhaps the most significant difference from the PCP, participants met over the course of four days (instead of the PCP's three hours) to discuss the issues in depth.[125] Discussion facilitators "gave particular attention to ensuring that all voices were heard and no views glossed over in the formulation of final recommendations."[126]

This last concern with respect to participants' voices, while seemingly self-evident, gains salience in light of the observations made by anthropologist Karen-Sue Taussig while at one of the actual GPPC town hall events.[127] Taussig speaks of being haunted by the interactions between a participant and the moderator at a town hall in Portland, Oregon.[128] The exchange began following the showing of an introductory video when the participant, whom Taussig calls "Sally," asked, "If we participate in this study and you find out we have the breast cancer gene, are you going to tell us?"[129] The moderator evaded the question because it did not fit in with the preset agenda, saying: "[T]hat is a really good question and it is one we are going to come to later. Right now we'd like to hear, based on what you know, do you think the study should be done?"[130] About twenty minutes later the moderator turned to the question of return of results, but asked the participants to discuss what kind of research they think people should be able

123. O'Doherty & Hawkins, *supra* note 121, at 201.

124. *Id.*

125. *Id.* at 201–02.

126. *Id.* at 202.

127. Karen-Sue Taussig, Annual Meeting of the American Anthropological Association, Fantasies of Human Perfectability: Conceptualizing Potentiality and the Molecular Medical Toolkit (Nov. 22, 2008) (unpublished manuscript) (on file with author).

128. *Id.* at 6–15.

129. *Id.* at 10.

130. *Id.* at 11.

to do, or not do, with materials in a biobank.[131] Participants began generating a list and Sally, whose hand has been raised, said: "[S]o, if you have the breast cancer gene are they going to tell you or not?"[132] The moderator responded, saying, "I'll come to that in a minute," and continued to call on people to add to the list he was generating.[133] More discussion ensued, and a while later Sally once again raised her hand and asked: "[C]ouldn't you pay a little extra to get your results?"[134] Taussig notes that at that point "the moderator turns to look at us with an expression that we read as meaning something like 'can you believe she's asking about this again?' The response is laughter from most of the rest of the audience. Nevertheless, the moderator does generate some discussion about the issue of getting results back."[135] At the end of the discussion, the moderator asked the participants to vote yes or no about whether researchers should try to return relevant information to biobank participants.[136] Taussig relates that at that point, she looked over to Sally's table and saw that she was gone.[137]

The story is haunting, in part, because it seems to conflict so starkly with the GPPC's avowed purpose of "making every voice count" in the public consultation process.[138] It also highlights the degree to which the process was not structured as a true dialogue, but as a means to elicit information from the participants.[139] This brings us back to Tutton's observation that discourses of participation and consultation may primarily be serving the ends of recruitment rather than empowerment.[140] Such engagement as that provided by the PCP, however, is only a first step toward recruitment. Indeed, one of the primary goals of the consultation was to identify concerns and fears that might be acting as barriers to

131. *Id.* at 12.
132. *Id.*
133. *Id.*
134. *Id.* at 14.
135. *Id.*
136. *Id.* at 14–15.
137. *Id.* at 15.
138. *E.g.*, *Making Every Voice Count: Public Consultation on Genetics, Environment, and Health*, *supra* note 57.
139. *See supra* notes 83–86 and accompanying text.
140. *See supra* notes 119–20 and accompanying text.

participation.[141] As it turned out, foremost among these were concerns over loss of privacy and the related "possibility that insurance companies might obtain individuals' genetic information and use it against them."[142] Many participants also expressed a strong desire for research results; that is, to have relevant information discovered from their samples returned to them.[143] GPPC researchers found this particularly noteworthy in light of the fact that they had the moderator explain to the participants "that individual research results are usually not returned to study participants because of logistical burdens."[144]

That the moderator provided no similar intervention regarding the burdens of protecting privacy seems to indicate an implicit understanding on the part of those framing the discussion (i.e., the GPPC) that concerns over privacy were somehow more legitimate and addressable than those involving return of research results (ROR).[145] Indeed, with respect to privacy concerns, the introductory video made clear that participants' information would be "coded to hide their identities," but made no mention of ROR or other concerns, such as commercialization of research results.[146] The parallel GPPC online survey of 4659 people similarly found strong interest in ROR and observed, "[p]roviding individual research results is a strong motivation to participate; compensating participants $200 may increase participation a similar amount. Incentives, recruitment, and return of results could be tailored to demographics groups' interests."[147] In analyzing the costs and benefits of such measures, the survey concluded "that providing even limited individual research results or graduated incentives over time could increase retention and recruitment."[148]

Notably, ROR may impose substantive burdens and responsibilities on researchers involving the actual content of

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141. *Making Every Voice Count: Public Consultation on Genetics, Environment, and Health*, *supra* note 57.

142. WILLIAMS ET AL., *supra* note 65, at 8.

143. *Id.* at 9–10.

144. *Id.* at 9.

145. *See id.* at 14 ("Town hall participants consistently placed privacy . . . among their top concerns about the proposed study.").

146. *Id.* at 5.

147. David Kaufman et al., *Subjects Matter: A Survey of Public Opinions About a Large Genetic Cohort Study*, 10 GENETICS MED. 831, 831 (2008).

148. *Id.* at 838.

the information they are deriving from the samples.[149] By contrast, protecting privacy primarily imposes procedural burdens concerning management of and access to information.[150] These are real burdens, but they do not materially implicate the way research itself is conducted. That is, ROR involves concerns about what researchers themselves are doing with the data, whereas privacy concerns primarily involve insuring that *other people* (e.g., non-researchers) do not have access to the data.[151] Perhaps more to the point, concerns over privacy were soon to be addressed by legislation that imposed little burden on researchers but promised to greatly alleviate concerns over privacy as a potential barrier to recruitment.

## II. GINA: LAW AS AN ADJUNCT TO RECRUITMENT

The 2008 GPPC report on the town halls highlighted the passage of the Genetic Information Nondiscrimination Act of 2008 (GINA) in May of that year.[152] The law has two major components: Title I, which prohibits group and individual health insurers from using a person's genetic information in determining eligibility or premiums and from requesting or requiring that a person undergo a genetic test;[153] and Title II, which prohibits employers from using a person's genetic information in making employment decisions, such as hiring, firing, job assignments, or any other terms of employment, and from requesting, requiring, or purchasing genetic information about persons or their family members.[154] GINA does not cover

149. *See, e.g.*, WILLIAMS ET AL., *supra* note 65, at 9 (stating the logistical burdens placed on researchers regarding the return of research results).

150. *See, e.g.*, *id.* at 12, 14 (providing the obligation of researchers to protect a participant's privacy and against the misuse of information).

151. *Cf. id.* at 14 (discussing participant concerns that law enforcement agencies, pharmaceutical companies, or insurance companies might obtain and exploit individuals' data).

152. Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, 122 Stat. 881 (codified as amended in scattered sections of 26, 29, and 42 U.S.C.); WILLIAMS ET AL., *supra* note 65, at 14 (providing a brief summary of GINA).

153. Genetic Information Nondiscrimination Act, tit. 1; S. REP. NO. 110-48, at 2–3 (2007).

154. Genetic Information Nondiscrimination Act, tit. 2; S. REP. NO. 110-48, at 4–5.

life, disability, long-term care insurance, or veterans seeking "health care through the Department of Veterans Affairs."[155]

GINA had its roots in legislation introduced thirteen years earlier by Representative Louise Slaughter that garnered bipartisan support but did not pass.[156] Similar legislation was introduced during subsequent congressional sessions as the HGP moved toward its completion in 2003.[157] Between 1996 and 2002 the Senate Committee on Health, Education, Labor, and Pensions held five hearings on genetic discrimination, but no progress was made toward enacting specific legislation.[158] In 2003, just as the HGP was coming to a close, Representative Slaughter and Senator Olympia Snowe introduced the first bills with the title "Genetic Information Non-Discrimination Act."[159] Their efforts continued during subsequent congresses, but it would take five more years to achieve final passage.[160]

While always animated by concerns to insure that advances in genetic technologies could be pursued productively without being used to discriminate unfairly against individuals on the basis of their genetic makeup, the need for GINA took on new valences as it moved toward ultimate passage in 2008. Roughly coincident with the rising interest in developing a federally sponsored LPS and the GPPC's efforts to gauge citizen attitudes toward participating in such a study, GINA's advocates began to emphasize more heavily its potential to facilitate recruitment of subjects for biomedical research.[161] Thus, the GPPC town hall report's reference to GINA was not

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155. Kathy L. Hudson, *Genomics, Health Care, and Society*, 365 NEW ENG. J. MED. 1033, 1038 (2011).

156. *Genetic Discrimination*, GENETIC ALLIANCE, http://www.geneticalliance.org/advocacy/policyissues/geneticdiscrimination (last visited Feb. 8, 2014).

157. *See id.* (mentioning the nearly thirteen years spent by the Genetic Alliance to pass GINA).

158. S. REP. NO. 110-48, at 13–14.

159. S. REP. NO. 108-122, at 1, 14–15 (2003) (summarizing the legislative history of GINA).

160. S. REP. NO. 110-48, at 13.

161. *See id.* at 1 ("Establishing these protections will allay concerns about the potential for discrimination and encourage individuals to participate in genetic research . . . .").

incidental, but central to emerging understandings of the significance of the legislation.[162]

By the mid-2000s, recruitmentologists of many stripes (i.e., all those interested in promoting the broad participation of citizens in large-scale biomedical research projects) consistently identified fear, specifically fear of discrimination, as a primary barrier to recruitment.[163] Fear as a barrier to be overcome became a powerful and pervasive trope in the drive toward the ultimate adoption of GINA in 2008. In contrast, concerns over individual well-being had been manifest from Representative Slaughter's original legislation in 1995 but never seemed sufficient to achieve passage of the bill.[164] The 1995 bill had as its stated purpose, "[t]o prohibit insurance providers from denying or canceling health insurance coverage, or varying the premiums, terms, or conditions for health insurance coverage on the basis of genetic information or a request for genetic services, and for other purposes."[165] When introducing the bill, Representative Slaughter spoke of the need to "prevent the potentially devastating consequences of discrimination based on genetic information,"[166] but said nothing there, or in subsequent remarks, about fears of discrimination as a barrier to research recruitment.[167] The bill itself made no mention of research.[168] Senator Snowe, when introducing her companion bill, mentioned that "people may be unwilling to participate in potentially ground-breaking research trials because they do not

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162. *See* WILLIAMS ET AL., *supra* note 65, at 14 (framing GINA as a way to protect privacy and potential misuse of genetic information, two primary concerns of town hall participants).

163. Kathy L. Hudson et al., *Keeping Pace with the Times—The Genetic Information Nondiscrimination Act of 2008*, 358 NEW ENG. J. MED. 2661, 2663 (2008) ("Studies have shown the 'fear factor' to be a major obstacle to patients' participation in research studies that involve the collection of genetic information.").

164. *See* Genetic Information Nondiscrimination in Health Insurance Act of 1995, H.R. 2748, 104th Cong. § 2 (1995) (emphasizing the protection of individuals against discrimination, in addition to providing limits on the collection and disclosure of genetic information).

165. *Id.*

166. 141 CONG. REC. 36,987 (1995) (statement of Rep. Louise Slaughter).

167. *See id.* at 36,987–88; *see also* 142 CONG. REC. 6945–46 (1996) (statement of Rep. Louise Slaughter).

168. Genetic Information Nondiscrimination in Health Insurance Act of 1995, H.R. 2748, 104th Cong. (1995).

want to reveal information about their genetic status."[169] But the bill itself made no reference to research.[170]

By 2003, things had changed. That year the Senate held full hearings on a direct precursor to GINA, introduced again by Senator Snowe.[171] The bill itself, while clearly animated by a concern to prevent invidious discrimination, also prominently mentions in its initial statement of findings that the law was "necessary to fully protect the public from discrimination and allay their concerns about the potential for discrimination, thereby allowing individuals to take advantage of genetic testing, technologies, research, and new therapies."[172] The Senate report accompanying the bill, opened with a clear declaration that,

> The purpose of this legislation is to protect individuals from discrimination in health insurance and employment on the basis of genetic information. *Establishing these protections will allay concerns about the potential for discrimination and encourage individuals to participate in genetic research* and to take advantage of genetic testing, new technologies, and new therapies. The legislation will provide substantive protections to those individuals who may suffer from actual genetic discrimination now and in the future. These steps are essential to fulfilling the promise of the human genome project.[173]

The report here cast GINA as an adjunct to recruitmentology—a means to overcome the barrier of fear that might obstruct participation in research.[174] As the HGP came to a conclusion, lawmakers were addressing the perceived need to recruit individuals into the next phase of the genomic enterprise. By invoking the "promise of the human genome project," lawmakers also made demands on fellow legislators to adopt the bill or else, by implication, be responsible for frustrating the potential of genomic medicine.[175]

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169. 142 CONG. REC. 8504 (1996) (statement of Sen. Olympia Snowe).

170. Genetic Information Nondiscrimination in Health Insurance Act of 1996, S. 1694, 104th Cong. (1996).

171. S. REP. NO. 108-122, at 13–15 (2003).

172. Genetic Information Nondiscrimination in Health Insurance Act of 2003, S. 1053, 108th Cong. § 2 (2003).

173. S. REP. NO. 108-122, at 1–2 (2003) (emphasis added).

174. *See id.* at 1 (including the encouragement of participation in research in the purpose and summary section of the report).

175. *See id.* at 1–2 ("These steps are essential to fulfilling the promise of the human genome project.").

This too was not accidental. As debates about GINA unfolded in the 2000s, critics expressed the view that fears of discrimination were irrational because there had been little or no evidence of any significant genetic discrimination, nor would there likely be any.[176] Others had been stating for years that they saw no problem with certain forms of genetic discrimination—particularly in the area of insurance, where, they argued, preventing access to genetic information might allow individuals to game the system.[177] As GINA progressed, such criticisms threatened to undermine this major rationale for its passage. They did not, however, weaken the rationale of using GINA to promote research recruitment. If fears of discrimination, whether justified or not, were real and impeding recruitment, then GINA would still be needed to realize the full potential of genomic medicine.

Many of these views were in evidence in comments presented to the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) in 2004.[178] The Committee was created in 2002 to explore a broad array of health and societal issues raised by new genetic technologies and to make recommendations to the Secretary of Health and Human Services as needed.[179] In the fall of 2004 the SACGHS solicited

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176. *E.g.*, Louis P. Garrison et al., *A Review of Public Policy Issues in Promoting the Development and Commercialization of Pharmacogenomic Applications: Challenges and Implications*, 40 DRUG METABOLISM R. 377, 395 (claiming that there is "virtually no evidence of genetic discrimination in the insurance market"); Mark A. Hall & Stephen S. Rich, *Laws Restricting Health Insurers' Use of Genetic Information: Impact on Genetic Discrimination*, 66 AM. J. HUM. GENETICS 293, 293 (2000) ("[W]e found that a person with a serious genetic condition who is presymptomatic faces little or no difficulty in obtaining health insurance.").

177. *E.g.*, Colin S. Diver & Jane Maslow Cohen, *Genophobia: What is Wrong with Genetic Discrimination?*, 149 U. PA. L. REV. 1439, 1456–59 (2001) (describing the distortions and disturbances that might result in an insurance industry denying access to genetic testing results); Richard Epstein, *The Legal Regulation of Genetic Discrimination: Old Responses to New Technology*, 74 B.U. L. REV. 1, 12–13, (1994).

178. *See generally* SEC'YS ADVISORY COMM. ON GENETICS, HEALTH & SOC'Y, PUBLIC PERSPECTIVES ON GENETIC DISCRIMINATION, SEPTEMBER 2004–NOVEMBER 2004 (2004), *available at* http://oba.od.nih.gov/oba/sacghs/reports/Public_Perspectives_GenDiscrim.pdf (compiling comments from the public and health care professionals on genetic discrimination).

179. *See Secretary's Advisory Committee on Genetics, Health, and Society Archives*, NAT'L INSTS. HEALTH, http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy/genetics-health-and-society/sacghs-archives (last visited Mar. 20, 2014).

input from the general public and health professionals specifically on the issue of genetic discrimination, which it compiled into a compendium that it published later that year.[180] Much of the testimony involved individual stories from people who had suffered discrimination in insurance or employment.[181] They did not directly connect their stories to issues of research participation, but were concerned primarily to show that fear of discrimination was not irrational or unfounded.[182]

In contrast, a statement by an executive from Aetna, made "[o]n [b]ehalf of America's Health Insurance Plans"[183] asserted that the idea that insurers would use genetic information to discriminate was a myth.[184] Myriad Genetics, whose patents on breast cancer genes made it a major player in the field of diagnostic tests, similarly cast fears of discrimination as unfounded.[185] Instead of dismissing such fears as irrational, however, Myriad insisted they be addressed by "comprehensive legislation"[186] in order "to allow the public to participate in the benefits of genetic medicine,"[187] (i.e., their product). These sentiments were echoed in the statement from another diagnostic firm, LabCorp, which asserted that "[t]he benefits of genetic testing can only be fully realized when the fear of genetic discrimination, and its actual practice, are eliminated from the health care system."[188]

Participating in the benefits of genetic medicine thus emerged alongside concern to encourage participation in research as dual reasons to address fears of discrimination that

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180. *See generally* SEC'YS ADVISORY COMM. ON GENETICS, HEALTH & SOC'Y, *supra* note 178 (including emails, letters, meeting minutes, policy statements, reports, and other records).

181. *See, e.g.*, *id.* at 2–20 (providing the statements of Heidi Williams, Phadra Malatek, Rebecca Fisher, Tonia Phillips, and Paula Funk).

182. *See, e.g.*, *id.*

183. *Id.* at 109 (providing the statement of Joanne Armstrong, Senior Medical Director of Women's Health Aetna).

184. *Id.* at 114 (arguing that there is "little, if any, empirical evidence that genetic information has, or is being misused" by insurance companies).

185. *Id.* at 205 (providing the statement of Gary Martucci, Director of Strategic Alliances for Myriad Genetics Laboratories, who claimed that "the insurance coverage barrier ha[d] been effectively eliminated . . . . [but] the fear of genetic discrimination ha[d] not").

186. *Id.* at 207.

187. *Id.* at 208.

188. *Id.* at 203.

exerted force independently of whether such discrimination actually existed. The Senate report directly juxtaposed fear and potential as driving frames for GINA.[189] The invocation of the promise of the HGP was forward-looking. Taking advantage of existing therapies, however, would do little to fulfill the promise. It was participation in research that the Senate most clearly identified as essential to realizing the potential of new genomic knowledge to improve health.[190] As the report noted a few pages on (shifting the frame from "promise" to "potential"):

> Despite the apparent conflict between actual discrimination versus the fear or perception of discrimination, consumers remain worried that, once acquired by an insurance company or employer, genetic information could be used in a discriminatory manner. Such concerns about the misuse of genetics are already hindering the potential of the human genome project. . . .
>
> Fear of discrimination, or even potential discrimination, threatens society's ability to use new genetic technologies to improve human health and the scientific community's ability to conduct research needed to understand, treat, and prevent disease. And, although there may not be proof of widespread discrimination, it is difficult to ignore the few, albeit egregious, cases that have been publicly documented.[191]

Critically, the report acknowledged that actual discrimination need not exist as a real threat to individuals to justify GINA.[192] The reality of public perception and fear of discrimination themselves posed a sufficient threat to realizing the potential of the HGP to warrant legislative action.[193] The Senate report here framed the real threat to be addressed by GINA as fear, and the threatened subject was not the individual but the enterprise of genomic medicine itself.

In his 2007 testimony before Congress on GINA, then-director of the NHGRI, Francis Collins, neatly exemplified this interweaving of fear as a barrier and a threat:

> We stand on the brink of a revolution in healthcare . . . . Yet, there is a *cloud on the horizon* and it is a cloud that has been getting darker and more frightening over the course of the last more than 12 years, since I have had the privilege of leading the genome effort and worrying about this issue, and that is that this

189. *See* S. REP. NO. 108-122, at 8 (2003).

190. *Id.* at 1–2.

191. *Id.* at 8.

192. *Id.*

193. *Id.* ("Many of the problems outlined in this section stem from the lack of a comprehensive federal law prohibiting the use of genetic information to deny health insurance coverage or affect employment status.").

> kind of genetic information, as valuable as it is, might be used against people . . . . Unless Americans are *convinced* this information will not be used against them**,** *this era of personalized medicine may never come to pass*.[194]

Collins brackets this statement with the idea of a coming revolution and a new era in genomics.[195] These advances however, lie on a clouded horizon off in the distance. At first, it seems that the clouds are the threat of discrimination. In fact, however, the way to clear the clouds is not by addressing discrimination per se, but rather by convincing Americans that they will not be discriminated against. These are two very different, though obviously related, things. The real cloud on the horizon, then, or the true threat to realizing the promise of genomics, is the barrier to participation in research erected by fears of discrimination. In her testimony before the same committee, Kathy Hudson was quite explicit about this: "growing uncertainty and fear threaten the future of genetic medicine."[196]

GINA had broad bipartisan support. It was passed by a Democratic Congress and signed by the Republican President George W. Bush.[197] The theme of fear enjoyed a similarly wide embrace. In addition to Democratic Representative Louise Slaughter and the Republican Senator Olympia Snowe,[198] industry and patient advocacy groups also invoked the specter of fear as an obstacle to progress. For example, the Personalized Medicine Coalition, representing "a broad spectrum of more than 225 innovator, academic, industry, patient, provider and payer communities"[199] issued a press release calling for the passage of GINA because fear of genetic discrimination was deterring patients from taking advantage of

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194. *Genetic Information Nondiscrimination Act: Hearing on H.R. 493 Before the Subcomm. on Health of the Comm. on Energy & Commerce*, 110th Cong. 12–13 (2007) (statement of Francis Collins, M.D., Director of National Human Genome Research Institute, National Institutes of Health, Department of Health and Human Services) (emphasis added).

195. *See id.* at 12.

196. *Id.* at 44 (providing the testimony of Kathy Hudson).

197. *Genetic Information Nondiscrimination Act (GINA) of 2008*, NAT'L HUM. GENOME RES. INST., http://www.genome.gov/24519851 (last updated Mar. 16, 2012) (tracking the passage and legislative chronology of GINA).

198. *See supra* notes 166–67, 169 and accompanying text.

199. *About the Personalized Medicine Coalition (PMC)*, PERSONALIZED MED. COALITION, http://www.personalizedmedicinecoalition.org/about (last visited Jan. 30, 2014).

clinical care and making them "less willing to participate in studies that search for linkages between genes and disease, to enroll in clinical trials for new targeted drugs, or to provide samples for DNA analysis to optimize their own disease prevention and treatment."[200]

The GPPC clearly echoed this framing of GINA as it gauged public attitudes toward participation in large-scale genomic research. For example, in 2007, Kathy Hudson, then still director of the GPPC (and soon to become Francis Collins's Deputy Director for Science, Outreach, and Policy at the NIH),[201] emphasized the importance of using law to overcome public fear that threatened to impede genomic progress:

> Without comprehensive legal protections, the public fears genetic discrimination, and that fear has negative effects on both medical research and clinical care. Today, genetics is incorporated into almost all areas of clinical research, and scientists are proposing massive population-based studies that will enable them to identify and distinguish genetic, environmental, and lifestyle-based contributors to disease. *But many potential research participants are deterred by the fear that their information could be used against them by employers or insurers* . . . . The nondiscrimination legislation under consideration *would allow researchers, for the first time, to assure participants* that it is simply against the law for health insurers or employers to use genetic information to discriminate against them.[202]

Here, Hudson cast GINA as a recruitment tool that would allow researchers to increase participation by allaying fears about discrimination. Further, a GPPC *Discussion Guide for Clinicians* explicitly stated that discussing GINA "might help your patients feel more comfortable about . . . participating in genetic research."[203]

In a similar vein, a 2007 GPPC report found that, despite clear support for such testing, there was also widespread public

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200. Press Release, Personalized Med. Coal., Personalized Medicine Coalition Applauds Senate Approval of the Genetic Information Nondiscrimination Act (Apr. 24, 2008), *available at* http://www.personalizedmedicinecoalition.org/communications/press-releases/2008-04-24.

201. *See infra* notes 509–11 and accompanying text.

202. Kathy L. Hudson, *Prohibiting Genetic Discrimination*, 356 NEW ENG. J. MED. 2021, 2022 (2007) (emphasis added).

203. JOHNS HOPKINS UNIV. GENETICS & PUB. POLICY CTR., A DISCUSSION GUIDE FOR CLINICIANS 3 (2010), *available at* http://www.dnapolicy.org/resources/GINAfinal-discussionguide-3June10.pdf.

concern about discrimination.[204] The survey also found that "[t]hree in four Americans support laws to ban such discrimination."[205] The report concluded, much like Collins in his testimony before Congress, that "[w]ithout such laws, much of the promise of the Human Genome Project to identify the causes of disease and promote public health is likely to remain unfulfilled."[206] The following year, in an article co-authored with Hudson and M.K. Holohan, Collins noted that "studies have shown the 'fear factor' to be a major obstacle to patients' participation in research studies that involve the collection of genetic information."[207] The article went on to quote Representative Judy Biggert, a co-sponsor of GINA, for the proposition that, "[t]his bill unlocks the great promise of the Human Genome Project by alleviating the most common fear about genetic testing."[208] In this model of genomic progress, public willingness to participate in research is a sort of latent resource that needs a new law, GINA, in order to be actualized. The effectiveness of GINA as a recruitment tool depended on its status as a formal law, invoking the authority of the state to reassure recruits and surmount the barrier of their fear of discrimination.

Perhaps more significantly, the extensive discourse linking GINA to recruitment locates barriers to genomic progress external to the enterprise of "science" in the logistical realm of getting bodies. In this scheme, the complexities or uncertainties of genomics are not themselves barriers to progress. Rather, the implicit message is give "science" the proper resources and it will somehow naturally realize the great potential of genomics. Here the subtle difference between promise and potential comes into play as substantive demands are being made upon actors external to science (e.g., legislators considering the passage of GINA, or later prospective recruits to research) to realize its potential. Only through their actions may the latent potential of genomics be actualized. It is as if

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204. JOHNS HOPKINS UNIV. GENETICS & PUB. POLICY CTR., U.S. PUBLIC OPINION ON USES OF GENETIC INFORMATION AND GENETIC DISCRIMINATION 1 (2007), *available at* http://www.dnapolicy.org/images/reportpdfs/GINAPublic_Opinion_Genetic_Information_Discrimination.pdf.

205. *Id.* at 3.

206. *Id.*

207. Hudson et al., *supra* note 163, at 2663.

208. *Id.*

the science were there, ready and waiting but simply in need of some external ingredient to proceed. *In the first phase of the enterprise, the HGP, the required resources were primarily monetary. Now, in this second phase the resources are corporeal. In the world of genomic potential, GINA derived its primary value from its ability to contribute to mobilizing those bodily resources into the service of biomedical research.*

In these discussions of the future of genomics we have a progression of identifying and addressing major barriers to realizing its full potential. First, to move to the next phase of development after the HGP, researchers need to conduct an LPS; second, to conduct an LPS they need lots of bodies; third, to get bodies they need recruitmentologists; fourth, recruitmentologists cannot get bodies without addressing subject's fears of discrimination; fifth, GINA, a piece of legislation conceptualized long before the need to recruit people to an LPS, emerges as a ready means to address this fear and thereby works to make all the preceding steps fall into place. This scheme casts fear less as a concern to be addressed than a barrier to be overcome. Its salience derives not from the likelihood that the fears of discrimination might be realized and result in harm to individuals but from the certainty that such fears will obstruct the progression of science if not allayed.

## III. CITIZENSHIP: DUTY AS AN ADJUNCT TO RECRUITMENT

Fear is one type of barrier to recruitment. In many respects it is relatively straightforward: someone who might otherwise be willing to participate in a study holds back because of fear of potential discrimination. GINA emerged as a potentially effective response. Perhaps an even greater barrier to recruitment is inertia; that is, motivating individuals to even consider joining a study in the first place.[209] In studies of specific diseases, individuals with the condition being studied have a built-in incentive to participate in research—the hope that knowledge gained may directly improve their lives or those in the future who share the same condition. This incentive is so great as to give rise among bioethicists to a

209. *Cf.* Charles W. Lidz & Paul S. Appelbaum, *The Therapeutic Misconception: Problems and Solutions*, 40 MED. CARE (SUPP.) V-55, V-61 (2002) (evaluating potential research subject declination of participation as a cost to researchers).

concern for what has come to be known as the "therapeutic misconception": the belief among potential subjects that participating in a research study involving their condition might actually be a form of treatment.[210]

An LPS is a different sort of study. It involves the population at large and is general, not focused on any particular condition or disease.[211] Individuals have no immediate personal stake in participating.[212] Recruiters, therefore, need some additional means to get people in the door. The GPPC town halls explored attitudes toward return of results and monetary payments as possible incentives, but also appealed to altruism.[213] The ideal of serving the common good can be a powerful motivator for some people, but it is also a somewhat passive and abstract sort of appeal. Recruiters have also found a more aggressive adjunct to altruism in recent appeals to civic duty as a basis for demanding participation,[214] particularly for a large-scale enterprise such as an LPS that is not linked to any specific biomedical advance, such as curing diabetes, but only to the general promise of biomedical advance.

In 2009, the year after GINA was signed into law, G. Owen Schaefer, Ezekiel J. Emanuel, and Alan Wertheimer, all of the Department of Bioethics at the Clinical Center of the National Institutes of Health, published an article in *JAMA* (*Journal of the American Medical Association*) titled, *The Obligation to Participate in Biomedical Research*.[215] Ezekiel Emanuel was

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210. *See, e.g.*, G.E. Henderson et al., *Clinical Trials and Medical Care: Defining the Therapeutic Misconception*, 4 PLOS MED. 1735, 1736 (2007) (defining "therapeutic misconception" as existing "when a research subject fails to appreciate the distinction between the imperatives of clinical research and of ordinary treatment, and therefore inaccurately attributes therapeutic intent to research procedures"); Lidz & Appelbaum, *supra* note 209, at V-55.

211. *See, e.g.*, Collins, *supra* note 36, at 476 tbl.1 (describing how his proposed study required "[a] broad range of ages . . . to provide information on disorders from infancy to old age").

212. *But see infra* notes 213–14.

213. *See, e.g.*, WILLIAMS ET AL., *supra* note 65, at 8 (describing how participants cited "disease prevention and/or treatment" as the most important benefits of an LPS).

214. *See infra* notes 228–34 and accompanying text (outlining the civic duty argument of C.D. Herrera).

215. G. Owen Schaefer, Ezekiel J. Emanuel & Alan Wertheimer, *The Obligation to Participate in Biomedical Research*, 302 JAMA 67, 67 (2009) [hereinafter Emanuel et al.]. Though not the first author, I refer subsequently

Chair of the Department, and brother to Rahm Emanuel who was then President Obama's chief of staff.[216] In a nutshell, the article argued that, "[b]iomedical knowledge is a public good, available to any individual even if that individual does not contribute to it. Participation in research is a critical way to support an important public good. Consequently, all have a duty to participate."[217] Recognizing the current "social norm" where most participants in biomedical research have some sort of affirmative stake in the outcome (as in those whose own or family member's condition is being studied), the article used the notion of biomedical knowledge as a "public good" to shift the burden of participation from the equivalent of an "opt-in" system ("individuals participate only if they have good reason to do so") to an "opt-out" system ("individuals should participate unless they have a good reason not to").[218] This duty to participate has implications far beyond the possible implementation of any particular LPS. It frames an entire approach to situating the citizen in relation to the enterprise of biomedical research in the United States.

Calling for a duty to participate was not particularly new or striking in itself, but three things distinguished this article: first, it came at a time when the energies and attention of a wide array of genomic researchers, drug developers, and policy makers were increasingly looking toward large-scale population-based biobanks as essential to moving genomics forward from knowledge to application;[219] second, it articulated a distinctive vision of citizenship as a function of participation in research;[220] third, it was co-authored by a prominent NIH official with direct ties to the White House.[221]

The Emanuel et al. article falls in a line of recent debate that dates back at least to a 1984 article by bioethicist Arthur Caplan titled, *Is There a Duty to Serve as a Subject in*

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to this article as "Emanuel et al." because Emanuel was the lead official involved in the research.

216. Ryan Lizza, *The Gatekeeper*, NEW YORKER (Mar. 2, 2009), http://www.newyorker.com/reporting/2009/03/02/090302fa_fact_lizza?currentPage=all (describing Rahm Emanuel in his role as President Obama's chief of staff).

217. Emanuel et al., *supra* note 215, at 67.

218. *Id.* at 70.

219. *See, e.g.*, Collins, *supra* note 36, at 475–77.

220. *See supra* notes 217–18 and accompanying text.

221. *See supra* note 216 and accompanying text.

*Biomedical Research*?[222] Here Caplan reviewed attempts made during the previous decade to locate a moral basis for participation in biomedical research.[223] He discussed arguments by physicians such as Walsh McDemott, Louis Lasagna, and Leon Eisenberg that the results of biomedical research are public goods (much as Emanuel et al. would later argue) and hence require a measure of public participation.[224] Caplan then discussed counter arguments by the likes of Hans Jonas and Charles Fried to the effect that "it is not self-evident" that such results are in fact public goods and that even if they were, their value does not necessarily outweigh concerns for personal autonomy.[225] Caplan moved on to make his own argument that biomedical research, particularly in the context of a research hospital, constituted a sort of "voluntary social cooperation"[226] and that "any competent person who voluntarily seeks out and takes the benefits of care resulting from biomedical research can legitimately be said to be a consenting participant in the enterprise and, thus, the bearer of a duty to share in the costs of producing the desired goods."[227]

More recent arguments made since the completion of the HGP include a 2003 article by C.D. Herrera that argued for a more robust duty to participate, along the lines of jury duty, which would actually compel people to serve.[228] Herrera argued that such a system could remain responsive to principles of autonomy and justice "if it centered on broad public education, community representation, and a lottery-type selection process."[229] In 2005, Rosamund Rhodes, Director of Bioethics Education at Mount Sinai School of Medicine, generated much debate with her article *Rethinking Research Ethics*, published

222. Arthur L. Caplan, *Is There a Duty to Serve as a Subject in Biomedical Research?*, 6 IRB: ETHICS & HUM. RES. 1 (1984).

223. *Id.* at 1.

224. *Id.* at 2.

225. *Id.*

226. *Id.* at 4.

227. *Id.*

228. C.D. Herrera, *Universal Compulsory Service in Medical Research*, 24 THEORETICAL MED. 215, 215 (2003) (describing a "system of full civic participation").

229. *Id.*

in the *American Journal of Bioethics*.[230] Invoking language of promise and potential that echoed Francis Collins, Rhodes asserted that "we stand on the brink of a cascade of insights into human genetics and the promise of spectacular related advances in biomedical technology."[231] She went on to assert that "[w]ithout human subject research, those treatments are less likely to be available[;]" therefore "reasonable people should endorse policies that make research participation a social duty" analogous to paying taxes or jury service.[232] Those who do not participate still benefit from medical advances and are therefore engaged in morally objectionable free riding.[233] In this scheme, the great promise of biomedical technology demands the participation of human subjects to be realized.[234] The duty derives not simply from shared benefits but also from a moral imperative to actualize the latent potential of genomics.

Responding to Rhodes, Robert Wachbroit and David Wasserman questioned the validity of her analogy to jury service and focused particularly on the argument about free riding, questioning the idea that non-participants were "*unfairly* benefitting" from the value created by the service of participants.[235] They concluded that "research participation should be seen as a valuable civic activity, like school tutoring, volunteer fire-fighting, and neighborhood patrolling. . . . [B]ut there is no reason to single it out as the subject of a universal duty."[236] Three years later, Immaculada de Melo-Martín published *A Duty to Participate in Research: Does Social Context Matter*?, in which she directly took issue with Rhodes's arguments for a universal duty to participate.[237] Central to her critique was the assertion that Rhodes neglected the context in which decisions to participate occur or the specific risks of

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230. Rosamond Rhodes, *Rethinking Research Ethics*, 5 AM. J. BIOETHICS 19 (2005).

231. *Id.* at 25.

232. *Id.*

233. *Id*.

234. *Id.* at 26.

235. Robert Wachbroit & David Wasserman, *Research Participation: Are We Subject to a Duty?*, 5 AM. J. BIOETHICS 48, 48 (2005).

236. *Id.* at 49.

237. Immaculada de Melo-Martín, *A Duty to Participate in Research: Does Social Context Matter?*, 8 AM. J. BIOETHICS 28, 28 (2008).

participation the subjects might incur.[238] Particularly galling to de Melo-Martín was the idea that a country such as the United States, without universal health insurance, might impose duties to participate upon subjects who might have no access to the benefits that might result from subsequent research.[239] Additionally, she noted that among the key beneficiaries of such a duty would not be the abstract world of scientific advancement, but the very material world of multinational pharmaceutical corporations who would literally capitalize on the knowledge gained and perhaps control the underlying data as well.[240]

Rhodes's response to de Melo-Martín, *In Defense of the Duty to Participate in Biomedical Research*,[241] elaborated upon the free-rider aspects of her previous article, arguing that "[b]ecause we each expect ourselves and our loved ones to share in the benefits of future medical advances, at least to some degree, each of us must participate."[242] Now writing in 2008, Rhodes also expressly addressed the issue of biobanks and their role in promoting genetic research. "Looking into the genetics-informed future,"[243] she wrote,

> makes the case even more strongly. The expectation is that researchers will learn a great deal more about the human genome and the human microbiome and that this new knowledge will allow medicine to tailor treatments to individuals. These advances promises [sic] to make medicine more effective and, therefore, more affordable. The studies, however, will require the development of biobank and sample bank repositories with the participation of a tremendous number of subjects. To reap the rewards of advancing the practice of medicine, broad public participation will be required.[244]

Here, Rhodes connected the advance of biomedicine directly to recruitment for biobanks of the sort that would necessarily underpin the type of large-scale population study advocated by Francis Collins and explored by the GPPC. As a complement to the GPPC's exploration of willingness and possible incentives

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238. *Id.*
239. *Id.* at 30.
240. *Id.* at 31–32.
241. Rosamond Rhodes, *In Defense of the Duty to Participate in Biomedical Research*, 8 AM. J. BIOETHICS 37, 37 (2008).
242. *Id.*
243. *Id.* at 38.
244. *Id.*

to participate, Rhodes added the idea of duty.[245] Rhodes's use of the passive voice in the last sentence side steps the issue of how robust such a requirement might be and who would enforce it (and how).[246] Nonetheless, it is clear in its directive that the imperatives of actualizing the latent potential of science (here in the form of the "expectation" and the "promise" to make medicine more effective) demand "broad public participation."[247] For Rhodes, as for Collins and the GPPC, it was all about getting more bodies.

It was on the heels of this exchange that Emanuel et al. published their article in *JAMA*. Taking a slightly different tack from Rhodes, the article carefully distinguished its "public good" idea from similar arguments calling for participation based on the market idea of "free riding."[248] As defined by the authors, free riding "occurs when an individual receives a benefit that others pay for and takes advantage of the contributors by refusing to share the burden of obtaining it."[249] While an attractive argument, the authors assert that the idea of paying one's fair share is inapposite to participation in research because "[t]he burdens of participating in biomedical research that current participants assume are not alleviated when other individuals participate."[250] Conceiving of biomedical research as a public good surmounts this problem. A public good, as defined in the article, has two characteristics: "First, one individual's use of that good does not diminish another's use of that good; and second, it is impractical to prevent individuals from using the good."[251] A critique of free riding involves imposing an obligation based on paying one's fair share to relieve current burdens on others. In contrast, "discharging a public goods obligation makes society better off in the future," thus making it more apt to the case of research participation than the free-rider argument.[252]

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245. *Id.* ("[W]e are duty-bound to participate in research.").

246. *Id.* ("The risk associated with research should also be minimized through proper oversight of study design so that the expected harms are never undue and through required insurance to indemnify subjects from harms that are consequent to their research participation.").

247. *Id.*

248. Emanuel et al., *supra* note 215, at 67.

249. *Id.* at 67–68.

250. *Id.* at 68.

251. *Id.*

252. *Id.* at 69.

As Emanuel et al. conceive it, the obligation to participate in biomedical research is not so much grounded in a sense of fairness (as is free riding) as in a duty to society as a whole—a public duty, "[b]ecause the enterprise of biomedical research produces the important benefit of medical knowledge that is an advantage to all, every individual has an obligation to support that system of knowledge generation by participating in biomedical research."[253] This obligation, they argue, must be understood as an attribute of contemporary citizenship in the United States that demands "a cultural and moral change, not a legal one."[254] The authors make this connection explicit when they state that, "[j]ust as many claim that citizens have an obligation to vote even though they are not legally required to do so, society should recognize that everyone has an obligation to participate in research when it is not excessively burdensome to do so."[255] This new attribute of citizenship, then, does not involve formal rights and duties (as for example, the right to equal protection of the laws or the duty to serve on a jury) but rather a developing normative argument about what makes a "good citizen"[256] in the post-genomic age.

## IV. CITIZENS, GOOD CITIZENS, AND BIO-CITIZENS

These largely bioethical discussions of the specific duties of citizenship in relation to biomedical advancement are surprisingly short on theorization or historical contextualization of the concept and meaning of citizenship in American society. Diverse scholars have invested modern citizenship with an array of attributes and characteristics. In one typology, Ronald Beiner offers three theoretical perspectives on citizenship: liberal, emphasizing the individual and individual rights; communitarian, emphasizing the cultural or ethnic group and solidarity among those sharing a history or tradition; and civic republican, emphasizing "civic"

253. *Id.* at 68.
254. *Id.* at 70.
255. *Id.*
256. *See generally* MICHAEL SCHUDSON, THE GOOD CITIZEN: A HISTORY OF AMERICAN CIVIC LIFE (1998) (examining citizenship in the context of American political life).

bonds and duties to the polity.[257] In one of the most influential contemporary discussions of citizenship, T.H. Marshall focuses primarily on rights-based liberal conceptions of citizenship, which he breaks down into three elements: civil, political, and social.[258] The civil element involves those rights necessary for individual freedom, such as freedom of speech, thought, and faith, as well as basic property rights and the right to justice in a formal legal system.[259] The political element involves the right to participate in the exercise of political power—as through voting or running for elective office.[260] The social element involves rights to basic economic welfare and "security to the right to share to the full in the social heritage and to live the life of a civilized being according to the standards prevailing in society."[261] Marshall goes on to situate these rights historically, broadly locating the formative period for civil rights in the eighteenth century, political rights in the nineteenth, and social rights in the twentieth.[262] Citizenship, as elaborated through these rights, is a matter of ensuring that individuals are accorded a status as full and equal members of society.[263]

Marshall, however, was primarily concerned with aspects of citizenship related specifically to rights.[264] As Will Kymlicka and Wayne Norman note, "[c]itizenship is not just a certain status, defined by a set of rights and responsibilities. It is also an identity, an expression of one's membership in a political community."[265] As a function of participation in one's community, they define citizenship as an activity as well as a

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257. Ronald Beiner, *Introduction: Why Citizenship Constitutes a Theoretical Problem in the Last Decade of the Twentieth Century, in* THEORIZING CITIZENSHIP 1, 13–14 (Ronald Beiner ed., 1995).

258. T.H. Marshall, *Citizenship and Social Class*, *in* INEQUALITY AND SOCIETY: SOCIAL SCIENCE PERSPECTIVES ON SOCIAL STRATIFICATION 148, 148 (Jeff Manza & Michael Sauder eds., 2009).

259. *Id.*

260. *Id.* at 149.

261. *Id.*

262. *Id.*

263. *Id.* at 149–50.

264. *Cf. id. But see* Will Kymlicka & Wayne Norman, *Return of the Citizen: A Survey of Recent Work on Citizenship Theory*, 104 ETHICS 352, 369 (1994) (arguing that Marshall "saw citizenship as a shared identity that would . . . provide a source of national [British] unity").

265. Kymlicka & Norman, *supra* note 264, at 369.

status.[266] Or as Ruth Lister puts it, citizenship may be "conceptualized . . . both as a *status*, carrying a wide range of rights, and as a *practice*, involving both obligations and political participation, broadly defined."[267]

The notion of citizenship as a practice has roots in Aristotle's *Politics*, in which, as J.G.A. Pocock notes, "[c]itizenship is not just a means to being free; it is the way of being free itself."[268] Aristotle's model lies at the root of a civic republican conception of citizenship that developed through a lineage that includes Machiavelli and Guicciardini in the Italian Renaissance into British republican thinkers of the seventeenth and eighteenth century, such as James Harrington; the model ultimately came to play a signal role in shaping the ideology of the American Founders.[269] Bound up with ideals of civic virtue, corruption, and decay, Pocock distinguishes civic republicanism from a second "great Western definition of the political universe," expounded by the second century Roman jurist Gaius, wherein the individual "became a citizen . . . through the possession of things and the practice of jurisprudence. . . . A 'citizen' came to mean someone free to act by law, free to ask and expect the law's protection . . . . Citizenship has become a legal status, carrying with it rights to certain things."[270] Here, perhaps, lay the roots of modern liberal understandings of the citizen as a bearer of legal rights.

Feminist scholars have noted that the liberal subject historically has been implicitly coded as white and male.[271] These critiques focus on the importance of contextualizing the exercise of citizenship within actual historical communities and argue that any consideration of citizenship must also involve

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266. *Id.*

267. RUTH LISTER, CITIZENSHIP: FEMINIST PERSPECTIVES 41 (1997).

268. J.G.A. Pocock, *The Ideal of Citizenship Since Classical Times*, *in* THEORIZING CITIZENSHIP 29, 32 (Ronald Beiner ed., 1995).

269. *See generally* BERNARD BAILYN, THE IDEOLOGICAL ORIGINS OF THE AMERICAN REVOLUTION (1992); J.G.A. POCOCK, THE MACHIAVELLIAN MOVEMENT: FLORENTINE POLITICAL THOUGHT AND THE ATLANTIC REPUBLICAN TRADITION (2003).

270. Pocock, *supra* note 268, at 34–36.

271. *See, e.g.*, LISTER, *supra* note 267, at 66 ("The universalist cloak of the abstract, disembodied individual has been cast aside to reveal a definitely male citizen and a white, heterosexual, non-disabled one at that.").

an examination of the conditions that make it meaningful.[272] Similarly, feminists have challenged civic republican ideals of citizenship as grounded in an excessively rigid divide between the public and the private, reason and emotion, the particular and the universal; in each case, promoting civic ideals that exclude, deny or degrade women.[273]

Coming specifically to the case of citizenship in the American tradition, Michael Schudson focuses on the civic republican strain of citizenship to explore the evolving norms of what constitutes a "good citizen."[274] Schudson identified four historical phases of American civic life, beginning with the period of the Founders, which he sees as characterized by a "politics of assent" where the personal authority of gentleman elites dominated political discourse and action.[275] This gave way in the early nineteenth century to the era of Jacksonian mass democracy where the interpersonal authority of parties, coalitions, and electoral majorities ruled the day.[276] Early twentieth-century Progressive Era reformers emphasized an impersonal educational model of democracy, where the good citizen was a rational and informed one.[277] Finally, since the post-war civil rights era, the model of the "rights-bearing citizen" has been dominant in our own time, adding law to science and expertise as impersonal bases of authority.[278] Schudson makes clear that these models are not strictly sequential but accretive, each layering upon the previous, perhaps becoming more dominant but never wholly supplanting earlier models.[279]

As the title of Schudson's book, *The Good Citizen*, makes clear, he is concerned more with the practice of citizenship than with status. In contrast, in her study of contemporary American citizenship, Judith Shklar focuses on the idea of "standing" arguing that "the struggle for citizenship in America

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272. *See generally* LISTER, *supra* note 267; CAROL PATEMAN, THE DISORDER OF WOMEN (1989); Iris Marion Young, *Polity and Group Difference: A Critique of the Ideal of Universal Citizenship*, 99 ETHICS 250, 253–54 (1989).

273. *See, e.g.*, LISTER, *supra* note 267, at 69; ANNE PHILLIPS, ENGENDERING DEMOCRACY 46–53 (1991).

274. SCHUDSON, *supra* note 256.

275. *Id.* at 5.

276. *Id.* at 5–6.

277. *Id.* at 6.

278. *Id.* at 7.

279. *Id.* at 5–10.

has . . . been overwhelmingly a demand for inclusion in the polity, an effort to break down existing barriers to recognition, rather than an aspiration to civic participation as a deeply involving activity."[280] Central to her analysis of the emblems of public standing are the right to vote and the opportunity to earn; above all, these are what historically distinguished the free white man from the black slave.[281] The dignity of work and franchise were the key attributes of full standing in the American polity.[282] Nonetheless, Shklar fully acknowledges other components to American citizenship. She cites citizenship as "nationality"—a legal condition;[283] as "active participation or 'good citizenship'"—focusing on practices;[284] and the ideal of "republican citizenship"—where civic virtue requires constant and direct involvement in ruling and being ruled. [285]

Rogers Smith chronicles the darker side of American "civic ideals" of status and standing, arguing "that U.S. citizenship laws have always expressed illiberal, undemocratic ascriptive myths of U.S. civic identity, along with various types of liberal and republican ones, in logically inconsistent but politically effective combinations."[286] His "multiple traditions" thesis holds that these more hierarchical ascriptive ideologies (most prominently based on race and gender) have always been blended in with liberal and democratic republican civic ideologies.[287] As a critical complement to Schudson's analysis of the historical phases of American civic life, we have Smith asserting that:

> [F]rom Thomas Paine's identification of European-descended American men as the new chosen people of the Protestant God, to the Federalists' and the Whigs' Anglophilic nativism, to the Jeffersonian and Jacksonian doctrines of scientific racism, to the stark evolutionary theories of racial and gender hierarchies during the Gilded Age and the Progressive Era, U.S. leaders always

280. JUDITH SHKLAR, AMERICAN CITIZENSHIP: THE QUEST FOR INCLUSION 3 (1991).

281. *Id.* at 1–2.

282. *Id.*

283. *Id.* at 3–5.

284. *Id.* at 5.

285. *Id.* at 11–12.

286. ROGERS M. SMITH, CIVIC IDEALS: CONFLICTING VISIONS OF CITIZENSHIP IN U.S. HISTORY 470 (1997).

287. *Id.* at 471–72.

> fostered senses of what made Americans a distinct "people" that relied in part on inegalitarian ascriptive themes.[288]

The tapestry of American citizenship is thus complex, interwoven with many themes and informed by multiple ideological traditions.

## V. CONSTRUCTING CITIZENSHIP IN A POST-GENOMIC AGE

It is within this context that some significant recent social science scholarship on modern genomics has begun to explore its broader implications for contemporary understandings of citizenship.[289] Employing terms such as "Genetic Citizenship,"[290] "Genomic Citizenship,"[291] "Biopolitical Citizenship,"[292] and "Biological Citizenship,"[293] these scholars examine how the emergence of modern genetics and related enterprises have been changing individuals' understandings of their political identities in relation to themselves, their bodies, biomedical practices and the state.

Deborah Heath, Rayna Rapp, and Karen-Sue Taussig coined the term "genetic citizenship" to describe an emergent

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288. *Id.* at 471.

289. *See, e.g.*, Bruce Jennings, *Genetic Literacy and Citizenship: Possibilities for Deliberative Democratic Policymaking in Science and Medicine*, 13 GOOD SOC'Y 38 (2004); Anne Kerr, *Rights and Responsibilities in the New Genetics Era*, 23 CRITICAL SOC. POL'Y 208, 209 (2003).

290. *See, e.g.*, Deborah Heath et al., *Genetic Citizenship*, *in* A COMPANION TO THE ANTHROPOLOGY OF POLITICS 152 (David Nugent & Joan Vincent eds., 2004).

291. *See* Janet Elizabeth Childerhose, Genetic Discrimination: Genealogy of an American Problem 52–53 (Nov. 2008) (unpublished Ph.D. thesis, McGill University), *available at* digitool.library.mcgill.ca/thesisfile86665.pdf (explaining her use of the "genomic citizenship" construct).

292. STEVEN EPSTEIN, INCLUSION: THE POLITICS OF DIFFERENCE IN MEDICAL RESEARCH 116 (2007).

293. *See, e.g.*, ADRIANA PETRYNA, LIFE EXPOSED: BIOLOGICAL CITIZENS AFTER CHERNOBYL (2002); NIKOLAS ROSE, THE POLITICS OF LIFE ITSELF: BIOMEDICINE, POWER, AND SUBJECTIVITY IN THE TWENTY-FIRST CENTURY 131–54 (2007); Nikolas Rose & Carlos Novas, *Biological Citizenship*, *in* GLOBAL ASSEMBLAGES: TECHNOLOGY, POLITICS, AND ETHICS AS ANTHROPOLOGICAL PROBLEMS 439, 439 (A. Ong & S.J. Collier eds., 2008). Other similar terms include "biomedical citizenship," João Biehl, *The Activist State: Global Pharmaceuticals, AIDS, and Citizenship in Brazil*, 80 SOC. TEXT 105, 130 n.48 (2004), and "therapeutic citizenship," Vinh-kim Nguyen, *Antiretroviral Globalism, Biopolitics, and Therapeutic Citizenship*, *in* GLOBAL ASSEMBLAGES: TECHNOLOGY, POLITICS, AND ETHICS AS ANTHROPOLOGICAL PROBLEMS 124 (A. Ong & S.J. Collier eds., 2005).

phenomenon whereby individuals "connect[ ] discussions of rights, recognitions, and responsibilities to intimate, fundamental concerns about heritable identities."[294] Their analysis takes aim, in part, at the traditional divide between public and private in classical theories of citizenship.[295] Their notion of citizenship is intimate and involves an ethic of care that they connect both to Michel Foucault's notion of "technologies of the self" and to feminist moral philosophy emerging from Carol Gilligan's work on moral development.[296] They argue that organizations built around shared genetic traits, such as the lay advocacy group the Genetic Alliance, are giving rise to "new forms of democratic participation, blurring the boundary between state and society, and between private and public interests."[297] They also note, however, a phenomenon whereby health advocacy groups that began grass-roots mobilizing efforts to make demands on the state for resources and support may become corporatized as they go national.[298] This "corporatization" of grass-roots voluntary associations, they argue, "represents not merely assimilation into early twenty-first-century capitalist culture, but also a strategic intervention, a move to gain access to resources."[299]

Janet Childerhose distinguishes her idea of "genomic citizenship" from Heath, Rapp, and Taussig's genetic citizenship by observing that, the latter "describes the claims for scientific inclusion by marginalized populations with rare genetic disorders," whereas genomic citizenship "describes the geneticization of all Americans by some genetic activists."[300] In her study of the campaign to pass GINA, Childerhose notes that these activists, including the same Genetic Alliance studied earlier by Heath, Rapp, and Taussig, sought to "enroll everyone into a biosociality of a flawed genome that is being

294. Heath et al., *supra* note 290, at 157.
295. *Id.*
296. *Id.*
297. *Id.* at 152.
298. *Id.*
299. *Id.* at 161. This phenomenon provides an interesting counter-example to Robert Putnam's argument in his much discussed book, *Bowling Alone*, that American structures of solidarity and community have become increasingly eroded in the past century, leaving us civically isolated and disconnected. *See* ROBERT D. PUTNAM, BOWLING ALONE: THE COLLAPSE AND REVIVAL OF AMERICAN COMMUNITY (2000).
300. Childerhose, *supra* note 291, at 336.

made transparent by researchers. According to these activists, all Americans are members of the 'genetics community,' whether they realize it or not," because we all have flaws in our genome.[301] Childerhose argues that while this model of citizenship may appear inclusive and egalitarian, it is actually coercive in its insistence that "all Americans . . . take responsibility for their genetic liabilities" and lays the foundations for discrimination against those who fail to conform to this norm of good genomic citizenship.[302]

Nikolas Rose and Carlos Novas frame "biological citizenship" as a more general version of genetic citizenship and place it in the context of a tradition of "citizenship projects," which they define as "the ways in which authorities thought about (some) individuals as potential citizens, and the ways in which they tried to act upon them."[303] They argue that "specific biological presuppositions . . . have underlain many citizenship projects," and use the term "biological citizenship" descriptively "to encompass all those citizenship projects that have linked their conceptions of citizens to beliefs about the biological existence of human beings, as individuals, as families and lineages, as communities, as population and races, and as a species."[304] Echoing the arguments of Heath, Rapp, and Taussig, Rose and Novas assert that solidaristic ties formed through biological commonalities allow groups to make certain types of ethical demands—on themselves, on communities, and on the state.[305] These demands may come through the sort of advocacy groups identified by Heath, Rapp, and Taussig;[306] in contrast to their conceptualization of genetic citizenship as a basis for solidaristic organization and political engagement, Rose and Novas foreground the consumerist attributes of biological citizenship, presenting the human body as an object to be targeted by enhancement technologies in a global market that exists separate from nation-states.[307] As they put it, "[t]his is the citizenship of brand culture, where trust in brands appears capable of supplanting trust in neutral scientific

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301. *Id.*
302. *Id.* at 357.
303. Rose & Novas, *supra* note 293, at 439; *see* ROSE, *supra* note 293.
304. Rose & Novas, *supra* note 293, at 440.
305. *Id.* at 441.
306. *Id.* at 440–42.
307. *Id.* at 448.

expertise."[308] Like Childerhose, Rose and Novas note that biological citizenship also makes demands on subjects "to inform him- or herself not only about current illness, but also about susceptibilities and predispositions. . . . [and] to take appropriate steps" to minimize the risk of illness and maximize health.[309] As consumers, biological citizens have duties, but unlike those articulated by Emanuel et al., these duties primarily involve their own self-fashioning rather than participating in a common enterprise for the greater good.[310] Some critics have expressed concerns that this vision of citizenship, with its apparent celebration of citizenship as a function of consumption, is a dangerous departure from more traditional conceptions of social and political citizenship.[311]

Childerhose's argument that the campaign for GINA involved casting the entire nation as a genomic citizens jibes with Shklar's focus on citizenship as standing with its concomitant demand for inclusion in the polity. Yet, as Steven Epstein ably shows, inclusion in the life sciences can be complex and contested, implicating politics that may exacerbate inequalities even as it is trying to address them.[312] Shklar's idea of citizenship focused on the quest for civic inclusion as full members of the polity. Epstein's biopolitical citizens, in contrast, seek inclusion primarily as subjects of biomedical research.[313] Inclusion also may be double edged insofar as the grant of standing may also impose duties.[314] The duties elaborated by previous analyses of the diverse facets of modern genetic or biological citizenship focus primarily on issues of individual self-care, education, and consumption. Ironically, even as these models involve genetic identities forming the basis for new communal ties, they reproduce

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308. *Id.*

309. *Id.* at 451.

310. *Id.*

311. Roger Cooter, *Biocitizenship*, 372 LANCET 1725, 1725 (2008) *available at* http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(08)61719-5/fulltext.

312. EPSTEIN, *supra* note 292, at 4 ("Since the mid-1980s, . . . reformers ha[ve] argued that expert knowledge about human health is dangerously flawed . . . because of inadequate representation of groups within research populations in studies of a wide range of diseases.").

313. *Id.* at 6 (describing his "inclusion-and-difference paradigm").

314. *Id.* at 11.

classically liberal conceptions of citizens as atomized individual consumers—making demands for particular goods and services.

This last model of citizen as consumer actually has its roots in Progressive Era America.[315] As Schudson notes, this period was marked by a shift to impersonal authority grounded in the authority of science and law, where a good citizen was an informed and rational one.[316] Progressive reformers worked diligently to recast citizenship as a function of consuming information about government and then using their vote as a means, in effect, to purchase the leaders and policies they preferred.[317] Central to this reconfiguration of citizenship was a national campaign to create public budgets at all levels of government.[318] Difficult as it may be to conceive today, no governmental entity in the United States had anything looking like a modern budgetary system before the twentieth century.[319] Budget reformers of the Progressive Era conceived of public budgets as presenting fundamental information about the constitution of government to the people.[320] They deemed access to such information as critical to maintaining a viable representative democracy in modern, urban, industrialized society.[321] This scheme effectively aimed to deracinate citizenship by realigning its duties from old schemes of deference to elites or tribal party affiliation toward the rational and systematic consumption of information about the working of the state as presented through well-publicized budgets.[322]

This involved quite literally putting the state on display.[323] In 1908, New York City inaugurated the first of several grand "Budget Exhibits," something akin to the public fairs and expositions that swept the country in the preceding decades but focused on graphically representing the functions of local government to the citizens.[324] Over one million people attended

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315. SCHUDSON, *supra* note 256, at 294–95.

316. *Id.*

317. JONATHAN KAHN, BUDGETING DEMOCRACY: STATE BUILDING AND CITIZENSHIP IN AMERICA, 1890–1928, at 93–119 (1997).

318. *Id.*

319. *Id.* at 1 ("Before the twentieth century, no government in the United States, local, state, or national, had a coherent budget system.").

320. *Id.* at 1–2.

321. *Id.* at 2.

322. *Id.* at 1–6, 104–11, 120–64.

323. *Id.* at 104–11.

324. *Id.*

the last and grandest of these annual exhibits, held during the month of October, 1911.[325] As budget reform went national with the passage of the Budget and Accounting Act of 1921, this function was taken over by the budget document itself, which purported to present a detailed public accounting of governmental priorities and allocation of resources.[326] In some respects, one may (somewhat anachronistically) consider the budget to have been understood as an early political analogue to DNA—information deemed fundamentally constitutive, not of the body, but of the body politic.

Whereas the budget reformers of the early twentieth century deemed consumption of budgetary information about the state to be a preeminent mark of the "good" citizen,[327] modern analysts of biotechnology, particularly Rose and Novas, see consumption of genetic information about the self to be the distinguishing feature of the "good" citizen in the early twenty-first century.[328] The former model of deracinated citizenship aimed to strip personal identity from a civic life based on science and expertise but was ultimately oriented toward the state and a sense of common civic obligation to a larger public good. The latter model layers new genetic identities on citizenship, creating the basis for new types of communal bonds, but it is ultimately oriented toward corporations and the market as source of redress for their concerns.

In a sense, what has happened here is a shift from an early twentieth-century model of the citizen as consumer to an early twenty-first-century model of the consumer as citizen. Both, perhaps, are grounded in Lawrence Friedman's characterization of twentieth century America as a "Republic of Choice."[329] Friedman contrasts the self-disciplined individualism of the nineteenth century with the self-expressive individualism of the twentieth century in which "the right to 'be oneself,' to *choose* oneself, is placed in a special and

325. *Id.*

326. *Id.* at 104–11, 120–64.

327. *See supra* notes 315–26 and accompanying text.

328. *See* Rose & Novas, *supra* note 293, at 441 ("[N]ow one must also know and manage the implications of one's own genome.").

329. LAWRENCE M. FRIEDMAN, THE REPUBLIC OF CHOICE: LAW, AUTHORITY, AND CULTURE (1990).

privileged position."[330] The literal refashioning of the embodied self-enabled by modern biotechnology marks perhaps the apotheosis of this vision. The result is a kind of republican consumerism, where one's duty to the polity is exercised through market virtues, not civic ones. Where earlier groups based campaigns for voting rights or school desegregation on civic standing and inclusion as a function of human dignity, the inclusion sought by genetic citizens often involves demands for access to biotechnological products.

## VI. PRIVATIZING CITIZENSHIP

How then, do recent efforts at recruitment for large-scale genomic population studies and Emanuel et al.'s call for an obligation to participate in research fit into the traditions of American citizenship? In analogizing the duty to participate in biomedical research to the duty to vote, Emanuel et al. clearly frame it as civic, a central attribute of good citizenship in the communitarian or civic republican strains that emphasize virtuous practice.[331] The idea here is that participating in biomedical research is a kind of public service.[332] They are not alone in this general approach, but it involves a critical shift from a liberal, rights-focused conception of an active citizenry of patient advocacy groups making demands of biomedical researchers, to recruiters invoking a civic republican duty-based model of citizenship to make demands of potential subjects. As Steven Epstein notes, early health activists "invoked ideas of citizenship to demand that researchers attend to the health research needs of disadvantaged groups, investigators seeking to recruit subjects have counterposed such citizenship *rights* with citizenship *duties*: the good citizen is one who volunteers on behalf of his or her community."[333] Epstein focused on "community" largely as a term related to

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330. *Id.* at 3. Friedman's contrast echoes the categories elaborated by Robert Bellah, Richard Madsen, and William Sullivan. *See* ROBERT N. BELLAH ET AL., HABITS OF THE HEART: INDIVIDUALISM AND COMMITMENT IN AMERICAN LIFE (1985). In particular, *Habits of the Heart* notes the rise of expressive individualism in the twentieth century. *See id.* at 27–54, 142–66. Expressive individualism is marked by a therapeutic ideal of individual self-realization. *See id.*

331. *See* Emanuel et al., *supra* note 215, at 70; *supra* note 257 and accompanying text.

332. *See* Emanuel et al., *supra* note 215, at 71.

333. EPSTEIN, *supra* note 292, at 190.

fellow sufferers,[334] much as did Heath, Rapp, and Taussig.[335] Emanuel et al., however, move beyond the notion of a community of fellow sufferers to extend the call of duty to all citizens,[336] more in line with Childerhose's notion of a genomic citizenship that embraces us all.[337]

Emanuel et al. also stand out in their explicit embrace of the idea that service to the community is to be realized first through service to the needs of private corporations.[338] Unlike voting, which ostensibly manifests a form of citizen control over the state, participating in biomedical research introduces the citizen-subject into a commercial nexus that extracts value from her body while conferring no control whatsoever over the ultimate disposition of the knowledge and products derived therefrom.[339] Emanuel et al. are aware of this problem and address it by trying to elide the difference between private gain and ultimate service to the final good of public health.[340] To a certain degree, this elision may be understood as a sort of civic analogue to the therapeutic misconception. Where the classic therapeutic misconception involves blurring the distinction between research and therapy,[341] its civic analogue—a civic misconception, as it were—here blurs the distinction between biomedical service to one's community and commercial service to a corporation. Demanding the right to participate in a trial to promote the interests of your biomedical-identified political community—as in the case of AIDS activists in the late 1970s and early 1990s[342]—is one thing; positing a duty for all citizens to participate may sound like a similar kind of call for

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334. *Id.*

335. Heath et al., *supra* note 290, at 152–67; Taussig, Hoeyer & Helmreich, *supra* note 17, at S10–S12.

336. Emanuel et al., *supra* note 215, at 68–70.

337. Childerhose, *supra* note 291, at 335.

338. Emanuel et al., *supra* note 215, at 71.

339. *Cf. id.* at 71 ("[I]t could be objected that patented biomedical knowledge is not a public good, and hence participation in industry-sponsored research that may produce patented knowledge is not an obligation.").

340. *Id*. at 70–71.

341. Lidz & Appelbaum, *supra* note 210, at V57.

342. EPSTEIN, *supra* note 292, at 118–24. *See generally* STEVEN EPSTEIN, IMPURE SCIENCE: AIDS, ACTIVISM, AND THE POLITICS OF KNOWLEDGE (1996) [hereinafter EPSTEIN, IMPURE SCIENCE], *available at* http://publishing.cdlib.org/ucpressebooks/view?docId=ft1s20045x;chunk.id=0;doc.view=print (discussing the changing role of activism within the AIDS movement).

inclusion, but it is externally imposed and only indirectly serves the public good through the vehicle of a corporate intermediary which holds all substantive control over the process and its products.

When dealing with a public good such as biomedical knowledge, Emanuel et al. declare, "[w]ho provides the good is irrelevant to whether it is public or private. A private company might provide a public good like fireworks, whereas a government could provide unemployment benefits, which is a private good because it can be given to unemployed individuals but not to others."[343] This, of course, overlooks the fact that private companies do not provide fireworks for free, nor do construction companies build roads and schools for free. They do so pursuant to government contracts that specify the terms and conditions of the service. Such is not the case with pharmaceutical and medical device developers.[344] Perhaps a more apt analogy would be to the building of railroads across the old West, which involved a massive transfer of public assets (i.e., land) to private railroad companies.[345] In the case of biomedical research, however, the massive transfer of assets does not involve exploiting land but the bodies of citizens.

Perhaps most striking is the contrast between Emanuel et al.'s model and the civic ideals promulgated from the Progressive Era ideal up through modern notions of genetic or biological citizenship. These earlier models cast the citizen as a consumer whose primary duty was to take in information (whether about the state or about their own biological condition) and act on it in a reasoned and responsible manner.[346] In characterizing participation as a duty of citizenship, Emanuel et al. recast the good citizen from being a consumer to being herself an object of consumption.[347] The early twentieth-century model citizen was encouraged to consume political information about the state; the early

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343. Emanuel et al., *supra* note 215, at 68.

344. Bernard H. Munos & William W. Chin, *How to Revive Breakthrough Innovation in the Pharmaceutical Industry*, SCI. TRANSLATIONAL MED., June 29, 2011, at 2–3.

345. RICHARD WHITE, RAILROADED: THE TRANSCONTINENTALS AND THE MAKING OF MODERN AMERICA 24–25 (2011) (explaining that the land granted to railroads east and west of the Mississippi, if concentrated into a single state, would be the third-largest state in America).

346. Emanuel et al., *supra* note 215, at 69–71.

347. *Id.* at 71.

twenty-first century genetic or biomedical citizen was encouraged to consume biological information about him- or herself; and Emanuel et al.'s ideal citizen herself becomes a source of information that is consumed by corporate drug developers. *The citizen moves from being a consumer to being the consumed*.

This latest model of citizenship is complementary to that of Rose and Novas. The biomedical products that Rose and Novas's good biocitizen is duty-bound to consume are produced through the participation of Emanuel et al.'s good citizen in biomedical research. Each model, however, implicates privatization and power differently. Rose and Novas's model privatizes citizenship simply insofar as the good biocitizen exercises her primary duties—of informed self-care and consumption of biomedical interventions—in the private realm of the marketplace.[348] The model elaborated by Emanuel et al., and in related endeavors such as the GPPC town halls, privatizes citizenship more profoundly by conscripting the core values and meaning of citizenship into the service of private corporate entities, thereby commodifying citizenship as a resource to be exploited for commercial product development.[349]

Consider further how the original politics of budgets and of biomedicine were both built on display: the one putting the state on display through exhibits that employed such cutting edge technology as film (to show, for example, the fire department putting out a fire);[350] the other putting the body on display through such similarly cutting edge technologies as gel electrophoresis, magnetic resonance imaging, and electron microscopes.[351] In the early twentieth century the state was to be put on display to the citizens as a basis for reasoned political action; in the early twenty-first century one's body was to be put on display to oneself as a basis for reasoned self-care. In Emanuel et al.'s model, however, one's body is to be put on display to biomedical researchers as a basis for product development.[352]

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348. *See* Rose & Novas, *supra* note 293, at 441–42, 458–59.

349. *See supra* Part III.

350. EPSTEIN, IMPURE SCIENCE, *supra* note 342, at 325 (discussing the impact of a film and the public's perception of issues it presented).

351. DEP'T OF ENERGY & NAT'L INST. OF HEALTH, *supra* note 30, at 16.

352. Emanuel et al., *supra* note 215, at 68.

Nonetheless, Emanuel et al. assert that because "the enterprise of biomedical research" produces the public good of medical knowledge, which benefits all, it creates an obligation for all to support it.[353] They readily acknowledge that the great majority of such research is sponsored by pharmaceutical corporations, but argue that since a private company can provide a public good, "there can be obligations to help private companies produce public goods."[354] Keith Faulks notes that the obligations of citizenship "may be seen as . . . an expression of solidarity and empathy with others."[355] Certainly this is the feeling Emanuel et al. wish to invoke. But under their model citizen research subjects express their sympathy and solidarity elsewhere—with private companies.[356] The fact that such private companies may patent the public good of biomedical knowledge produced by broad citizen participation does not trouble them because patents eventually expire and in any event, the knowledge underlying the patent remains public.[357]

This model also imposes duty asymmetrically. Here the good citizen has an obligation to contribute to the production of the public good of biomedical knowledge by serving as a human subject for research.[358] The corporation, however, has no corresponding duty whatsoever. Rather, it is merely assumed that the logic of the market will impel the corporation to develop that knowledge rapidly and efficiently into an effective product that improves human health.[359] The corporation may patent the knowledge, charge fees for the product that place it out beyond the reach of many of the same human subjects who provided the information critical to its development, strike deals with potential generic manufacturers (if the product is a drug) to stave off early introduction of lower priced alternatives, lobby for and exploit tax preferences for research and development, withhold information from the public about negative results, skew clinical trial designs to favor their

353. *Id.* at 68.
354. *Id.* at 71.
355. KEITH FAULKS, CITIZENSHIP 82 (2000).
356. Emanuel et al., *supra* note 215, at 71.
357. *Id.*
358. Caplan, *supra* note 222, at 4.
359. *Id.* at 2 (discussing how the first step to the production of new drugs is the participation of citizens thus inferring that a reliance exists but not a duty to produce new drugs).

products, conduct misleading marketing campaigns, and so forth[360]—all without offending any duty to serve the public good. The model thoroughly decontextualizes the production of biomedical knowledge, stripping it of any connection to the actual conditions under which corporations conduct research, development, and marketing.

This is more than the sort of "enclosure" of the human genome through patenting examined by critics such as James Boyle[361] and recently litigated in the case of *Association for Molecular Pathology v. Myriad Genetics*.[362] It is the appropriation of the embodied citizenry—a privatization of citizenship itself. Emanuel et al.'s ideal citizen owes a duty not to the state but to private corporations, which, they assume will go on to provide public goods.[363] The conditions under which such goods are provided are irrelevant for them. In contrast to the model of activist groups, such as the Genetic Alliance, who use genetic identities to enlist individuals into groups that can make claims on the state (or on corporations),[364] Emanuel et al. use biological identity (as broadly conceived by Rose and Novas) to make claims on the individual. Where basic duties of self-care and education still involve a sense of duty to the civic community—particularly to fellow-sufferers—the duty to participate in corporate research is owed primarily and directly to the private corporation.[365] Such a duty may be conceived of as civic only to the extent that it is mediated through the presumed ability of the corporation to serve the larger public good.[366] Here the locus of engagement

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360. *See, e.g.*, MARCIA ANGELL, THE TRUTH ABOUT DRUG COMPANIES 109–12 (2004) (discussing the Remone research paper controversy, in which public researchers were sued when the private drug manufacturer disliked their negative findings); JERRY AVORN, POWERFUL MEDICINES: THE BENEFITS, RISKS, AND COSTS OF PRESCRIPTION DRUGS 401–17 (2004); MELODY PETERSON, OUR DAILY MEDS 123–29 (2008).

361. JAMES BOYLE, THE PUBLIC DOMAIN: ENCLOSING THE COMMONS OF THE MIND 42–54 (2008).

362. Adam Liptak, *Justices, 9-0, Bar Patenting Human Genes*, N.Y. TIMES, June 13, 2013, http://www.nytimes.com/2013/06/14/us/supreme-court-rules-human-genes-may-not-be-patented.html; *see* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013).

363. Emanuel et al., *supra* note 215, at 71 ("[T]here can be obligations to help private companies produce public goods.").

364. *Genetic Discrimination*, *supra* note 156.

365. Emanuel et al., *supra* note 215, at 71.

366. *See* Caplan, *supra* note 222, at 2.

where a citizen discharges her duty is not the public sphere of civic space, it is the private clinical research trial.[367] The citizen does not engage with other citizens, articulate, or make demands; rather the citizen is himself articulated, rendered transparent, open, and susceptible to exploitation—in the name of science but in the service of the corporate enterprise.[368] Finally, to the extent that the very concept of citizenship itself is a public resource, capable of mobilizing and directing loyalty, allegiance, and related civic virtues, this call to serve biomedical research transfers the authority of the state to make claims based on citizenship into the hands of private enterprise.[369]

From the GPPC's town halls to Emanuel et al.'s focus on duty, these initiatives are developing a model of biomedical citizenship that is characterized by market negotiation (as in the GPPC focus group research), consumerist practices (as observed by Rose and Novas), and product development (the ultimate goal of Emanuel et al.'s call to participate in research). To the extent that rights (such as access to information or return of research results) matter at all, they are only those rights that individuals are able to bargain for through the sort of market-mediated quid pro quo presented in the GPPC discussion groups. *This model privatizes biomedical citizenship as a function of market relations by appropriating civic republican traditions of the practices of good citizenship to enlist the populace to serve private corporate interests while obscuring or marginalizing the liberal tradition's focus on the individual rights of citizenship conferred by virtue of one's basic status as a member of the political community.*

## VII. CALL OF DUTY: THE MILLION VETERAN PROGRAM

The story here takes a brief detour to the Department of Veterans Affairs (VA), where a parallel large population study

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367. *See id.* at 5.

368. *See* Rhodes, *supra* note 230, at 21–22 (discussing the exploitation of subjects in Nazi experiments and the lack of consideration of the substantial risks, all for the benefit of society or in this case, the society that the Nazis deemed important).

369. *Contra* Herrera, *supra* note 228, at 225 (asserting that authority will be given back to the citizen and they will be able to decide their participation if they have been chosen from the suggested lottery system).

initiative emerged invoking similar but distinctly military tropes of duty and service to recruit participants.[370] Since our founding, the citizen-soldier has been a central figure in constructing ideals of America citizenship.[371] During the American Revolution the symbol of the Roman patrician Cincinnatus, who left his plow to take up arms and then returned to civilian life, became a model of civic virtue for the citizen-soldiers fighting for the new republic.[372] America's oldest patriotic organization, the Society of the Cincinnati, was founded in 1783 to honor this ideal.[373]

In 2007, while it was working in conjunction with the NIH to develop its scheme of town halls and surveys to assess attitudes among the general public toward participating in genetic research, the GPPC also received nearly half a million dollars to assess the attitudes toward genetic research and genomic medicine of veterans who receive their health care through the VA.[374] This project was deliberately conceived as a companion to the GPPCs work for the NIH.[375] As the GPPC noted at the time, working with the VA presented a distinct opportunity because it is one of the largest health care systems in the United States, providing care to over 5.3 million patients with an integrated electronic medical record system.[376] The GPPC conducted a survey of 931 veterans enrolled in the VA health system about attitudes toward participating in a VA-based biobank to conduct research on issues of distinct interest

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370. PRESIDENTIAL COMM'N FOR THE STUDY OF BIOETHICAL ISSUES, MORAL SCIENCE: PROTECTING PARTICIPANTS IN HUMAN SUBJECTS RESEARCH 37 (2011), *available at* http://bioethics.gov/sites/default/files/Moral%20Science%20-%20Final.pdf (supporting the concept of research with human subjects).

371. *See, e.g.*, R. CLAIRE SNYDER, CITIZEN-SOLDIERS AND MANLY WARRIORS: MILITARY SERVICE AND GENDER IN THE CIVIC REPUBLICAN TRADITION 80 (1999) ("The early American allegiance to the ideals of civic republicanism included a commitment to the ideal of the Citizen-Solider.").

372. N.S. Gill, *Lucius Quinctius Cincinnatus,* ABOUT.COM ANCIENT / CLASSICAL HISTORY, http://ancienthistory.about.com/od/rulersleaderskings/p/Cincinnatus.htm (last visited Feb. 8, 2014).

373. Ross G. Perry, *President General's Welcome*, SOC'Y CINCINNATI, http://societyofthecincinnati.org/about (last visited Jan. 26, 2014).

374. Press Release, Johns Hopkins Univ. Genetics & Pub. Policy Ctr., Center Conducts Public Consultation Project for VA (June 20, 2007), *available at* http://www.dnapolicy.org/news.release.php?action=detail&pressrelease_id=80.

375. *Id.*

376. *Id.*

to veterans, such as possible genetic factors affecting post-traumatic stress disorder (PTSD).[377] A large majority of respondents supported the idea of creating such a database, with seventy-one percent indicating they would definitely or probably participate.[378]

With these results in hand, the VA launched the Million Veteran Program (MVP) in 2011.[379] As described by the VA:

> MVP is a national, *voluntary* research program funded entirely by the Department of Veterans Affairs Office of Research & Development. The goal of MVP is to partner with Veterans receiving their care in the VA Healthcare System to study how genes affect health. To do this, MVP will build one of the world's largest medical databases by safely collecting blood samples and health information from one million Veteran volunteers. Data collected from MVP will be stored anonymously for research on diseases like diabetes and cancer, and military-related illnesses, such as post-traumatic stress disorder.[380]

On November 11, 2013, the VA announced it had enrolled its 200,000th participant in the program, making it the largest research program ever conducted by the VA.[381] It hopes to reach its goal of one million enrolled veterans by 2017.[382]

Reporting and promotional materials on the MVP repeatedly invoke tropes of service, comradeship, and duty.[383] Given the military context, such framings seem to have been far more readily accepted and generally less contested than Emanuel et al.'s similar call to duty in a civilian context.[384] The

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377. Jane Sherwin, *New VA Program Could Pave the Way for Personalized Care*, AAMC REPORTER (July 2011), https://www.aamc.org/newsroom/reporter/july11/254618/veterans.html; *see* Carolyn Johnson, *Veterans Taking Part in Massive DNA Project*, KGO-TV (Jan. 4, 2012), http://abclocal.go.com/kgo/story?section=news/health&id=8490606.

378. Sherwin, *supra* note 377.

379. *Id.*

380. *Million Veteran Program*, U.S. DEP'T VETERANS AFF. (last updated Nov. 20, 2013), http://www.research.va.gov/mvp/default.cfm.

381. Turna Ray, *With Enrollment at 200K, VA's Million Veteran Program Inks Contracts for Genetic Analysis*, PHARMACOGENOMICS REP. (Nov. 13, 2013), http://www.genomeweb.com/clinical-genomics/enrollment-200k-vas-million-veteran-program-inks-contracts-genetic-analysis.

382. *Id.*

383. Jay Price, *Veterans Give Even More; 1 Million Sought for DNA Data*, NEWS & OBSERVER (Feb. 8, 2012), http://www.newsobserver.com/2012/02/08/1837995/veterans-give-even-more.html.

384. Press Release, U.S. Dep't of Veterans Affairs, The Million Veteran Program: VA's Genomics Game-Changer Launches Nationwide (May 5, 2011) [hereinafter Genomics Game-Changer], *available at* http://www.va.gov/opa/

VA describes the MVP as a "partnership with veterans"[385] that is well-positioned to succeed "thanks to its large, diverse, and altruistic patient population."[386] Similarly, Dr. Joel Kupersmith, the VA's chief research and development officer expressed confidence about subject recruitment because "vets are very altruistic people and they're likely to help if you tell them it will benefit someone else."[387]

News reports of the MVP have repeatedly cited veterans' own invocations of service and duty as underlying their decision to participate.[388] "It's just one more way to serve my country," said Army veteran Clarence Gray.[389] Becky Carpenter, a third generation veteran, framed her participation as growing out of her "strong history of service," casting the MVP as another opportunity for veterans "to serve our country."[390] Marine Corps veteran Andrew Peters, enrolling in California, framed participation as a duty to the service, to medicine and to each other.[391] The sense of duty to each other also invokes ideals of military fraternity echoed by JD LeBlanc, a Vietnam veteran who said he enrolled because "[a]nything I can do to help future vets is worthwhile."[392] Similarly, Robert Stephens, assistant Army chaplain in the Vietnam War asserted that "[w]e have to help each other."[393] Throughout, powerful tropes of duty and service—specifically military attributes of good citizenship—frame the efforts to recruit veterans into a massive genomic research project. Though running on a parallel course to the NIH efforts to develop an

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pressrel/pressrelease.cfm?id=2090 (discussing a willingness to help other veterans with the "care they have earned").

385. *Million Veteran Program*, *supra* note 380.

386. Genomics Game-Changer, *supra* note 384.

387. Meredith Cohn, *Project Seeks 1 Million Veterans to Give Blood, DNA for Disease Research Department of Veterans Affairs Working to Uncover Genetic Mysteries*, BALTIMORE SUN (Feb. 5, 2012), http://www.baltimoresun.com/health/bs-hs-million-veteran-program-20120204,0,1502812.story (internal quotation marks omitted).

388. *Id.*; Price, *supra* note 383.

389. Price, *supra* note 383.

390. Kristen Moulton, *Salt Lake Veterans Affairs Enlists Vets for Huge Medical Research Project*, SALT LAKE TRIB. (Jan. 26, 2012, 7:35 PM), http://www.sltrib.com/sltrib/news/53381550-78/veterans-program-veteran-million.html.csp.

391. Johnson, *supra* note 377.

392. Moulton, *supra* note 390.

393. *Id.*

LPS, the MVP similarly invoked, perhaps even more explicitly, ideals of duty and service as a tool of recruitment.

## VIII. THE PROBLEM OF CONSENT: REVISING THE COMMON RULE

Coming back to the civilian sector: to this point we have had Francis Collins calling for a large cohort population study to follow on the heels of the completion of the HGP;[394] the NIH enlisting the GPPC to conduct preliminary studies exploring how best to recruit people to such a study;[395] and Emanuel et al. positing a moral obligation to participate in order to get willing recruits in the door.[396] The next essential piece to proceeding with research is to obtain the subjects' *consent*. At the federal level, questions of consent in human subject research are most fully dealt with under a series of regulations first issued in 1991 that have come to be known as the "Common Rule," codified at 45 C.F.R. pt. 46.[397]

The Common Rule governs eighteen federal departments and agencies (most prominently the Department of Health and Human Services) and applies as well to all research funded by the agencies.[398] The Rule generally requires informed consent, independent ethical review by Institutional Review Boards (IRBs), and the minimization of avoidable risks.[399] The Food and Drug Administration (FDA), while not formally covered by the Common Rule, applies essentially the same standards to all research supporting submissions for regulatory approval.[400]

The concerns for human subjects protections embodied in the Common Rule have their roots in the Nuremberg Code, promulgated in the aftermath of World War II, and revelations of Nazi abuses of prisoners for research.[401] At the core of the

394. *See supra* notes 35–39 and accompanying text.

395. *See supra* notes 57–60 and accompanying text.

396. Emanuel et al., *supra* note 215, at 67.

397. *45 CFR 46—FAQs*, U.S. DEP'T HEALTH & HUM. SERVICES, http://answers.hhs.gov/ohrp/categories/1562 (last visited Jan. 24, 2014).

398. *Id.*

399. *Id.*

400. For a chart of the differences between FDA regulations and the Common Rule, see *Comparison of FDA and HHS Human Subject Protection Regulations*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/educationalmaterials/ucm112910.htm (last updated Mar. 10, 2009).

401. Rhodes, *supra* note 230, at 21–22.

Code is a concern for informed consent and a balancing of risks and benefits to protect the human subject.[402] In 1964 the World Health Association adopted additional "Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects" in its Declaration of Helsinki.[403] The Declaration has been revised many times since. Like the Nuremberg Code, it is also concerned with consent and also extensively discusses the management of risk to the human subject.[404] In particular, its most current iteration specifies that research "must be preceded by careful assessment of predictable risks and burdens to the individuals and communities involved in the research in comparison with foreseeable benefits to them and to other individuals or communities affected by the condition under investigation;"[405] that "[p]hysicians may not participate in a research study involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed;"[406] and that "[m]edical research involving human subjects may only be conducted if the importance of the objective outweighs the inherent risks and burdens to the research subjects."[407]

Revelations of research abuses such as the Tuskegee Syphilis Study in the early 1970s led to the passage in 1974 of the National Research Act,[408] which created the Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.[409] Four years later the Commission published *Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, known as the Belmont Report, which became a foundational document for contemporary

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402. *See The Nuremberg Code*, U.S. DEP'T HEALTH & HUM. SERVICES, http://www.hhs.gov/ohrp/archive/nurcode.html (last visited Feb. 7, 2014).

403. *See WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects*, WORLD MED. ASS'N, http://www.wma.net/en/30publications/10policies/b3/17c.pdf (last visited Jan. 28, 2014).

404. *Id.* at 3–5.

405. *Id.* at 3.

406. *Id.*

407. *Id.*

408. *U.S. Public Health Service Syphilis Study at Tuskegee: Research Implications*, CENTERS FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/tuskegee/after.htm (last updated Sept. 24, 2013).

409. *See* National Research Act, Pub. L. No. 93-348, 88 Stat. 342 (1974).

bioethics in the United States.[410] Using the Belmont Report as a guide, the Department of Health and Human Services (HHS) began to revise and expand its regulations governing human subjects research.[411] This work evolved into the uniform set of regulations adopted as the Common Rule in 1991.[412]

In July 2011, less than two years after Emanuel et al. published their call for a civic obligation to participate in biomedical research, HHS published an advanced notice of proposed rulemaking (ANPRM) concerning possible revisions to the Common Rule.[413] The announcement noted that "[t]he current regulations governing human subjects research were developed years ago when research was predominantly conducted at universities, colleges, and medical institutions, and each study generally took place at only a single site."[414] Expansion of human subject research into many new scientific disciplines and venues and an increase in multi-site studies have highlighted ambiguities in the current rules and have led to questions about whether the current regulatory framework is effectively keeping up with the needs of researchers and research subjects.[415] Consent and IRB review are at the center of this problem.[416] Most consent protocols commonly limit the use of information or biospecimens to the particular study or institution where the information is gathered.[417] This makes open-ended research of the kind called for in a large population study exceedingly difficult. As for IRBs, Coleman et al. note that the "goal for IRBs is not to eliminate the risks of research, but to ensure that the risks have been minimized to the extent reasonably possible and that any remaining risks are justified by the benefits the study is likely to achieve."[418] Yet, as biomedical research has become increasingly complex and

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410. *See* Belmont Report, 44 Fed. Reg. 23,192 (Apr. 18, 1979).

411. Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, 76 Fed. Reg. 44,512, 44,512–31 (July 26, 2011) (to be codified at 21 C.F.R. pts. 50, 56).

412. *See 45 CFR 46—FAQs*, *supra* note 397.

413. Human Subjects Research Protections, 76 Fed. Reg. at 44,512.

414. *Id.*

415. *Id.*

416. *Id.* at 44,518.

417. *Id.* at 44,519.

418. CARL H. COLEMAN ET AL., THE ETHICS AND REGULATION OF RESEARCH WITH HUMAN SUBJECTS 245 (2005).

geographically dispersed, many researchers have come to see IRB review as excessively burdensome and time-consuming.[419]

The ANPRM identified seven key concerns animating the call for revisions, focusing broadly on issues relating to risk, efficiency, and consent.[420] Its "fundamental goal" was "to enhance the effectiveness of the research oversight system by improving the protections for human subjects while also reducing burdens, delays, and ambiguity for investigators and research subjects."[421] While unremarkable in itself, this framing creates a direct relationship and possible tension between providing adequate protections for human subjects and increasing the efficiency of the process. Implicitly, requirements that protect subjects are cast as presenting potential barriers to research and development. While much of the ANPRM involves consideration of reducing regulatory burdens placed on relatively low-risk social science research,[422] a central component of the proposed revisions focuses on expanding existing exemptions from full IRB review (to be recast under the heading of "excused" rather than "exempt" research) to cover research on biospecimens, provided certain new consent requirements are satisfied.[423]

Biospecimens provide the foundation for the sort of large-scale, longitudinal population study called for by Francis Collins and presented by the GPPC for consideration in its town halls and focus groups.[424] They comprise the biobanks that provide access to the genetic information that many researchers hope may be correlated with ongoing phenotypic traits and etiology of particular health conditions over time.[425] Currently, using such information in a research study is generally exempt from the burdens of IRB review if the information has been "de-identified"—that is, if it cannot be

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419. Human Subjects Research Protections, 76 Fed. Reg. at 44,512–31, 44,518 (portraying the process as burdensome and asking how to streamline it).

420. *Id.* at 44,513.

421. *Id.* at 44,514.

422. *E.g.*, *id.* at 44,516 (providing for "expedited review" for minimal risk studies, "particularly those in the social and behavioral field").

423. *Id.* at 44,515.

424. Kaufman et al., *supra* note 147, at 831.

425. *Id.* at 831–32.

traced back to an individual source.[426] The sort of large-scale population studies proposed by Collins and the GPPC, however, are much more useful if the information can be connected to the type of specific phenotypic information that would render the biospecimens "identifiable."[427]

The ANPRM addressed this problem by proposing to allow open and free use of biospecimens for research from subjects who first signed a "brief standard consent form agreeing to generally permit future research."[428] All future studies using such biospecimens, whether for clinical purposes or not, would fall under the new "excused" category and hence "not require IRB review or any routine administrative review but would be subject to the data security and information protection standards" proposed elsewhere in the ANPRM.[429] The purpose here is to "calibrate[ ]" the levels of review "to [the] . . . degree of risk" involved in the research;[430] the idea being that review itself presents a burden or barrier to the conduct of research that needs to be minimized to a degree commensurate with the level of risk it is intended to manage. As a result, the previous "limitation that the researcher cannot record and retain information that identifies the subjects would be eliminated."[431]

The ANPRM casts the risks of biospecimen research as primarily informational in nature, involving, for example, the unintended release of private information or the public identification of basic genetic information with a particular individual.[432] It proposes a new regime for data security to manage such information and therefore argues that "only noninformational risks would be considered in determining the level of risk posed by research studies."[433] Here, the ANPRM neatly casts the risks of biospecimen collection as a matter of data management rather than involving ethical questions relating to the status of or possible harms to participants.[434] It

426. *See* Human Subjects Research Protections, 76 Fed. Reg. at 44,527 (noting that de-identified information does not require written consent for future research or IRB review).

427. *Id.* at 44,524–26.

428. *Id.* at 44,515.

429. *Id.*

430. *Id.*

431. *Id.* at 44,519.

432. *Id.* at 44,515–16.

433. *Id.* at 44,516.

434. *See id.*

proposes adherence to standards for data security and confidentiality modeled on those for health information in the Health Insurance Portability and Accountability Act (HIPAA).[435] The ANPRM would thus transfer risk management for biospecimens from IRB review to a technical realm largely devoid of ethical considerations, with little oversight or accountability.[436]

By reconfiguring risk, and hence removing IRB review from the realm of biospecimen collection, the ANPRM leaves consent as the only major regulatory hurdle to be crossed in constructing a biobank for an LPS.[437] There are two basic components to the consent process: one must, of course, get potential subjects actually to consent to participate in the research; this consent additionally must be "informed."[438] In this regard, the ANPRM's proposal to allow general open-ended consent for all potential future use of identifiable information is both very powerful and highly problematic.

As it turns out, Ezekiel Emanuel was part of the working group convened by the Office of Management and Budget to consider revisions to the Common Rule that came to be published in the ANPRM.[439] In 2011, while still at the NIH, Emanuel co-authored an article with Jerry Menikoff discussing the ANPRM and the rationale for it.[440] Published in the *New England Journal of Medicine*, the article largely summarizes the main points of the ANPRM.[441] It begins by noting that the Common Rule has persisted largely unchanged since it was first introduced in 1991, while research practices had developed dramatically in both size and scope since that time, giving rise to much criticism of the current regulatory regime.[442] Emanuel and Menikoff identify two key themes in these critiques: first, "the regulations impose a variety of burdensome bureaucratic procedures that seem to do little to protect research

435. *Id.* at 44,514.
436. *Id.*
437. *See id.* at 44,522.
438. *See id.* at 44,517.
439. Ezekiel J. Emanuel & Jerry Menikoff, *Reforming the Regulations Governing Research with Human Subjects*, 365 NEW ENG. J. MED. 1145, 1145 (2011).
440. *Id.*
441. *Id.*
442. *Id.*

participants, yet consume substantial resources;" and second, "current regulations could be doing a significantly better job in protecting research subjects."[443] They cast regulatory burden and risk to human subjects as the two primary barriers to the progress of research.[444] With respect to biospecimens, the proposed revisions deal with the first barrier by removing this category of research from IRB review, and with the second by redefining risk as primarily informational and hence manageable through technical means that, again, involve minimal ethical oversight.[445]

Further expressing concern over the need to revise regulation governing the use of biospecimens, Emanuel and Menikoff note that "[m]any commentators have argued that uncertainty about the regulations on biospecimens has impeded research. Yet research with biospecimens is becoming increasingly important;"[446] they state this despite their assertion that "such research often entails no or minimal physical risk."[447] Having established a frame that juxtaposes excessive regulatory burden against minimal risk, they move on to make a case for the ANPRM's suggestions that:

> [A] standard, brief, and general form be used to obtain consent for the future open-ended use of biospecimens in research. Further, such a form need not be signed each and every time a specimen is collected. Rather, researchers or hospitals might ask participants to sign one form in which they agree to such future use of all specimens (existing or to be collected in the future).[448]

Significantly, these arguments appear under the heading "Enhancing Protections for Research Participants."[449] Such revisions, however, are clearly calibrated more to reduce the burden on researchers than to substantively enhance protections for research subjects. Hence Emanuel and Menikoff do not justify the proposal for open-ended consent by discussing the benefits it might provide to participants, but by asserting that such revisions will help to realize "the huge benefits to be gained from such research."[450] The Nuremberg Code, the

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443. *Id.*
444. *Id.*
445. *Id.* at 1147.
446. *Id.* at 1148.
447. *Id.*
448. *Id.* at 1149.
449. *Id.* at 1148–49.
450. *Id.* at 1149.

Helsinki Declaration, and the Belmont Report embraced consent as a foundational recognition of the agency and dignity of human subjects.[451] While clearly still adhering to that view in cases of clinical research, Emanuel and Menikoff here cast consent, like risk, primarily as a burden to be managed in order to realize the research potential of biospecimens.

In many respects, this view follows logically upon Emanuel et al.'s call for a duty to participate in human subjects research. Both are oriented toward promoting the basic conditions necessary to develop large-scale genetically-based population studies. The call of duty serves to bring people in the door; the exemption from IRB review facilitates the development and implementation of research protocols; and the relaxed consent process eases the final step of actually enrolling people in the study while opening up their data for free and unrestricted use in the future.

Following the publication of the ANPRM, HHS collected comments from the public responding to its proposals.[452] A majority of the more than eleven hundred comments received favored the provision allowing for a general consent form to permit future use of biospecimens and related data, clearly recognizing the burden this would lift from their research endeavors.[453] Some comments, however, expressed grave reservations, particularly with respect to issues of consent.[454] The American Association of Medical Colleges (AAMC), for example, asserted that,

> An individual who is asked to sign a blanket consent document without any information about what type of research might be done in the future and with no opportunity to ask questions about the research that may be conducted (for example, if such consent is obtained just prior to surgery or on admission to a hospital) cannot be said to have provided meaningful informed consent. This could be more accurately characterized as "notice cloaked in consent's clothing," providing individuals with a false sense of individual control when, in fact, there is none.[455]

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451. *See supra* notes 402–03, 410, and accompanying text.

452. *See* EDWARD BARTLETT, OFFICE FOR HUMAN RESEARCH PROTS., U.S. DEP'T OF HEALTH & HUMAN SERVS.: SEC'YS ADVISORY COMM. ON HUMAN RESEARCH PROTS. (SACHRP), ANPRM: SUMMARY OF COMMENTS (2012), *available at* http://www.hhs.gov/ohrp/sachrp/mtgings/2012%20Feb%20Mtg/anprmsummaryebartlett.pdf.

453. *Id.* at 2.

454. *Id.* at 10.

455. *Id.*

In contrast to viewing consent as a burden to be managed, the AAMC emphasized the role of consent as recognition of individual autonomy.[456] It argued that completely open consent to all possible future use cannot be truly informed insofar as a subject cannot know to what purposes her biospecimens may ultimately be put.[457]

Similarly, the Secretary's Advisory Committee on Human Research Protections (SACHRP) (created in 2001 and tasked with providing expert advice and recommendations to the Secretary of HSS on issues and topics pertaining to the protection of human research subjects)[458] pushed back against some of the ANPRM's suggestions regarding consent.[459] It noted that the consent process had indeed become cumbersome, but attributed this less to the need to manage risk to subjects than to concerns "about minimizing the potential risk of adverse legal actions."[460] Here the SACHRP introduced a new type of risk into the review of the consent process. In contrast to the classic bioethical concerns to mitigate risk of personal harm, the SACHRP here recognized that risks of legal action introduced their own, distinctive burdens to the research process.[461] A consent regime based on mitigating risks of personal harm to subjects may focus on issues of autonomy and informed consent in one way; but a consent regime shaped by concerns to mitigate risks of legal harm to researchers and their sponsors may give rise to very different sorts of approaches to consent. Certainly, the sort of brief, standardized open-consent form for biospecimens research proposed by the ANPRM was well tailored to mitigating legal risk.

The SACHRP, however, expressed concern that the ANPRM focused "too much on the consent *form* as opposed to the consent *process*."[462] This concern comports well with the

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456. *Id.*

457. *Id.*

458. *Secretary's Advisory Committee on Human Research Protections (SACHRP)*, DEP'T HEALTH & HUM. SERVICES, http://www.hhs.gov/ohrp/sachrp/ (last visited Apr. 28, 2014).

459. *See* Letter from Barbara E. Bierer, Chair, Sec'ys Advisory Comm. on Human Research Prots., to Kathleen Sebelius, Sec'y of Health & Human Servs. [hereinafter SACHRP Letter], *available at* http://www.hhs.gov/ohrp/sachrp/commsec/sachrpanprmcommentsfinal.pdf.pdf.

460. *Id.* at 14.

461. *Id.* at 14–15.

462. *Id.* at 14.

findings of a group of researchers from the University of North Carolina who studied the attitudes of research subjects toward participating in a genomic biobank.[463] In their 2010 paper, the researchers report that "whereas medical practice treats [consent] as an event, our subjects talk about it as a discursive process—that is, a process that unfolds over the course of multiple communicative interactions."[464] They found that while medical researchers focus on the actual act of signing a consent form, this means relatively little to subjects, who may give their consent for a wide range of reasons and may continue to be interested in ongoing issues of consent long after the basic form has been signed.[465]

The SACHRP identified six core elements of a good consent process: "(1) statement that the project involves research; (2) purpose; (3) 'voluntary statement' (including withdrawal); (4) duration of participation; (5) risks related to the research itself; (6) potential benefits of the research to subjects and society."[466] Under the Common Rule, consent is inextricably bound up with weighing risks and benefits; but as the SACHRP makes clear, risks are to be balanced against "potential" benefits.[467] Each enables the other: risks must be managed to realize potential; potential must be substantial to outweigh risk. The balance is not a direct calculus; rather it is part of informing a subject and hence shaping her decision. One might well ask why potential benefit should be made part of the subject's calculus at all. Making potential benefits a part of the consent process implicitly makes demands upon the subject, informing her not only of the dimensions of her altruism but also presenting a picture of what may be lost if she does not participate.

The SACHRP went on to express concerns regarding the ANPRM's proposed general open consent model for biospecimen research, stating that it

> believes that a general consent for future use should not be a necessary predicate for any and all future research uses, and that such a general consent cannot act as a substitute for careful

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463. John M. Conley et al., *The Discourse of DNA: What Research Subjects Say About Participating (or Not) in a Genomic Biobank* (UNC Legal Studies Research, Working Paper No. 1554744), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1554744.

464. *Id.* at 4.

465. *Id.* at 11–12.

466. SACHRP Letter, *supra* note 459, at 15.

467. *Id.*

> consideration by an IRB, through the existing waiver of consent process, of specific future research uses and their risks for subjects.[468]

While perhaps placing unwarranted faith in the efficacy and rigor of IRB review, the SACHRP nonetheless understood that procedurally it was important to keep some formal mechanism or institution in the ongoing oversight of biomedical research—even when risks were low and potential benefits high.[469] It went on to observe that many industry-sponsored clinical trials already offered a form of tiered consent that presented an array of possible future uses to which participants could opt-in.[470] It further noted that foregoing general open consent would not preclude future unanticipated uses of biospecimens "because, presently, researchers have the option of seeking from an IRB a waiver of informed consent for the future use."[471] The core of its objection to general consent, however, echoed the AAMC assertion about the inherent impossibility of providing truly informed general consent to all future uses.[472] Participants, the Committee declared,

> cannot accurately and fully be apprised of future benefits, or of risks, or even of the research methods that might be employed, to an extent that would allow a researcher to "skip the step" in future specific studies of seeking either IRB waiver of consent, or subject re-consent, under the Common Rule.[473]

Lest we consider the SACHRP as erecting excessive barriers to future research on biospecimens, it is important to realize that it was not advocating that control over such research be located directly with the research participants.[474] Rather, it argued for continuing under a regime that would allow experts on IRBs to make decisions about waiving consent for possible future uses.[475] That is, it was arguing for keeping IRBs in the loop—not necessarily the participants

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468. *Id.* at 31.
469. *Id.*
470. *Id.*
471. *Id.*
472. *Id.* at 32.
473. *Id.* A 2012 feature article in the journal *Nature* noted that "[t]he research coordinators who develop consent forms cannot predict how such data might be used in the future, nor can they guarantee that the data will remain protected." Erika Check Hayden, *A Broken Contract*, 486 NATURE 312, 312 (2012).
474. *See* SACHRP Letter, *supra* note 459, at 33.
475. *Id.*

themselves.[476] It makes this case clearly in raising the problem of free riding in a manner quite reminiscent of Emanuel et al.'s call for a duty to participate:

> It seems . . . contrary to the principles of beneficence and justice as put forth in the Belmont Report to advocate a state of affairs in which persons may refuse use of their own data and biospecimens, even when risk to them is negligible, but who nevertheless themselves benefit from such research by depending upon the beneficence of others. Further, one cannot then ensure that the results of any such research will be representative and not biased or skewed.[477]

The SACHRP concluded that, counterintuitively, general consent might therefore actually impede the ability of investigators to use biospecimens for future research because of the ability of participants to opt out under general consent.[478] Moreover, it framed the ethical, legal and social policy implications of consent regimes as involving primarily tensions "between the needs of science and the rights of individuals."[479]

This characterization of the issue rather conveniently elides the role that commercial enterprises play in research and development based on biospecimens. This is particularly striking given the fact that the ANPRM itself mentioned the case of Henrietta Lacks, whose cells, taken without her knowledge or consent, provided the basis for billions of dollars' worth of medical research and products.[480] Moreover, the earlier GPPC town hall meetings had found widespread concern "that pharmaceutical or other companies might profit off of the taxpayer-funded proposed study."[481] One participant, for example, was worried that "[t]hey may produce drugs that are so expensive that most people couldn't afford them."[482] For the SACHRP, however, such concerns did not play a part in

476. *Id.*

477. *Id.* at 36.

478. *Id.* at 35.

479. SEC'YS ADVISORY COMM. ON HUMAN RESEARCH PROTS., FAQS, TERMS AND RECOMMENDATIONS ON INFORMED CONSENT AND RESEARCH USE OF BIOSPECIMENS 1 (2011), *available at* http://www.hhs.gov/ohrp/sachrp/commsec/attachmentdfaq'stermsandrecommendations.pdf.pdf.

480. Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, 76 Fed. Reg. 44,512, 44,524 (July 26, 2011) (to be codified at 21 C.F.R. pts. 50, 56). For a discussion of the story of Henrietta Lacks, see generally REBECCA SKLOOT, THE IMMORTAL LIFE OF HENRIETTA LACKS (2010).

481. WILLIAMS ET AL., *supra* note 65, at 8.

482. *Id.* (internal quotation marks omitted).

structuring the relationship between participant and researcher—that was cast solely in terms of realizing the potential of scientific progress—to which it cast individual rights as a barrier. To the extent commercial considerations entered the discussion, it was only in reference to having investigators make disclosures of their own financial interests in any research, not with reference to possible patenting of material or other commercial issues related to equity or distributional justice.[483]

In December 2011, just months after the publication of the ANPRM, the Presidential Commission for the Study of Bioethical Issues issued a report titled, *MORAL SCIENCE: Protecting Participants in Human Subjects Research*.[484] While the President's charge to the Commission came largely in response to revelations by historian Susan Reverby concerning U.S. involvement in serious research abuses in Guatemala in the late 1940s (including the deliberate infection of vulnerable and uninformed subjects with venereal diseases),[485] the Commission nonetheless was tasked to conduct "a thorough review of current regulations and international standards to assess whether they adequately protect human subjects in federally supported scientific studies."[486] The Bioethics Commission directly considered the ANPRM proposals to revise the IRB review and consent process.[487] In contrast to the SACHRP, the Commission expressed few reservations.[488] It formally endorsed numerous of the ANPRM's proposals, including the elimination of "continuing review for certain lower-risk studies and regularly update the list of research categories that may undergo expedited review;" and providing "standardized consent form templates with clear language

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483. *See* SACHRP Letter, *supra* note 459, at 39 (providing sample regulations requiring investigators to "report[ ] . . . all financial interests relevant to their institutional commitments").

484. PRESIDENTIAL COMM'N FOR THE STUDY OF BIOETHICAL ISSUES, *supra* note 370.

485. *See id.*; *cf.* PRESIDENTIAL COMM'N FOR THE STUDY OF BIOETHICAL ISSUES, "ETHICALLY IMPOSSIBLE": STD RESEARCH IN GUATEMALA FROM 1946 TO 1948, at 2 (2011), *available at* http://bioethics.gov/sites/default/files/Ethically%20Impossible%20%28with%20linked%20historical%20documents%29%202.7.13.pdf.

486. PRESIDENTIAL COMM'N FOR THE STUDY OF BIOETHICAL ISSUES, *supra* note 370, at 2.

487. *Id.* at 25.

488. *Id.* at 25–27.

understandable to subjects."[489] Significantly, apart from one passing reference in a footnote,[490] the Commission's 208 page report makes no mention at all of biospecimens or the ANPRM's proposals regarding general consent for their future use. Rather, its approach to the ANPRM appeared to be shaped by a frame of regulatory oversight as a barrier to scientific progress, noting early on that "the Commission heard from a wide range of research professionals that the procedural requirements of human subjects regulations are often viewed as unwelcome bureaucratic obstacles to conducting research."[491]

The ANPRM thus serves as a complement to and logical extension of the GPPC town halls, GINA, and the call for a duty to participate in research, as they lay the foundations necessary to sustain and capitalize on the sort of large-scale longitudinal population studies called for by Francis Collins back in 2003.[492] Each effort is fundamentally oriented toward overcoming perceived barriers to realizing the potential of biomedical research in a post-genomic age. First, you must find potential recruits and identify their interests and concerns. This was the job of the GPPC's town halls and related surveys.[493] Second, you need to give recruiters some tools to address those concerns. Here, GINA emerged as a formal legal structure that recruiters could invoke to address some of the primary concerns regarding privacy and discrimination.[494] Third, once you have addressed the negative barriers impeding possible recruitment, you need to develop a message to encourage potential recruits to take affirmative steps to enroll in biomedical research studies. Emanuel et al.'s call for a duty to participate asserted just such a positive claim upon individuals to enroll in research studies;[495] the MVP served as a military adjunct to this call.[496] Fourth, once you have recruits in the door, you have to minimize the burdens of consent and

489. *Id.* at 98, 102.

490. *Id.* at 108 n.14.

491. *Id.* at 9.

492. *See* Collins, *supra* note 36, at 476.

493. *See Making Every Voice Count: Public Consultation on Genetics, Environment, and Health*, *supra* note 57.

494. *See supra* notes 152–54 and accompanying text.

495. Emanuel et al., *supra* note 215, at 1145; *see* PRESIDENTIAL COMM'N FOR THE STUDY OF BIOETHICAL ISSUES, *supra* note 370, at 2.

496. *See supra* note 374 and accompanying text.

regulatory oversight, particularly with respect to the type of information needed for the type of open-ended research central to large-scale population studies. The ANPRM directly addresses this issue, setting the stage for the development of massive new amounts of data that Collins hoped in 2003 would allow us to realize "the promise of genetic and environmental research for reducing disease burden on a population basis."[497]

## IX. NCATS: FROM POPULATIONS TO CORPORATIONS

Once you get people in through the door and obtain their consent, you ultimately need to use the information resulting from any study to create the promised therapies meant to actualize the potential of genomic medicine. Realizing Collins's promises, in short, requires more than information and research. It demands that such research be *translated* into viable treatments—most prominently as new pharmaceuticals. Translational research is the concept of the moment at the NIH.[498] It is framed by a widely held belief that some new initiative is needed to overcome the "valley of death" between basic science and applied interventions that obstructs the development of new molecular entities to treat disease.[499] It is driven by a concern that drug company pipelines are drying up with no new blockbusters on the horizon.[500] So powerful is this concept that it led to a structural reconfiguration of the NIH to create the National Center for Advancing Translational Science (NCATS) in 2011.[501]

A central component of NCATS's purpose is to conduct early stage research on molecular entities that show promise as potential treatments for disease but are deemed by private industry as too risky to invest in.[502] This might also involve

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497. Collins, *supra* note 36, at 477.

498. Jocelyn Kaiser, *NIH to Create National Science Center*, SCI. INSIDER (Dec. 7, 2010, 4:18 PM), http://news.sciencemag.org/2010/12/nih-create-translational-science-center.

499. *See* David Bornstein, *Helping New Drugs out of Research's 'Valley of Death'*, N.Y. TIMES (May 2, 2011, 9:15 PM), http://opinionator.blogs.nytimes.com/2011/05/02/helping-new-drugs-out-of-academias-valley-of-death/?_php=true&_type=blogs&_r=0.

500. Kaiser, *supra* note 498.

501. *Id.*

502. *Research*, NAT'L CENTER FOR ADVANCING TRANSLATIONAL SCI., http://www.ncats.nih.gov/research/research.html (last visited Feb. 10, 2014).

rescuing drugs previously seen to be failures.[503] An article in the *New York Times* analogized NCATS's role "to that of a home seller who spruces up properties to attract buyers in a down market. In this case the center will do as much research as it needs to do so that it can attract drug company investment."[504] Collins later described the new Center's mission as "catalyz[ing] the generation of innovative methods and technologies that will enhance the development, testing, and implementation of diagnostics and therapeutics across a wide range of diseases and conditions."[505] NCATS boosters frequently relate need for such a catalyst to data purporting to show the astronomical cost of bringing a new drug to market—often in excess of $1 billion.[506]

Strictly speaking, NCATS is not currently involved in directly exploiting the information derived from biobanks.[507] Its creation, however, was driven by similar concerns to overcome barriers to realizing the potential of genomic medicine—most particularly the perceived bottleneck in drug development.[508] There is also a significant continuity in personnel between these earlier initiatives and NCATS—not only in Francis Collins, who now oversees all activities at the NIH, but more particularly in the person of Kathy Hudson. A prominent promoter of NCATS in 2011, Hudson had by then come to the NIH where she served as Francis Collins's deputy director for science, outreach and policy.[509] As director of the GPPC at Johns Hopkins, Hudson had been instrumental in developing the town halls and surveys that served as the foundation for both the NIH's efforts to explore the feasibility of conducting a large population study and the Department of Veterans Affairs'

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503. Gardiner Harris, *Federal Research Center Will Help Develop Medicines*, N.Y. TIMES, Jan. 23, 2011, at A1.

504. *Id.* at A25.

505. Collins, *supra* note 5, at 1.

506. *See, e.g.*, Matthew Harper, *The Cost of Creating a New Drug Now $5 Billion, Pushing Big Pharma to Change*, FORBES (Aug. 11, 2013, 11:10 AM), http://www.forbes.com/sites/matthewherper/2013/08/11/how-the-staggering-cost-of-inventing-new-drugs-is-shaping-the-future-of-medicine/.

507. Collins, *supra* note 5, at 3.

508. *Id.* at 1.

509. RICH MCMANUS, NCATS HOLDS FIRST ALL-STAFF MEETING, OTHERS EXPECTED, NIH RECORD 1, 6 (2012), *available at* http://nihrecord.od.nih.gov/pdfs/2012/03032012_Record.pdf.

development of the Million Veteran Program.[510] By 2012, Hudson was taking on new duties as acting deputy director of NCATS.[511]

NCATS also deals with common concerns regarding the proper allocation of risk in biomedical research—although it focuses more on questions of commercial risk than personal.[512] Logically building on these earlier initiatives, it constitutes a model for how best to handle the information produced through recruitment and research in order to create actual marketable biomedical products.[513] In this regard, it provides a critical bookend to Emanuel et al.'s privatization of citizenship by similarly placing the public resources of the NIH's infrastructure of publicly supported research at the disposal of private corporate entities—all in the name of serving the public good of improved health.[514]

For fiscal year 2012, NCATS received $576,456,000 in funding, with the bulk going to support the ongoing Clinical and Translational Sciences Awards program, which supports a consortium of medical research institutions working to improve the way clinical and translational research is conducted nationwide.[515] Other key NCATS initiatives include working with the Defense Advanced Research Projects Agency and the FDA to develop chips to mimic how humans respond to drugs so as better to predict drug safety and efficacy; working with industry to provide academic investigators and small businesses with the funding and information they need to investigate new uses for compounds from industry-provided drug collections; and working with the Environmental Protection Agency to screen environmental chemicals and drugs for toxicity.[516]

Calls to create and fund NCATS consistently invoked the need to overcome bottlenecks in the drug development pipeline

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510. *Deputy Directors*, NAT'L INSTS. HEALTH, http://www.nih.gov/about/almanac/historical/deputy_directors.htm#hudson (last visited Feb. 10, 2014).

511. MCMANUS, *supra* note 509, at 6.

512. Collins, *supra* note 5, at 2.

513. *Id.*

514. *Id. See generally* Emanuel et al., *supra* note 215 (putting publicly supported research at the disposal of private corporate entities).

515. *Budget Archive*, NAT'L CENTER FOR ADVANCING TRANSLATIONAL SCI., http://www.ncats.nih.gov/about/budget/archive.html#fy2012 (last visited Apr. 28, 2014).

516. Collins, *supra* note 5, at 2–3.

by "de-risking" early stage research on potential drug compounds.[517] Thus, for example, in 2012 testimony before Congress seeking appropriations for the coming year, NCATS's first acting director Thomas Insel noted that "NCATS will focus on addressing scientific and technical challenges in order to reduce, remove, or bypass significant hurdles across the continuum of translational research;" and went on to assert that "[k]ey to the success of the NCATS mission is identifying, studying, and reducing significant bottlenecks in the process of translation."[518] In 2011, during the run up to creating NCATS, Francis Collins emphasized the need for public intervention to address "a downturn in the number of approved new molecular entities over the last few years," noting that "drug development research remains very expensive and the failure rate is extremely high."[519] Collins here paired the bottleneck in the drug development pipeline with the idea that such activity is highly risky, causing pharmaceutical companies to cut back on research and development.[520] "So we have this paradox," Collins asserted, "we have a great opportunity to develop truly new therapeutic approaches, but are undergoing a real constriction of the pipeline."[521] One solution to the paradox, he concluded, was creating NCATS to help foster drug development.[522]

In reaching this conclusion, Collins argued that "[w]e can't count on the biotech community to step in and fill that void [in research and development] . . . because they are hurting from an absence of long-term venture capital support."[523] Elsewhere he stated that an

> array of new opportunities should portend a revolution in therapeutics discovery. . . . [However,] the potential utility of most of the newly discovered molecular targets will not be easy to validate. Even worse, the serious challenges that currently

517. *Id.* at 5.

518. THOMAS INSEL, NAT'L INSTS. OF HEALTH, DEP'T OF HEALTH & HUMAN SERVS., FISCAL YEAR 2013 BUDGET REQUEST 1 (2012), *available at* http://www.ncats.nih.gov/files/FY13-NCATS-Opening-Statement.pdf.

519. Asher Mullard, *An Audience with Francis Collins*, 10 NATURE REV. DRUG DISCOVERY 14, 14 (2011).

520. *Id.*

521. *Id.*

522. *Id.*

523. *Id.*

> confront the private sector may make it difficult to capitalize on these new opportunities.[524]

For Collins, then, market failure in the pharmaceutical industry implicitly created the essential preconditions for NCATS.[525] In 2011, Garret FitzGerald, McNeill Professor of Translational Medicine and Therapeutics at the University of Pennsylvania, echoed Collins's attention to commercial problems as creating a space for NCATS when he noted that at a recent conference "industry representatives pointed out that drugs in development are often deprioritized for reasons other than toxicities, especially in this era of repeated mergers."[526] He followed this identification of how non-scientific ("other than toxicities") market forces ("mergers") might be impeding research and development with a discussion of how NCATS would be able to "foster industry-academia interactions" by "de-risking" approved compounds and pushing to expand a "precompetitive space" to foster translational medicine.[527]

These schemes present the fundamental causes of the drug development bottleneck as economic, not scientific. This comports well with Collins's ongoing promotion of the great potential of genomics to meet important human needs.[528] A January 2011 article on NCATS in the *New York Times* noted that "Dr. Collins has been predicting for years that gene sequencing will lead to a vast array of new treatments, but years of effort and tens of billions of dollars in financing by drug makers in gene-related research has largely been a bust."[529] Collins responded by saying he was "frustrated to see how many of the discoveries that do look as though they have therapeutic implications are waiting for the pharmaceutical industry to follow through with them."[530] In his various comments, Collins thus located the failure to realize the early potential of the HGP with industry, not science.[531] Moreover, he emphasized this same commercial failure so as to create the space for NCATS to intervene into provinces hitherto occupied

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524. Collins, *supra* note 5, at 2.

525. *Id.* at 5.

526. Garret A. FitzGerald, *NCATS Purrs: Emerging Signs of Form and Function*, SCI. TRANSLATIONAL MED., May 18, 2011, at 1, 2.

527. *Id.* at 2.

528. Collins, *supra* note 5, at 2.

529. Harris, *supra* note 503.

530. *Id.* (internal quotation marks omitted).

531. *Id.*

by industry—early stage drug development.[532] Even in the face of a historical failure to realize the initial *promise* of the HGP, Collins still invoked the *potential* for science to develop new therapeutic interventions to drive the creation of NCATS.[533] Collins cast science as the realm of continued potential, demanding more support to be actualized, while he laid the unfulfilled promises of the HGP at the feet of market failure.[534]

The failures Collins refers to characterize a space that has come to be known as the "valley of death" between research discoveries and medical treatments.[535] NCATS's advocates argue that it will provide a "bridge" over this valley by conducting early stage research that is too risky for private industry and developing candidate compounds to the point where a corporation might step in to license the compound and bring it forward for more advanced stage clinical trials.[536] Dr. Jon Reed, CEO of the Sanford-Burnham Medical Research Institute in La Jolla, cast NCATS as "just the shot in the arm basic research needs to reach forward across that valley."[537] The basic idea here is that risk-induced market failure has led to a bottleneck that has created a valley that needs to be bridged.[538] There are really two distinct valleys that need to be bridged here.[539] The first is one of translational science—getting early stage research on potential drugs into late-stage clinical trials.[540] The second is corporate—getting pharmaceutical companies interested in investing the funds necessary to take the drugs across that first bridge.[541]

The corporate valley of death demands public investment and a socialization of economic risk to be bridged.[542] This

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532. *Id.*
533. *Id.*
534. *Id.*
535. Lili M. Portilla et al., *Advancing Translational Research Collaborations*, SCI. TRANSLATIONAL MED., Dec. 22, 2010, at 1.
536. *Id.*
537. John C. Reed, *NCATS Could Mitigate Pharma Valley of Death*, GENETIC ENGINEERING & BIOTECHNOLOGY NEWS (Feb. 1, 2013), http://www.genengnews.com/gen-articles/ncats-could-mitigate-pharma-valley-of-death/3662/.
538. *Id.*
539. *Id.*
540. *Id.*
541. *Id.*
542. *Id.*

layering of obstacles to be overcome sets the stage for allocating massive public resources (i.e., NCATS) to be put at the service of private enterprise (primarily pharmaceutical companies) in the name of serving the greater good (improved health).[543] Hence we have Collins responding to concerns about "whether it is appropriate for taxpayer dollars to facilitate the success of commercial enterprise," by asserting that "medical advances that benefit the public generally arise from NIH-funded biomedical research only if actual products are developed and brought to market—and partnerships with the private sector are essential for this translation to succeed."[544] Or, as he put it in testifying before a Senate subcommittee on appropriations, "NCATS will benefit all stakeholders, including academia, biotechnology firms, pharmaceutical companies, the FDA, and—most importantly—patients and their families."[545] Collins thus presents NCATS as a win-win, non-zero sum investment that deserves, indeed demands, public investment because the ultimate beneficiary will be the public itself. *His call to place the public resources of scientific research at the disposal of private enterprise provides an institutional counterpart to Emanuel et al.'s call to place the public resource of citizens' bodies similarly at the disposal of private enterprise—all for the greater good.*

### A. DELINEATING THE PRECOMPETITIVE SPACE

Collins and Thomas Insel took great pains to emphasize that NCATS was not a government-sponsored drug company and that its activities would complement, not compete with, other drug development efforts.[546] "As with sequencing of the human genome," Collins asserted, "many of the most crucial challenges confronting translational science today are precompetitive ones."[547] The particular risks NCATS means to manage are those populating the precompetitive space where state intervention may ease the concerns of apprehensive

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543. *Id.*

544. Collins, *supra* note 5, at 5.

545. *Education Appropriations Hearing of NIH FY 2012 Budget Request: Hearing on S. 1599 Before the S. Comm. on Appropriations*, 112th Cong. 1 (2011) (testimony of Francis Collins before the Senate Subcommittee on Labor).

546. *See* INSEL, *supra* note 518; Collins, *supra* note 5, at 5.

547. Collins, *supra* note 5, at 2.

corporations wary of investing their own resources in uncertain endeavors.[548] This space is one of commercial promise and therapeutic potential but also one of risk and danger.[549] Here, the risks to be managed are primarily economic, as manifest in the high failure rate for candidate drug compounds and the great expense of drug development.[550] These risks are cast as barriers to realizing the potential of drug development. The barrier, however, is not the failure rate; it is the reluctance of private capital to invest in early stage research.

Collins characterized NCATS's mission as to "identify opportunities for precompetitive innovation that are not currently being supported by academic or industry initiatives."[551] He went on to list such areas as including virtual drug design, preclinical toxicology, biomarkers, efficacy testing, phase zero clinical trials, rescuing and repurposing drugs, clinical trial design, and "postmarketing" research.[552] A 2010 Institute of Medicine (IOM) workshop on precompetitive collaboration identified key players in the space as including "academic and industry scientists, government entities, foundations, and patient advocacy groups, or the public at large;"[553] certainly, a rather broad pool from which to draw. The resulting 2011 IOM report on the workshop, *Establishing Precompetitive Collaborations to Stimulate Genomics-Driven Product Development,* identified the precompetitive space as one where partnerships may "distribute the risks involved in research and development."[554] For Collins, many challenges to genomic progress are precompetitive.[555] For the IOM, the precompetitive space is where relevant risks can be managed.[556] Both views implicitly contrast the competitive

548. *Id.*

549. *Id.*

550. *Id.* (detailing the "economic stresses and patent expirations" that plague pharmaceutical companies).

551. *Id.* at 3.

552. *Id.*

553. Jill S. Altshuler et al., *Opening Up to Precompetitive Collaboration*, SCI. TRANSLATIONAL MED., Oct. 6, 2010, at 1.

554. STEVE OLSON & ADAM C. BERGER, ESTABLISHING PRECOMPETITIVE COLLABORATIONS TO STIMULATE GENOMICS-DRIVEN PRODUCT DEVELOPMENT: WORKSHOP SUMMARY 2 (2011), *available at* http://www.nap.edu/catalog.php?record_id=13015.

555. Collins, *supra* note 5, at 2–3.

556. OLSON & BERGER, *supra* note 554, at 2.

arena of the market as one that increases risk or impedes productive risk management.

Precisely what constitutes this precompetitive space, however, is contested and varies depending upon the party asked to define it. Those using the term generally imply it is somehow a safe space, a sort of commercial demilitarized zone where information may be shared without threat of losing some sort of edge in developing marketable products down the line.[557] Nonetheless, participants at the IOM workshop recognized that "[a] major challenge is defining the domain of precompetitive research,"[558] going on to note that the boundaries of precompetitive space may change over time and across domains, and concluding that "[t]he line may be drawn differently between academia, diagnostic companies, and pharmaceutical companies."[559] As Craig Lipset, head of clinical innovation within worldwide research and development at Pfizer, put it, "pre-competitive is in the eye of the beholder," because "what is pre-competitive to one stakeholder is likely a key revenue source, business opportunity, or competitive differentiator to another stakeholder."[560] In an article co-authored with Tania Bubela and E. Richard Gold, Garret FitzGerald added a temporal dimension to the precompetitive space, defining it as "the time during R&D in which there is collaboration but no competition."[561] Echoing Lipset, they went on to acknowledge that "the line between precompetitive and competitive research is in constant flux and has shown a tendency to move increasingly downstream toward clinical or therapeutic application up to and including proof of concept."[562] They then consider how different actors, with different stakes, may have different conceptions of the precompetitive space.[563] Small biotechnology companies, for example, may have an interest in expanding competitive space upstream to basic

557. *Id.*

558. *Id.* at 13.

559. *Id.* at 14.

560. Craig Lipset, *Consortia—Pre-Competitive Is in the Eye of the Beholder*, PHARMASHERPA (Dec. 17, 2008), http://www.pharmasherpa.com/2008/12/consortia-pre-competitive-is-in-eye-of.html.

561. Tania Bubela et al., *Recalibrating Intellectual Property Rights to Enhance Translational Research Collaborations*, SCI. TRANSLATIONAL MED., Feb. 22, 2012, at 3.

562. *Id.*

563. *Id.* at 3–4.

proofs of concept which may form the basis for patents that are central to their business models.[564] Allowing such a free upstream extension of patent rights, however, may deter downstream innovation by larger companies and unnecessarily add to the overall cost of drug development.[565]

What this often seems to come down to are legal questions of intellectual property (IP). Simply stated, a precompetitive space appears to be a space where patents cannot, or should not go.[566] As Collins put it, the precompetitive space is one "in which intellectual property claims are expected to be limited."[567] A 2010 Wellcome Trust report on "Precompetitive Drug Boundaries" emphasized that "there needs to be more research conducted in an IP-free environment and more flexibility with existing IP by both academia and industry."[568] Similarly, the 2011 IOM Report, asserted that, "numerous issues such as intellectual property (IP) protections and funding can be cumbersome or completely inhibitory to establishing collaborative ventures and must be overcome to facilitate this process and realize the potentially immense benefits."[569] Prominent among the key points raised by speakers at the IOM workshop was that "[e]stablishing IP-free zones would open new areas of R&D to precompetitive collaboration."[570] Here the IOM cast IP not only as obstructing collaboration, but as inhibiting the construction of a precompetitive space itself.[571]

Bubela, FitzGerald, and Gold argue that when IP rights intrude into precompetitive space, where most discovery has little or no commercial value, they act as "a real drag on the innovation system" by keeping "competitively focused actors—most often small biotechnology companies—alive despite the

564. *Id.* at 4.

565. *Id.*

566. OLSON & BERGER, *supra* note 554, at 49–50 (discussing IP-free zones as one potential solution to precompetition problems).

567. Collins, *supra* note 5, at 5.

568. WELLCOME TRUST, PRECOMPETITIVE DRUG BOUNDARIES: OPEN INNOVATION IN DRUG DISCOVERY AND DEVELOPMENT 1 (2010), *available at* http://www.wellcome.ac.uk/stellent/groups/corporatesite/@policy_communications/documents/web_document/wtvm050558.pdf.

569. OLSON & BERGER, *supra* note 554, at 2.

570. *Id.* at 49.

571. *Id.* at 49–50.

inefficiencies of doing so."[572] In this scheme, precompetitive space is a place where IP may do more harm than good. It is therefore a normative space—a place where patents *may* be able to go, but *should not* go because of the bad effect they have on innovation. This bad effect is due not to the existence of patents per se, but to their premature introduction into the stream of invention.[573] Ideally, patents are supposed to serve as an efficient spur to innovation, but in a precompetitive space patents are seen to inhibit efficiency.[574] The boundaries of precompetitive space are thus here defined in part by inverting the logic of patent law: patents are supposed to increase efficiency; therefore they should not be allowed to go where they undermine efficiency.[575] This is one way to define precompetitive space.

In the context of promoting NCATS, IP thus emerges as a new and distinctive barrier to realizing the potential of genomic medicine. Previous barriers to realizing this potential primarily involved human subjects: overcoming resistance to participation by gauging the attitudes of potential recruits,[576] inculcating a sense of duty to participate,[577] and reducing regulatory burdens of consent.[578] In the realm of translational science, the barriers are legal and commercial.[579] NCATS's advocates characterize it as an instrument to create a space where such impediments cannot enter.[580] In this hallowed space of translational research, public resources may also be "translated" into private profit by de-risking early stage research to the point where corporate enterprises might be interested in taking over the reins of further research and development.[581] This point of hand-off presents yet another

572. Bubela et al., *supra* note 561, at 3.

573. *Id.* at 4.

574. *Cf. id.* at 2 (describing how collaborations, which may involve patent sharing, use resources more efficiently when conducting research).

575. WELLCOME TRUST, *supra* note 568, at 5 ("Patenting stifles innovation.").

576. *See supra* Part I.

577. *See supra* Part III.

578. *See supra* Part VIII.

579. Bubela et al., *supra* note 561, at 1.

580. *Id.* at 3–4.

581. WELLCOME TRUST, *supra* note 568, at 5–6 (discussing public-private partnerships).

market to define the limits of the precompetitive space.[582] It also defines the point at which corporate interests effectively privatize public resources—both monetary and intellectual—first through IP rights and later through general commercial development and marketing.[583] More than this, it also marks the point at which the Emanuel et al.'s call to service effectively completes the privatization of citizenship—turning over the benefits of public participation in clinical research and biobanking to private interests.[584]

### B. THE ALCHEMY OF PRECOMPETITIVE SPACE

Though never explicitly discussed as such, the space occupied by human subjects recruitment and consent processes may also be characterized as precompetitive.[585] Though marketing techniques surely have been central to the discipline of recruitmentology, recruiters themselves generally take great pains to contain the scope and reach of market forces in the process.[586] This is especially true with respect to IP rights, the key to delimiting the precompetitive space.[587] Thus, while on occasion potential subjects may receive a modicum of compensation for their participation, they are almost never given an interest in the products derived from the information contained in their bodies.[588]

When it comes to NCATS, the notion of a precompetitive space provides an additional structuring metaphor to complement pipelines, bottlenecks, valleys, and bridges. Precompetitive space is presented as an arena where public and private, academia and industry, science and commerce can co-exist without conflict.[589] It is an alchemical arena of translation—most explicitly where basic research is translated into usable therapies, but it is also an arena where public

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582. *Id.*

583. *Id.*

584. *See supra* notes 253–56 and accompanying text.

585. Collins, *supra* note 5, at 3 (discussing experimenting with clinical trial design).

586. *Id.*

587. Bubela et al., *supra* note 561, at 3 ("[T]he economic impact of patents in the life sciences . . . have been hotly debated.").

588. The story of Henrietta Lacks is an early example of this practice. *See, e.g.*, SKLOOT, *supra* note 480.

589. Bubela et al., *supra* note 561, at 1.

resources are translated into private profits and where private risk is socialized into a public burden.[590]

Such concerns are prominent in a critique by Harvard Professors of Medicine and Public Health Jerry Avorn and Aaron Kesselheim of the assumptions underlying the creation of NCATS. In an article published in *Nature Medicine* titled *The NIH Translational Research Center Might Trade Public Risk for Private Reward*, they make clear their concerns that the model of de-risking research for industry places a double burden on taxpayers "who pay once for drug development and again for heavily marked-up products."[591] As they put it: "NCATS could require the public to absorb even more of the costs of risky basic biomedical research and then hand off the fruits of such investigation to manufacturers that have traditionally not been generous in sharing the profits from medications based on such discoveries."[592]

This amounts to a biomedical analogue of analyses of the 2008 financial crisis; arguing that providing bailouts to major financial interests amounted to socializing the risks of corporate speculation, while allowing those same corporations to privatize the profits underwritten by such state support.[593] De-risking, then, is not simply a means of spurring upstream research into potential drug candidates; it is also a means of transferring resources from public to private hands.[594] To a degree, the same can be said about the entire enterprise of recruiting participants for large-scale population studies. As

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590. *Id.* at 5.

591. Jerry Avorn & Aaron S. Kesselheim, *The NIH Translational Research Center Might Trade Public Risk for Private Reward*, 17 NATURE MED. 1176, 1176 (2011), *available at* http://www.nature.com/nm/journal/v17/n10/full/nm1011-1176.html.

592. *Id.*

593. *See, e.g.*, BAILOUTS: PUBLIC MONEY, PRIVATE PROFIT (Robert E. Wright ed., 2010); Nouriel Roubini, *Is Purchasing $700 Billion of Toxic Assets the Best Way to Recapitalize the Financial System? No! It Is Rather a Disgrace and Rip-Off Benefitting Only the Shareholders and Unsecured Creditors of Banks*, NOURIEL ROUBINI'S GLOBAL ECONOMONITOR (Sept. 28, 2008), http://www.economonitor.com/nouriel/2008/09/28/is-purchasing-700-billion-of-toxic-assets-the-best-way-to-recapitalize-the-financial-system-no-it-is-rather-a-disgrace-and-rip-off-benefitting-only-the-shareholders-and-unsecured-creditors-of-banks/.

594. *Cf.* FitzGerald, *supra* note 526, at 1 ("NIH did not plan to compete with the private sector but, rather, to facilitate its efforts in drug discovery and development.").

there may be latent potential value in unexamined molecular entities, so too may there be latent value in the information contained in unexamined individual bodies. Like NCATS, the call for a duty to participate in research facilitates the appropriation and transfer of the value inhering in public resources (in the form both of human bodies and in the very concept of citizenship itself) into private (corporate) hands. This is the inverse of what political scientist Jacob Hacker has called the "great risk shift," whereby an array of state sponsored social insurance programs—including health care—have been progressively dismantled and privatized, shifting the risks of ill-health, unemployment, and retirement upon isolated individuals and families.[595] Here, the state is creating new institutions, such as NCATS, to shift the risks of biomedical research from private corporations to the public.

Avorn and Kesselheim also question some of the basic assumptions driving the creation of NCATS.[596] They begin by noting that a disproportionate number of new products recently approved by the FDA (approximately two-thirds) are me-too drugs, members of an existing therapeutic class or else merely equivalent in efficacy to existing drugs already on the market.[597] They argue that this reality undermines "the assumption underlying NCATS . . . that many potential drug targets or compounds have been identified but are not being adequately exploited."[598] If this were the case, then creating NCATS to "pursue leads that drug companies or investors have overlooked or have chosen not to invest in" would make sense.[599] But, they ask: "Are there really many clinically promising compounds or targets that have been discovered but are languishing, neglected, in some laboratory—or that remain unexploited even though their properties are known?"[600] Beyond certain antibiotics, Avorn and Kesselheim are skeptical.[601]

B.H. Munos of the InnoThink Center for Research in Biomedical Innovation and W.W. Chin of Harvard Medical

595. HACKER, THE GREAT RISK SHIFT, *supra* note 14, at 6.
596. Avorn & Kesselheim, *supra* note 591, at 1176.
597. *Id.*
598. *Id.*
599. *Id.*
600. *Id.*
601. *Id.*

School upend Collins's discourse of risk by positing that drug companies need to take on *more*, not less risk, for the simple reason that reward correlates with risk.[602] They argue that much of the current contraction in the drug pipeline has its roots in "the adoption of a new research model that swept the industry in the mid-1990s" that directed inordinate amounts of research and development resources toward finding blockbuster drugs.[603] This model involved portfolio managers shunning risk in favor of pursuing a blockbuster drug development model that involved pursuing only "safe" incremental innovation.[604] As a result, "[w]here bold vision once ruled, cautious analytics now prevail."[605] They actually find the drug pipeline to be "gushing," but, like Avorn and Kesselheim, they find it producing marginal therapeutics that "struggle to rise above the standard of care or even placebo."[606] These safe drugs actually may be crowding the pipeline and diverting resources from more innovative approaches to drug development.[607]

To these critiques, Brandeis professor of biochemistry Gregory Petsko adds his belief that "the reason Collins is doing [NCATS] is that he is beset by people—in the U.S. Congress and from patient advocacy groups—who keep asking him, 'Where are all the cures you promised us?'"[608] For Petsko, NCATS is not simply about addressing a bottleneck in the drug development pipeline, it is Collins's latest attempt to maintain ongoing support for the successive promises made on behalf of genomic medicine going back two decades.[609] Echoing Avorn and Kesselheim, Petsko goes on to argue that problems underlying the slow-down in new drug approvals lie not in the risks of early stage research but in the recent "merger mania" among major pharmaceutical companies that has "often resulted in bloated entities that are so busy managing the

602. Munos & Chin, *supra* note 344, at 1.
603. *Id.*
604. *Id.*
605. *Id.* at 2.
606. *Id.*
607. *Id.*
608. Gregory A. Petsko, *Herding CATS*, SCI. TRANSLATIONAL MED., Aug. 24, 2011, at 1.
609. *Id.*

problems caused by the merger that they have forgotten how to make drugs."[610]

These critiques raise the question of whether lack of innovation is a symptom or a cause of the high risk of new drug development and the bottleneck in the pipeline. The lack of innovation indicated by the focus on profit-proven me-too drugs (e.g., the fifth statin or the twentieth beta-blocker)[611] may actually produce a higher level of risk for developing new therapeutics; this for the simple reason that the safe return on investment for a me-too drug makes the risks involved in pursuing a new, first-in-class drug appear relatively even greater.

Francis Collins and other supporters of NCATS tell a fairly straightforward story of how it will help promote innovation and ultimately serve the public good: the need arises from an identified slow-down in new drug development that is assumed to be grounded in a reluctance to engage in risky early stage research given the high cost of bringing a new therapeutic compound to the market;[612] NCATS can mobilize public resources to begin to analyze some of the literally thousands of untested molecular entities already stored in various public and private libraries and identify promising candidates for further development;[613] when NCATS initiatives develop evidence that a particular candidate shows concrete promise of becoming an effective therapeutic, then a drug company can step in and invest the funds to conduct the large-scale clinical trials needed to bring the drug to the FDA for approval.[614]

The critics tell a different story. For them, NCATS is part of a questionable attempt to address the wrong problem that is more likely to succeed in transferring massive public resources into private hands than it is to address any meaningful bottlenecks in new drug development.[615] They see industry's reluctance to engage in translational research as rooted in the

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610. *Id.* at 3.

611. Avorn & Kesselheim, *supra* note 591, at 1176 (finding that two-thirds of newly approved drugs in 2009–2010 were substantially similar to available treatments and that "we clearly need more and better innovation").

612. Collins, *supra* note 5, at 1–2.

613. Mullard, *supra* note 519, at 14.

614. Collins, *supra* note 5, at 2.

615. Petsko, *supra* note 608, at 3 ("Why should pharmaceutical companies increase their [research & development] spending if the government is putting its own money into solving the industry's problems?").

search for the quick and easy profits of me-too drugs, augmented by constraints imposed by recent structural changes in the corporate organization of the pharmaceutical industry that further inhibit innovation.[616]

Two recent studies, one concerning the productivity crisis in pharmaceutical research and development, the other examining preclinical cancer research, when viewed in relation to each other, raise additional questions about the logic underlying NCATS. The first article, authored by Fabio Pammolli, Laura Magazzini, and Massimo Riccaboni, argues that:

> [T]he decline in the productivity of pharmaceutical R&D cannot be fully explained by the forces of demand and competition, and we document an increasing focus of research activities in the development of selective drugs in complex research areas that are characterized by a low probability of success (POS). It seems that research efforts have been reoriented towards more difficult targets, while the number of options that can yield viable therapies has grown dramatically. Consequently, the cost of R&D of new drugs has risen.[617]

In particular, the authors note that "the increase in the number of R&D projects targeting specific cancers is the main driver behind the reorienting of the R&D effort during the past decade."[618] Their analysis shows these projects had the lowest of possibility of success of the range of classes examined; hence the decline in productivity.[619] The argument here is that the class of drugs being developed was centrally related to the rising rate of failure.

The second article, by C. Glenn Begley and Lee M. Ellis, examined the failure to translate basic cancer research into viable new therapies, noting that "clinical trials in oncology have the highest failure rate compared with other therapeutic areas."[620] At first, this would seem to comport nicely with the work of Pammolli et al., noting the very low possibility of

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616. *Id.*

617. Fabio Pammolli et al., *The Productivity Crisis in Pharmaceutical R&D*, 10 NATURE REV. DRUG DISCOVERY 428, 428 (2011), *available at* http://emoglen.law.columbia.edu/twiki/pub/LawNetSoc/BahradSokhansanjFirstPaper/10NatRevDrugDisc428_pharma_productivity_crisis_2011.pdf.

618. *Id.* at 433.

619. *Id.* at 436.

620. C. Glenn Begley & Lee M. Ellis, *Raise Standards for Preclinical Cancer Research*, 483 NATURE 531, 531 (2012).

success in cancer research and development.[621] Begley and Ellis, however, went beyond the statistics of rate of success to look at the underlying studies that drove the clinical trials. They found that the failure rate was not related to the "high-risk" nature of oncology research and development, but to the basic quality of the research itself.[622] They discussed a study conducted by Amgen (in which Begley participated) that tried to confirm published findings relating to oncology in fifty-three studies published in "landmark" journals (papers in top journals, from reputable labs).[623] Of the fifty-three papers, the Amgen study found only six (eleven percent) were replicated.[624] Begley and Ellis noted that "[i]n studies for which findings could be reproduced, authors had paid close attention to controls, reagents, investigator bias, and describing the complete data set. For results that could not be reproduced, however, data were not routinely analyzed by investigators blinded to the experimental versus control groups."[625] Moreover, the article goes on to note that its findings are consistent with those of a separate study conducted by Bayer HealthCare in Germany that found only about twenty-five percent of published preclinical studies could be validated to the point at which projects could continue.[626] "It was shocking," Begley told Reuters:

> These are the studies the pharmaceutical industry relies on to identify new targets for drug development. But if you're going to place a $1 million or $2 million or $5 million bet on an observation, you need to be sure it's true. As we tried to reproduce these papers we became convinced you can't take anything at face value.[627]

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621. *See* Pammolli et al., *supra* note 617, at 430 tbl.1 (noting that research and development projects focused on antineoplastic and immunomodulating agents, which are both forms of cancer treatment, had an average possibility of success of 1.80%).

622. Begley & Ellis, *supra* note 620, at 532.

623. *Id.*

624. *Id.*

625. *Id.*

626. *Id.*

627. Sharon Begley, *In Cancer Science, Many "Discoveries" Don't Hold Up*, REUTERS (Mar. 28, 2012), http://www.reuters.com/article/2012/03/28/us-science-cancer-idUSBRE82R12P20120328.

As the *Nature* editorial accompanying the article noted, "there are too many careless mistakes creeping into scientific papers—in our pages and elsewhere."[628]

When you connect the Begley and Ellis article to the one by Pammolli et al. you get a very different view of some possible reasons why the drug pipeline may be drying up. If, as Pammolli et al. show, pharmaceutical R&D is increasingly focused on developing cancer drugs and if, as the Amgen study shows, the overwhelming majority of studies driving the clinical trials underlying the development of new cancer drugs are flawed, then perhaps the "valley of death"[629] NCATS is seeking to bridge has not been caused by a lack of translational research but by fundamental problems in the way the basic research itself is being conducted. If this is the case, then the rationale for establishing NCATS must be called into question—or at the very least, reexamined in light of these findings.

Perhaps as significant as the findings of the Amgen study are what Begley and Ellis identify as possible causes of the problem. They note that the investigators studied "were all competent, well-meaning scientists who truly wanted to make advances in cancer research."[630] The problems they hypothesize were more structural and individual:

> To obtain funding**,** a job, promotion or tenure, researchers need a strong publication record, often including a first-authored high-impact publication. Journal editors, reviewers and grant-review committees often look for a scientific finding that is simple, clear and complete—a 'perfect' story. It is therefore tempting for investigators to submit selected data sets for publication, or even to massage data to fit the underlying hypothesis.[631]

Commenting on the Amgen study, Ken Kaitin, director of the Tufts Center for the Study of Drug Development, noted, "[i]f you can write it up and get it published you're not even thinking of reproducibility . . . . You make an observation and move on. There is no incentive to find out it was wrong."[632] Indeed, all the incentives work in the other

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628. *Editorial: Must Try Harder*, NATURE (Mar. 28, 2012), http://www.nature.com/nature/journal/v483/n7391/full/483509a.html.

629. Reed, *supra* note 537.

630. Begley & Ellis, *supra* note 620, at 532.

631. *Id.*

632. Begley, *supra* note 627.

direction—obtaining tenure, grant funding, or prestige all depends on high profile publications.[633]

In recent years, as biomedicine has become an idealized golden goose for many major research universities, additional incentives may be driving the premature publication of results that directly relate academic standing to commercialization of research. Most obvious in this regard has been the broad rise in patent applications streaming from research universities and the concomitant rise of industry-academia collaborations.[634] In an article in *Science Translational Medicine*, titled *Why University-Industry Partnerships Matter*, Anthony Boccanfuso lauds this development, noting that "some academic institutions have excelled at creating a supportive environment, and many more institutions are embracing this approach."[635] His model in this regard is Texas A&M, which "claims to be the first public university to officially consider technology commercialization in tenure and promotion decisions."[636] For "technology commercialization,"[637] one might just as easily read "translational research." Texas A&M, then, is engaged in precisely the type of effort NCATS aims to support.

Pammolli et al. identified a trend toward R&D investments in the high-risk, low probability of success area of cancer drugs.[638] Begley and Ellis identified shoddy cancer research that might be producing the low probability of success identified by Pammolli et al.[639] Begley and Ellis further identified some systemic problems incentivizing the production of such research, central among these being tenure, grants, and prestige, not to mention editorial preferences for neat "stories" of successful research.[640] Boccanfuso presents an additional incentive for publication at all costs by connecting

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633. *See* Begley & Ellis, *supra* note 620, at 533.

634. *See, e.g.*, SHELDON KRIMSKY, SCIENCE IN THE PRIVATE INTEREST 79–81 (2003); PHILLIP MIROWSKI, SCIENCE-MART: PRIVATIZING AMERICAN SCIENCE 144–52 (2011).

635. Anthony M. Boccanfuso, *Why University-Industry Partnerships Matter*, SCI. TRANSLATIONAL MED., Sept. 29, 2010, at 2.

636. *Id.*

637. *Id.*

638. Pammolli et al., *supra* note 617, at 437.

639. Begley & Ellis, *supra* note 620, at 532.

640. *Id.* at 533.

commercialization to tenure.[641] While he praises this development, it may be feeding precisely into the dynamic driving the systemic problems identified by Begley and Ellis.

NCATS embraces the translational approach of industry-academia collaboration discussed by Boccanfuso. It is premised on an idea that such collaboration will produce the research breakthroughs needed to replenish the anemic drug pipeline.[642] But given the findings of the Amgen study, NCATS may be targeting the wrong problem. If Begley and Ellis are correct, then NCATS, particularly when viewed in relation to initiatives such as those pursued by Texas A&M, may be feeding into the unhealthy dynamic that incentivized the production of so much shoddy cancer research in the first place. An uncritical promotion of translational research thus has the potential to exacerbate the very problem it is seeking to address.

For example, to the extent that research papers published in high profile journals (which themselves are often the subjects of patents) form a basis for technology commercialization, a dynamic of tenure review and potential profit provide a strong incentive for producing exactly the type of research that Begley and Ellis find to be so problematic.[643] Their critique shows up the false dream of trying to demarcate distinct and independent spheres of science and commerce in modern practice.

*While Collins and other boosters of unfettered biomedical potential may try to locate barriers to progress external to the scientific enterprise, (whether in corporate risk aversion, regulatory hurdles, or citizen reluctance to enroll in biobanks), in fact, these domains are inextricably interwoven, each shaping and creating the conditions under which they all develop*. Commercial considerations of drug development, in particular, may be directly shaping how scientific questions are being framed, pursued, and disseminated[644]—not simply in the heavy handed direct examples of suppression of problematic research

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641. Boccanfuso, *supra* note 635, at 2.

642. *See id.* at 1.

643. *See* Begley & Ellis, *supra* note 620, at 533 (arguing that "[t]he academic system and peer-review process tolerates and perhaps even inadvertently encourages" publishing "erroneous, selective or irreproducible data").

644. *Id.*

results documented in such notorious cases as Vioxx[645]—but in day-to-day scientific practice or the sort examined by Begley and Ellis.[646] More money, "de-risking" research, or creating a "precompetitive space" will not suffice to address this issue. An understanding of the interconnectedness of these domains and practices is essential to realizing the type of progress Collins and others envision for our collective biomedical future.

## X. CONCLUSION: *CUI BONO*? RISK, DUTY, AND POTENTIAL IN THE CIRCLE OF PHARMACEUTICAL LIFE

Francis Collins's interest in following up the HGP with a large-scale population study and his promotion of NCATS bookend this story. Throughout, Collins cast the major barriers to realizing the potential of genomic medicine as exterior to the scientific enterprise itself, residing in the domains of society, law, and the market.[647] As the sequencing of the first human genome did not in itself bring us to the promised land of genomic medicine, Collins and others identified bodies as the primary barrier to proceeding down this road of potential.[648] Science needed massive numbers of bodies enrolled in LPSs to get the information necessary to achieve genomic breakthroughs.[649] The barriers to recruitment were cast as social and legal. Prominent among social barriers were ignorance, fear, and inertia;[650] among legal barriers were regulatory oversight and informed consent.[651]

The GPPC town halls and surveys were designed to figure out ways to address popular ignorance and fear. Ignorance was to be addressed through education and outreach. Whatever fears were not addressed by education, GINA would resolve by

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645. *See, e.g.*, CARL ELLIOTT, WHITE COAT, BLACK HAT: ADVENTURES ON THE DARK SIDE OF MEDICINE 41–42, 103–07 (2010); Merril Goozner, *Conflicts of Interest in the Drug Industry's Relationship with the Government*, 35 HOFSTRA L. REV. 737, 743 (2006).

646. *See* Begley & Ellis, *supra* note 620, at 532.

647. Mullard, *supra* note 519, at 14.

648. Collins, *supra* note 36, at 475.

649. *Id.*

650. Emanuel et al., *supra* note 215, at 67; *Genetic Discrimination*, *supra* note 156.

651. Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, 76 Fed. Reg. 44,512, 44,512 (July 26, 2011) (to be codified at 21 C.F.R. pts. 50, 56); SACHRP Letter, *supra* note 459, at 30–31.

assuring potential recruits that their genetic information could not be used to discriminate against them.[652] Emanuel et al.'s call for a duty to participate aimed to overcome citizen inertia, providing a normative, if not formally legal, incentive to get new recruits in the door.[653] Revisions to the Common Rule were to serve, in part, to lessen and regularize the regulatory burdens of consenting recruits and providing ongoing oversight of the information derived from their participation.[654]

Once researchers had bodies to work on, promoters of NCATS located the barriers to fulfilling genomic potential in the realm of law and the market. Creating a precompetitive space where government and academic scientists could de-risk early stage research would compensate for market failures of the pharmaceutical industry that had created bottlenecks in the drug development pipeline.[655] In the enterprise of translational science, patents themselves could act as barriers to realizing potential if they were not kept in their proper place.[656] Central to the idea of the precompetititve space was delimiting an area where IP rights could or should not attach to innovation.[657]

NCATS is merely the most recent federally sponsored initiative intended to realize the full potential of genomic medicine. From the Human Genome Project itself, to the NIH/GPPC town halls, GINA, Emanuel et al.'s call for a duty to participate, the MVP, and revisions to the Common Rule, diverse federal actors centering primarily around the NIH have been making demands upon public resources—bodily, civic, intellectual, and monetary—in the name of serving a common good of better public health and well-being. Diverse critiques of NCATS and the broader privatization of science call upon us to recontextualize these initiatives, particularly as those promoting them have tended to elide the way in which they appropriate these myriad resources into the hands of private corporate interests. This appropriation may be accomplished fairly directly, as in NCATS's move to de-risk early stage

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652. WILLIAMS ET AL., *supra* note 65, at 14.

653. Emanuel et al., *supra* note 215, at 68–70 (aligning the civic duty to vote with the duty to participate in research).

654. Human Subjects Research Protections, 76 Fed. Reg. at 44,521–22.

655. *See* Collins, *supra* note 5, at 1.

656. *See* FitzGerald, *supra* note 526, at 2.

657. *See id.*

research for drug companies.[658] But it has also been accomplished more subtly through a manipulation of the very concepts of risk, duty, and barriers to realizing potential underlying these diverse initiatives. *There are, in short, two pipelines driving these initiatives: one is the explicitly defined pipeline for innovative therapeutics to improve health; the other is a tacit pipeline to privatize public resources (including citizenship itself) and to socialize risk for corporate interests.*

### A. ASYMMETRIES OF RISK

Tropes of risk run throughout this story, carrying different valences and implications depending on where they appear. Broadly speaking the story identifies three areas of risk on the road to realizing the potential of genomic medicine: Individual—harm to research subjects; Legal—primarily in the form of potential liability for harm to research subjects, but also as regulatory burdens and obstructive IP rights; and Commercial—as market failure and loss of return on investment. Significantly, these risks are generally cast as external to the scientific enterprise.[659] Except for the external critics of the NCATS model, there is very little discussion of any risks that might inhere within scientific practice itself. Rather, promoters of these diverse federal initiatives consistently locate the risks of failure in the purportedly distinct realms of society, law, and commerce. In doing so, they also mask the way risk-talk mediates between knowledge and power, in particular the ways in which even the most technologically framed assessments of risk in regulatory contexts invariably implicate value judgments about such matters as what counts as risk, how and by whom it is to be assessed, and by reference to what values its significance is to be gauged.[660]

Framing and addressing risk plays a central role in the recruitment of subjects to biobanks and other large-scale population studies. Recruiters articulate risk in recruitment in two distinct but overlapping registers. The first is exemplified by Francis Collins's initial call in 2003 for the development of

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658. *See* Collins, *supra* note 5, at 2.

659. *See* Reed, *supra* note 537 (describing how the initial drug development process is not undertaken by risk averse pharmaceutical companies).

660. *See, e.g.*, JASANOFF, *supra* note 15, at 134–35, 156–60.

LPSs without which the genomic enterprise may be jeopardized.[661] At a 2011 IOM workshop on "Public Engagement and Clinical Trials," Dr. Jeffrey Drazen, Editor-in-Chief of the *New England Journal of Medicine*, articulated this first concern in relation to a second type of risk to research subjects themselves, stating "that unless we can persuade more people to put themselves at risk, the rate at which we will be gathering knowledge will become smaller and smaller."[662] He acknowledges that "[p]rogress requires a population willing to put itself at risk,"[663] but implies that a failure of citizens to take such risks upon themselves itself constitutes a risk to biomedical progress that the IOM must address through such measures as public engagement.[664] The only way to reduce the risk to medical progress posed by low recruitment is to convince potential subjects to take a different type of risk upon themselves. This is not quite a risk shift, in that there are two distinct types of risks at issue here. It does illustrate, however, how different risks may be interrelated and made dependent upon one another.

In the realm of genomic research, Collins and others cast the primary risks to potential recruits as informational rather than bodily (as might be the case in, for example, pharmaceutical clinical trials).[665] The ANPRM for the Common Rule states that, "[s]ince there would be new mandatory standards for data security and information protection to address informational risks, only non-informational risks would be considered in determining the level of risk posed by research studies."[666] This presents informational risk as primarily a technical problem susceptible of management by improved data security standards. GINA similarly involves

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661. *See* Collins, *supra* note 36, at 475–77; *supra* notes 35–39 and accompanying text.

662. VICTORIA WEISFELD ET AL., PUBLIC ENGAGEMENT AND CLINICAL TRIALS: NEW MODELS AND DISRUPTIVE TECHNOLOGIES: WORKSHOP SUMMARY 3 (2011), *available at* http://www.nap.edu/catalog.php?record_id=13237 (internal quotation marks omitted).

663. *Id.*

664. *See id.*

665. *See, e.g.*, Emanuel & Menikoff, *supra* note 439, at 1146.

666. Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, 76 Fed. Reg. 44,512, 44,516 (July 26, 2011) (to be codified at 21 C.F.R. pts. 50, 56).

managing informational risk.[667] Its advocates presented it as a means to address the fears of potential recruits.[668] But many of these same advocates viewed those fears as minimal or irrational. For them, GINA's real purpose was less to manage information risks per se than, by so doing, to manage the underlying risk that a failure of recruitment would pose to medical progress.[669] This stands in stark contrast to how promoters of NCATS (often the same people) tend to treat corporate wariness of risky investment in early stage research as rational economic behavior that needs to be accommodated by providing public support for translational research.

Where GINA and related efforts at recruitment invoked risk in framing their aims and purpose, the Common Rule more directly engages the parameters of acceptable risk in human subjects research. The fundamental role of the IRBs established pursuant to the Common Rule is "to ensure that the risks have been minimized to the extent reasonably possible and that any remaining risks are justified by the benefits the study is likely to achieve."[670] This befits the Rule's emergence from the tradition that gave rise to both the Nuremberg Code and the Helsinki Declaration. Yet, the dominant theme of GINA and NCATS is "de-risking" aspects of research to promote participation and development. This imperative presents a possible challenge to the Common Rule.

While the *purpose* of the Common Rule is to minimize risk to human subjects, discussions of the need to *revise* it were informed by references to legal, regulatory, and commercial risk.[671] The ANPRM itself was framed by references to key concerns that the burdens of regulatory oversight were "not adequately calibrating the review process to the risk of research" and general "inefficiencies" in the process that inhibited both research and subsequent product development.[672] In commenting on the ANPRM to revise the

667. *See, e.g.*, *Genetic Discrimination*, *supra* note 156.

668. *See, e.g.*, *id.*

669. *See, e.g.*, Hudson, *supra* note 202, at 1146.

670. COLEMAN ET AL., *supra* note 418, at 245.

671. Emanuel & Menikoff, *supra* note 439, at 1145–48.

672. Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, 76 Fed. Reg. 44,512, 44,513 (July 26, 2011) (to be codified at 21 C.F.R. pts. 50, 56).

Common Rule, the Secretary's Advisory Committee on Human Research Protections attributed the long and legalistic nature of current standard consent forms to concerns "about minimizing the potential risk of adverse legal actions" and "regulatory oversight."[673] Managing these diverse types of risk can create tensions between the interests of the parties they threaten: research subjects, researchers, and institutions.

NCATS, of course, is suffused with the language of risk management. It exists to de-risk early stage research. Looking at the nature of the process more closely, however, we see that NCATS does not actually aim to make the scientific endeavor of research itself any less risky. That is, the development of cooperative endeavors in the precompetitive space does not aim to change how scientists proceed with the work of discovery, merely the external conditions under which discovery occurs. The risks NCATS seeks to manage are the legal and commercial risk that may be driving pharmaceutical corporations away from basic research.[674] Creating a precompetititve space is meant to reduce the threat posed by IP rights to the free flow of ideas among potential collaborators—patents can be risky things; and de-risking itself focuses on shifting the risk of commercial failure from private to public institutions. Such commercial risk, of course, is bound up with the risk of scientific failure, but it is not the same thing. The NCATS model does not manage the risk of scientific failure; it manages the commercial risk such failure poses to pharmaceutical companies. It is premised on drawing a clear line between commercial and scientific risk as operating independently of one another. This stands in stark contrast to the critiques by the likes of Munos and Chin who argue that risk aversion within scientific practice itself is a problem;[675] or the evidence brought to light by Begley and Pammolli challenging as problematic research strategies that focus on drug development in the class of cancer drugs, which have a high risk of failure;[676] or finally, the implication that commercial risk itself is shaping the way scientific risks are being conceptualized, framed, and addressed. Keeping science

673. SACHRP Letter, *supra* note 459, at 14–15.

674. *See* Collins, *supra* note 5, at 2.

675. Munos & Chin, *supra* note 344, at 2.

676. Begley & Ellis, *supra* note 620, at 532; Pammolli et al., *supra* note 617, at 431.

separate from law and commerce, however, allows advocates to more effectively make demands upon citizens and the state to realize its latent potential.

This regime of biomedical progress constructed a basic asymmetry in assignment of risks between individuals and corporations—just as there is with duties imposed. Great pains are taken to reduce or eliminate risks for corporations as a way of bringing them to the table of drug development. Risks to individuals, however, are managed by being cast largely as a technical function of information management. The work involved in creating a large-scale population study actually *produces* risks for individuals. To be sure, legal regimes such as GINA are intended to manage these new risks but the ANPRM also proposes ways for those risks, in effect, to exist for indeterminate amounts of time as research on biospecimens may be conducted into the indefinite future.[677]

### B. DUTIES WITHOUT RIGHTS

Citizen duties bracket the biomedical enterprise. At the front end, we have Emanuel et al.'s call for an obligation to participate in research in order to realize the potential of genomic medicine.[678] This participation provides the basis for developing new biomedical products and services. At the back end we have Rose and Novas's idea of a biological citizen with a duty to act as an informed consumer of these products and services.[679] Heath, Rapp, and Taussig's idea of genetic citizenship provides an alternative model of a more engaged and less atomized citizen, bound together by common concerns to make demands on government and industry.[680] This model, however, appears limited to more interest group-like, condition-specific activism, much like Epstein's notion of biopolitical citizenship.[681] The duties of the biological citizen as consumer embrace us all, along the lines of Childerhose's more coercive conception of genomic citizenship, where we are all deemed ultimately creatures of our genes with concomitant obligations to put our genetic information at the service of the public

677. Jessica Berg & Nicole Deming, *New Rules for Research with Human Participants?*, 41 HASTINGS CENTER REP. 10, 10 (2011).

678. Emanuel et al., *supra* note 215, at 68–70.

679. Rose & Novas, *supra* note 293, at 445–48.

680. Heath et al., *supra* note 290, at 159.

681. *See* EPSTEIN, *supra* note 292, at 282.

good.[682] We enter this cycle of pharmaceutical life with a duty to be consumed—to put our bodies at the disposal of biomedical research. We complete the cycle with a duty to consume the resulting products and services—thereby exercising proper care of ourselves. These duties effectively privatize citizenship, recasting service to the political community as a function of service to the corporate enterprise of biomedical research, development, and marketing.

Yet, unlike the traditional models of civic duty, there are no corresponding rights paired with these duties. In the conceptualization of biobanks, the GPPC and others simply did not entertain the idea that recruits might have an affirmative right of access to the data derived from their participation (as, for example, they have in the Estonian biobank referenced in the GPPC promotional materials).[683] At most, they conceived of subjects' rights as market-based goods to be bargained over as an incentive to recruitment. Similarly, in their call for a duty to participate in biomedical research, Emanuel et al. never posited a concomitant right of access to health care, nor has there been any articulation of a right of access on reasonable terms to the products developed by private corporations through the public support from NCATS.

Emanuel et al. invoked risk and potential in framing their call for an obligation to participate in medical research—the risk that failure to participate may jeopardize the ability to biomedicine to reach its full potential to serve the public good.[684] They argued that the fact that most of this research would be carried out by private corporations for private profit is not a problem because it all ultimately redounds to the public good in the form of improved health.[685] When considered in relation to the proposed revisions to the Common Rule and the creation of NCATS, the concept of a civic duty to help realize the potential of biomedical research becomes even more problematic. In the end, all these diverse initiatives serve primarily to appropriate and transfer public value into private hands. In this model, the public good of health exists only as

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682. *See* Childerhose, *supra* note 337, at 335–36.

683. *Cf.* R.E. Hewitt, *The European, Middle-eastern and African Society for Biopreservation and Biobanking (ESBB): Current Status and Plans for the Future*, 2 EPMA J. 189–90 (Supp. 2011).

684. Emanuel et al., *supra* note 215, at 68–69.

685. *Id.* at 68.

mediated through a market nexus controlled by private corporations. In the name of actualizing the latent potential of biomedical research, it imposes duties without rights and distributes risks asymmetrically and always to the benefit of corporate interests.

From biobanks to NCATS, powerful voices in the federal government and allied private entities are asking us to place a vast array of public resources, most notably our bodies, but also our shared public investment in biomedical research and development, in the service of private enterprise, all in the name of realizing the potential of genomic medicine. This potential may be real. Certainly, significant advances have been made over the past few decades. But the repeated promises made on behalf of achieving a biomedical millennium, where the blind shall see and the lame shall walk, also serve a political purpose of framing priorities and allocating resources in a manner that itself has the "potential," if you will, to transform long-held public understandings of civic commitment and community into privatized notions of citizenship that call upon us to place ourselves literally at the disposal of corporate interests.