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Pathways Across the Valley of Death: Novel Intellectual Property Strategies for Accelerated Drug Discovery

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INTRODUCTION

Most therapeutic interventions produced by pharmaceutical firms take the form of small molecule drugs,[1] which are mass produced at low marginal cost and ingested orally. Drug therapies typically work by affecting the activity of human proteins, known in the industry as targets,[2] that have been implicated in disease pathways. Thus far, medical science has identified safe and effective therapies for only a few hundred of the estimated 3000 protein targets in the human genome that are potentially susceptible to a drug.[3] Moreover, pharmaceutical firms have encountered major obstacles in producing fundamentally new small molecule drugs, especially those that work against new targets. According to one report, an average of only three drugs that act on novel targets have reached the market annually in recent years.[4]

This highly visible problem has attracted commentary in scholarly articles,[5]

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1. We use the term "small molecule" to distinguish that class of compounds that can alter the activity of DNA or proteins but are not themselves proteins, peptides, or nucleic acids.

2. Ideally, potential targets would include not only individual proteins but also protein-protein interactions. *See* Michelle R. Arkin & James A. Wells, *Small-Molecule Inhibitors of Protein-Protein Interactions: Progressing Towards the Dream*, 3 NATURE REVS. DRUG DISCOVERY 301 (2004).

3. Adrian Whitty & Gnanasambandam Kumaravel, *Between a Rock and a Hard Place?*, 2 NATURE CHEMICAL BIOLOGY 112, 112 (2006) (giving an estimate of about three hundred proteins); Andreas P. Russ & Stefan Lampel, *The Druggable Genome: An Update*, 10 DRUG DISCOVERY TODAY 1607 (2005). Under the definition used in this Article, susceptibility to a drug, or "druggability," is defined by whether the protein is capable of binding a chemical compound. This definition does not address the question of whether the binding will yield a result that is biologically useful.

4. *See* Brian P. Zambrowicz & Arthur T. Sands, *Knockouts Model the 100 Best-Selling Drugs—Will They Model the Next 100?*, 2 NATURE REVS. DRUG DISCOVERY 38, 39 (2003); *see also* U.S. GOV'T ACCOUNTABILITY OFFICE, NEW DRUG DEVELOPMENT: SCIENCE, BUSINESS, REGULATORY, AND INTELLECTUAL PROPERTY ISSUES CITED AS HAMPERING DRUG DEVELOPMENT EFFORTS 1 (2006) [hereinafter GAO REPORT], *available at* http://www.gao.gov/new.items/d0749.pdf (stating that FDA submissions for new chemical molecules have generally declined since 1995, even though industry research and development increased 147% in inflation-adjusted dollars between 1993 and 2004). New chemical molecules are drugs that differ fundamentally in structure from prior molecules. They are, therefore, the type of drugs that are most likely to be active against new targets (or show substantially increased efficacy against old targets).

5. *See, e.g.*, Iain M. Cockburn, *The Changing Structure of the Pharmaceutical Industry*, HEALTH AFF., Jan.-Feb. 2004, at 10, 11; Fredric J. Cohen, *Macrotrends in Pharmaceutical Innovation*, 4 NATURE REVS. DRUG DISCOVERY 78 (2005); Robert F. Service, *Surviving the Blockbuster Syndrome*, 203 SCIENCE 1796 (2004) (discussing low numbers of new chemical entities approved in

government white papers,[6] and the popular press.[7] Government agencies, such as the National Institutes of Health,[8] and industry insiders,[9] have also recognized that one of the most serious pitfalls involves the difficulty of moving across the so-called "valley of death" that separates upstream research on promising genes, proteins, and biological pathways from downstream drug candidates. For example, an upstream finding that a given protein is differentially expressed in individuals with a particular disease may suggest that the protein merits further investigation. However, much more work (especially medicinal chemistry) is necessary to determine how good a target the protein really is and whether a marketable drug candidate that affects the activity of the protein is likely to be developed.

As industry observers have noted, successfully translating upstream research into potential drugs will require experimentation with new models of research and development (R&D).[10] In this Article, we propose one such initiative: intensive, large-scale collaboration between academics, who possess unique skills in designing assays that can identify promising targets, and pharmaceutical firms that hold libraries of potentially useful small molecules as trade secrets, making them largely off limits to these same academic scientists.

As we discuss below, conventional patent-based strategies for commercialization of university research, of the type envisioned by statutes like the Bayh-Dole Act of 1980,[11] are unlikely to foster such intensive collaboration. Moreover, while R&D alliances between small biotechnology firms and large pharmaceutical companies can perhaps fill some of the collaboration gap, thus far these vertical alliances have not appreciably stimulated productivity in the area of small

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recent years).

6. *See, e.g.*, U.S. FOOD & DRUG ADMIN., INNOVATION OR STAGNATION: CHALLENGE AND OPPORTUNITY ON THE CRITICAL PATH TO NEW MEDICAL PRODUCTS (2004), *available at* http://www.fda.gov/oc/initiatives/criticalpath/whitepaper.pdf.

7. *See, e.g.*, *Billion Dollar Pills*, ECONOMIST, Jan. 27, 2007, at 69, 70 ("With its traditional approach, Big Pharma is not coming up with new drugs fast enough to fill its pipeline.").

8. *See, e.g.*, Christopher Austin et al., *NIH Molecular Libraries Initiative*, 306 SCIENCE 1138 (2004); *see also* GAO REPORT, *supra* note 4, at 40 (noting importance of "translational medicine" for addressing the drug discovery problem).

9. *See, e.g.*, Christopher A. Lipinski, *The Anti-Intellectual Effects of Intellectual Property*, 10 CURRENT OPINION IN CHEMICAL BIOLOGY 380 (2006).

10. *See, e.g.*, DataMonitor, Addressing Pharma's R&D Productivity Crisis: Technical and Strategic Initiatives To Improve Core Drug Discovery Capabilities, http://www.market-research-report.com/datamonitor/DMHC1960.htm (last visited Nov. 2, 2007) (noting that "[c]ompanies must fundamentally review R&D business models and exploit new strategies for re-establishing core drug discovery expertise").

11. Bayh-Dole Act of 1980, Pub. L. No. 96-517, 94 Stat. 3015 (codified as amended at 35 U.S.C. §§ 200-212 (2000)).

molecules.[12] To achieve the goal of inducing more well-trained "eyes" to search chemical space for useful molecules, we need a contract-based platform that makes these molecules broadly available to academic experts without compromising future patents.

The collaborative initiative we propose takes its inspiration from existing horizontal collaborations between pharmaceutical firms, which focus on identifying markers of drug safety and efficacy. However, our proposed effort aims to identify potential drugs that may someday reach the market and generate revenue. We therefore need to define ownership more deliberately than do current collaborations, which focus on information that is generally considered precompetitive at all stages. Although firms would not bring specific patents to the table ex ante (as they do, for example, in most vertical R&D alliances between smaller biotechnology firms and larger pharmaceutical companies),[13] future intellectual property rights would nonetheless be suitably allocated among collaborators.[14] Moreover, unlike existing horizontal collaborations that have focused on safety and efficacy issues, our proposed initiative would deliberately integrate academic scientists as a built-in vertical component.

We situate our proposal in the economic literature that has analyzed transaction costs and incomplete contracting in the context of inter-firm R&D alli-

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12. These alliances have been more successful in increasing productivity in the area of biological macromolecules (a class of specialty drugs known as "biologics") like proteins and large peptides. *See* Cockburn, *supra* note 5, at 12, 14; Service, *supra* note 5, at 1797-98. However, such biologics are expensive to develop and hence quite costly to patients (with prices ranging from thousands to hundreds of thousands of dollars for an annual supply). Moreover, the absence of a generic regime for biologics, *see infra* note 29, means that their prices do not decrease to any meaningful extent even after patents expire. *See, e.g.*, Geeta Anand, *As Costs Rise, New Medicines Face Pushback*, WALL ST. J., Sept. 18, 2007, at A1 (making these points and noting that spending on specialty drugs rose twenty-one percent in 2006, as contrasted with six percent for non-generic, non-specialty (i.e., small molecule) drugs); Geeta Anand, *Rx for an Industry: As Biotech Drug Prices Surge, U.S. Is Hunting for a Solution*, WALL ST. J., Dec. 28, 2005, at A1 [hereinafter Anand, *Rx for an Industry*] (noting that spending on specialty drugs represents twenty-five percent of national spending on biopharmaceuticals).

13. D. Gordon Smith, *The Exit Structure of Strategic Alliances*, 2005 U. ILL. L. REV. 303, 308 n.29 (noting that in a sample of 125 genomics alliances, 113 involved the licensing of intellectual property by smaller technology firms); *cf.* Josh Lerner & Robert P. Merges, *The Control of Technological Alliances: An Empirical Analysis of the Biotechnology Industry*, 46 J. INDUST. ECON. 125, 132 (1998) (noting that biotechnology firms with more intellectual property rights exercised more control over the alliance).

14. *See generally* OLIVER HART, FIRMS, CONTRACTS, AND FINANCIAL STRUCTURE 29-55 (1995) (discussing the importance of ex ante property rights allocation). Ex ante, the information at issue in our proposal is not patentable. Boilerplate patent law does not allow patents on biochemical inventions of unknown function. *See* Utility Examination Guidelines, 66 Fed. Reg. 1092, 1097-99 (Jan. 5, 2001).

ances.[15] The inter-firm alliance we propose would simultaneously redound to the financial benefit of the pharmaceutical industry and promote the interests of public sector researchers. Most importantly, under our scheme intellectual property would be used creatively to secure efficient pathways across the gap that separates upstream research from downstream products—a gap so economically perilous that it has earned the "valley of death" moniker.[16] If these arrangements generated a larger number of efficacious drugs, the public at large would become the ultimate beneficiary.

In Part I, we frame the problem and describe some alternative efforts, existing and proposed, to accelerate drug development. In Part II, we examine several new pharmaceutical industry collaborations that provide some precedent for our proposed collaboration. In Part III, we set out our proposed multi-firm collaboration model. Finally, in Part IV, we discuss the perspectives of various stakeholders (e.g., pharmaceutical companies, academic researchers, nonprofit funders), with a view toward finding common ground on which to develop the proposed public-private partnership. We also discuss the possibility of single firm public-private partnerships, which could represent a desirable option if a comparison of pharmaceutical firm libraries showed substantial overlap among

15. *See, e.g.*, Suzanne Majewski & Dean V. Williamson, *Incomplete Contracting and the Structure of R&D Joint Venture Contracts*, *in* INTELLECTUAL PROPERTY AND ENTREPRENEURSHIP 201 (Gary D. Libecap ed., 2004) (arguing that the allocation of property rights in innovation generated by R&D partners is an important part of contract design, particularly in patent sensitive industries like the biopharmaceutical industry); Rachelle Sampson, *The Cost of Misaligned Governance in R&D Alliances*, 20 J.L. ECON. & ORG. 484 (2004) (finding that alliance governance based on transaction cost arguments substantially improves collaborative benefits). The economic literature on incomplete contracting grows out of the literature on transaction cost economics (TCE). Both literatures emphasize the ex ante and ex post transaction cost challenges that managing uncertain future conditions poses for efficient contracting. Unlike the TCE literature, however, the property rights strand of the incomplete contracting literature tends to stress the role of ex ante property rights allocation. A related literature discusses how the availability of statutory intellectual property rights (typically patent rights) in modular information defines the boundaries of the firm and may also facilitate inter-firm market transactions. *See, e.g.*, ASHISH ARORA ET AL., MARKETS FOR TECHNOLOGY: THE ECONOMICS OF INNOVATION AND CORPORATE STRATEGY (2001); Ashish Arora & Robert P. Merges, *Specialized Supply Firms, Property Rights and Firm Boundaries*, 13 INDUS. & CORP. CHANGE 451 (2004); Dan L. Burk & Brett H. McDonnell, *The Goldilocks Hypothesis: Balancing Intellectual Property Rights at the Boundary of the Firm*, 2007 U. ILL. L. REV. 575. This literature is not as directly relevant to our proposal, as we do not purport to alter the statutory standards by which patent rights are granted or propose new statutory rights.

16. Although we focus here on translation of biological research into small molecule drugs, the term "valley of death" is widely used to describe difficulties of market translation across different fields of scientific endeavor. *See, e.g.*, COMM. ON ACCELERATING TECH TRANSITION, NAT'L RESEARCH COUNCIL, ACCELERATING TECHNOLOGY TRANSITION: BRIDGING THE VALLEY OF DEATH FOR MATERIALS AND PROCESSES IN DEFENSE SYSTEMS (2004).

them. We conclude by considering briefly antitrust concerns as well as the broader implications of the collaborative framework we construct for small molecule libraries.

I. FRAMING THE PROBLEM

Biomedical research in the pharmaceutical industry mainly focuses on small molecule chemical compounds. In contrast with proteins or other biologics, small molecule chemicals are usually mass produced at low marginal cost and are taken orally.[17] Many pharmaceutical firms own collections, or "libraries," of hundreds of thousands of small molecules that they have either synthesized internally or have purchased from outside vendors. Because the functional attributes of these molecules have not generally been studied in any depth, they typically do not meet even the relatively lax standards for patentability currently applied by the courts.[18] To protect their investment, firms impose a strict regime of trade secrecy.

In order to test the molecules for biological activity pertaining to disease processes, pharmaceutical firms must screen them against interesting proteins. The experimental protocol under which a target protein is screened is known as an assay. For the past few decades, pharmaceutical firms have been using high-throughput screening (HTS)[19] of small molecule libraries against assays containing target proteins to identify promising compounds that may lead to patentable drugs. HTS allows researchers to examine the interaction between the subject of the assay and all of the many thousands of small molecules housed in a single library in only a few hours, which vastly increases the scope of potentially useful information available to scientists. However, despite explosive growth in genomic and proteomic information about potential targets, and increasing levels of R&D spending,[20] results of the HTS approach have thus far been disappointing. As noted earlier, the production of drugs that work against new targets has been

17. The systemic bioavailability of small molecules tends to be greater as well. Depending on their construction, small molecules may simply diffuse through tissues, whereas proteins must be transported.

18. *See generally In re* Brana, 51 F.3d 1560, 1565-68 (Fed. Cir. 1995) (finding the patentability requirement of utility met where molecule in question had shown cancer-fighting properties in a mouse model).

19. *See* Konrad H. Bleicher et al., *Hit and Lead Generation: Beyond High-Throughput Screening*, 2 NATURE REVS. DRUG DISCOVERY 369 (2003); W. Patrick Walters & Mark Namchuk, *Designing Screens: How To Make Your Hits a Hit*, 2 NATURE REVS. DRUG DISCOVERY 259 (2003). The initial mechanical problem presented by high-throughput screening of thousands of chemical compounds was solved by the use of robotic devices. Current state-of-the-art scanners use robotics to test more than one million compounds per day against various assays. *See* Gretchen Vogel, *NIH Gears Up for Chemical Genomics*, 304 SCIENCE 1728 (2004).

20. *See* GAO REPORT, *supra* note 4.

particularly difficult.[21]

The pharmaceutical firms' failure to find new drugs has been accompanied by a significant decline in sales revenues on existing drugs. Large pharmaceutical firms have typically generated very high sales revenues (and profits) through patents on so-called blockbuster drugs that they can market to large population segments. Prominent examples of blockbuster drugs include cholesterol-lowering agents, anti-hypertensives, and antidepressants. But patents on many blockbusters are now expiring.[22] Moreover, insurers are becoming reluctant to pay high prices for so-called "me-too" drugs—new products that represent mere incremental improvements over existing molecules.[23] In order to maintain profitability, pharmaceutical firms must produce fundamentally new molecules that address new targets and thus represent substantial improvements over existing treatment.

A. The Dearth of Drugs Against New Targets

Although the genome is estimated to contain at least 3000 druggable targets, only a few hundred proteins are fully validated[24] in the sense that they are shown to be biologically interesting and also susceptible to regulation by metabolically accessible, non-toxic drugs. Despite the infusion of new information about possible targets, some pharmaceutical companies continue to focus on this group of a few hundred, already validated targets. While this strategy may indicate excessive risk-aversion, the fact that health insurance companies were once willing to

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21. *See supra* note 4 and accompanying text; *see also* Bleicher, *supra* note 19, at 370 ("[D]espite the massive growth in screening compound numbers over the past 15-20 years, no corresponding increase in successfully launched new chemical entities has resulted."). *See generally* U.S. FOOD & DRUG ADMIN., *supra* note 6.

22. *See* Adam Smith, *Generic Drug Flood Headed Our Way*, CNN MONEY, Aug. 3, 2005, http://money.cnn.com/2005/08/03/news/fortune500/generic/ (quoting drug industry analyst Andrew Forman of W.R. Hambrecht & Co. for the proposition that $100 billion worth of brand name drugs will lose patent protection between 2006 and 2010).

23. In 2005, sixty-eight percent of employers who provided insurance reported using tiered programs of co-payment to encourage the purchase of inexpensive pharmaceuticals (either generics or brand name drugs on which discounts had been negotiated). David Blumenthal, *Employer-Sponsored Insurance—Riding the Health Care Tiger*, 355 NEW ENG. J. MED. 195, 199 (2006). Historically, the market signals sent to pharmaceutical firms have been less than efficient. Not only have health care payers generally been reluctant to use cost-effectiveness analysis in determining coverage, but the information necessary for determining cost-effectiveness—a public good—has been undersupplied. Jerry Avorn, *Sending Pharma Better Signals*, 309 SCIENCE 669 (2005). However, this situation may be changing. *See id.* Moreover, at least in some cases, incremental improvements may not even be patentable. *See, e.g.*, Pfizer v. Apotex, 480 F.3d 1348 (Fed. Cir. 2007) (holding that a new salt form of an existing chemical compound was not patentable).

24. *See* Whitty & Kumaravel, *supra* note 3.

pay high prices for me-too drugs remains a factor. Validating new targets is also more risky and complex now than in the past. Many observers believe most of the "low hanging fruit"—that is, targets that can be readily modulated by well-tolerated, simple chemicals—has been found. This tendency to focus on a small number of known targets means that insufficient research has been undertaken on new targets.[25]

A number of discovery-oriented pharmaceutical firms continue to engage in target validation using in-house biological and chemical expertise. So do some small biotechnology firms. For the latter, patents on new targets can serve as the basis for both arms-length licensing and more vertically integrated R&D alliances with pharmaceutical firms. One empirical study indicates that biotechnology and pharmaceutical firms formed more than 1000 such two-firm alliances between 1993 and 2000.[26] Despite these alliances, which may be responsible for a growing pool of therapeutics that are biological macromolecules,[27] very few new small molecule drugs have emerged.[28] Given escalating health care expenditures, this dearth of cost-effective small molecules, which (unlike biologics) can be made at low marginal cost after relevant patents expire,[29] is particularly unfortunate.

Moreover, while biotechnology firms could previously use early stage patents to secure venture capital funding or form vertical alliances, such patents no longer guarantee either funding or an alliance. Industry analysts have recently emphasized the biomedical "funding gap" resulting from the increasing reluc-

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25. *See, e.g.*, Cockburn, *supra* note 5, at 12. It is theoretically possible that the low-hanging fruit that has already been found represents the sum total of biological targets on which research is justified as an economic matter. In other words, the costs of doing further research may exceed the health benefits achieved by any new drugs that might be found. There is little evidence to back this hypothesis, however.

26. Matthew J. Higgins, *The Allocation of Control Rights in Pharmaceutical Alliances* (Soc. Sci. Research Network, Working Paper No. 918980, 2006), *available at* http://ssrn.com/abstract=918980 (describing an empirical study using data from Recombinant Capital, a California-based biotechnology consulting firm). For a discussion of such licensing and alliance activity at one of its historical spikes (around 2000-2001) see Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry*, 16 BERKELEY TECH. L.J. 813, 815-18 (2001).

27. *See* Anand, *Rx for an Industry*, *supra* note 12 (noting the twenty-five percent market share now held by specialty drugs, primarily biologics).

28. *See* GAO REPORT, *supra* note 4.

29. Currently, there is no generic biologics regime. Moreover, even if a generic biologics regime were established, bioequivalence is likely to be harder to prove in the context of biologics than in the context of small molecules. In any given case, the FDA may require clinical trials to demonstrate comparable safety and efficacy. This will create a barrier to entry for generic competitors. *See* Henry Grabowski et al., *Entry and Competition in Generic Biologics*, 28 MANAGERIAL & DECISION ECON. 439 (2007).

tance of venture capital and pharmaceutical firms to invest far upstream.[30]

The failure of efforts to fill the small molecule pipeline may prove to be a transient phenomenon, particularly if the integration of information technology accelerates drug development efforts. However, despite optimistic predictions in the past,[31] information technology has not yet yielded significant efficiencies. This failure makes experimentation with supplementary approaches imperative.

Another candidate for undertaking financially risky target validation is academia. Indeed, a key economic argument for public funding of science is that the private sector will tend to undersupply research with uncertain commercial potential.[32] Even though it may need some assistance in identifying which targets are most likely to bind drug-like molecules, the academic sector generally possesses the combination of skills needed for assay development.[33] But most academics have lacked systematic access to high-throughput screening and to the small molecule libraries necessary for comprehensive target validation. Instead, academics who desire access to small molecules in a pharmaceutical firm's library must negotiate terms of access and the corresponding intellectual property considerations on an ad hoc basis. Knowledgeable observers have long suggested that the transaction costs associated with these individualized negotiations constitute a significant barrier.[34]

A recent survey of 414 academic scientists by John Walsh, Charlene Cho, and Wesley Cohen provides some evidence of the magnitude of these costs. In general, academic scientists report that negotiations between industry and academia concerning materials are likely to take longer, and cause more delay, than negotiations within academia: thirty-five percent of such negotiations require more than a month (as contrasted with twenty-one percent of negotiations with university suppliers) and sixteen percent of such negotiations result in a research delay of over one month (as contrasted with six percent of academic negotia-

30. *See, e.g.*, Arthur Klausner, *Mind the (Biomedical Funding) Gap*, 23 NATURE BIOTECHNOLOGY 1217 (2005) (tracking the history of funding for research, and noting the reluctance of venture capital firms to fund upstream biomedical ventures).

31 One of the authors of this Article previously made some optimistic predictions in this regard. Arti K. Rai, *The Information Revolution Reaches Pharmaceuticals: Balancing Innovation Incentives, Cost, and Access in the Post-Genomics Era*, 2001 U. ILL. L. REV. 173.

32. *See* Kenneth Arrow, *Economic Welfare and the Allocation of Resources for Invention*, *in* THE RATE AND DIRECTION OF INVENTIVE ACTIVITY 609 (Richard R. Nelson ed., 1962) (discussing problems of uncertainty, indivisibility, and lack of appropriability involved in the production of information).

33. *See* Adrian J. Ivinson, Letter to the Editor, *University Investment in Drug Discovery*, 310 SCIENCE 777 (2005) (contending that academics have been underutilized in drug research and discovery).

34. *See* Lipinski, *supra* note 9, at 382 (discussing individualized negotiations between principal investigators and pharmaceutical firms).

tions).[35] Where the material in question is a drug, the transaction becomes particularly arduous. All other factors being equal, an academic's request for a drug (whether from industry or from another academic) was *one-twelfth* as likely to be fulfilled as requests for other materials.[36]

Strains in academic-industry negotiations concerning drug-related materials should come as no surprise. Such negotiations would typically become an option only in cases where the firm's research on a drug compound had progressed to the point of disclosure through publication (and associated patenting).[37] Disclosure would serve to alert the academic researcher that a firm had discovered a promising compound. At that stage, much would be known about the drug compound, which would make the resulting transactions of relatively high value. The firm would probably demand significant compensation for transferring the drug. In fact, empirical data indicates that seventy percent of agreements involving the transfer of drugs to academics include reach-through rights on improvements.[38]

At some point, industry requests for reach-through rights in patented drugs may become routine. As matters currently stand, however, academics and university technology transfer officers remain uncertain about the appropriate use of such rights,[39] and their uncertainty can lead to impasse. The fact that seventy percent of agreements to transfer drugs to academics also include some restrictions on publication[40] no doubt exacerbates difficulties in negotiation.

Of course, information could flow in the opposite direction. Firms do monitor academic publications to determine whether researchers are working on promising targets. In some cases they successfully form partnerships with the academics in question.[41] But surmounting difficulties in negotiation across the

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35. John P. Walsh et al., *Where Excludability Matters: Material Versus Intellectual Property in Academic Biomedical Research*, 36 RESEARCH POLICY 1184, 1185-87 (2007).

36. *Id.* at 1190-91. When reporting this statistic, the authors do not control for whether the supplier is an academic or is in industry. Thus it is not possible to determine whether requests for drugs were less likely to be fulfilled by industry suppliers than academic suppliers.

37. *Cf.* Lipinski, *supra* note 9, at 381 (discussing circumstances where a firm refers to a compound in a peer reviewed publication). In order to preserve commercial value, the firm would presumably allow publications about the compound only after a relevant patent application had been filed.

38. Walsh et al., *supra* note 35, at 1193. A reach-through royalty is an industry term that refers to a royalty that extends beyond the licensed item to products made using the licensed item.

39. *See* Rebecca S. Eisenberg, *Bargaining Over the Transfer of Proprietary Research Tools*, *in* EXPANDING THE BOUNDARIES OF INTELLECTUAL PROPERTY 223 (Rochelle Cooper Dreyfuss et al. eds., 2001). It is also noteworthy that while academics often ignore patents on research materials and make the materials in-house if they have the ability to do so, drug patents represent a prominent exception. *See* Walsh et al., *supra* note 35, at 1192. In the case of drugs, *both* lack of in-house expertise and patents represent barriers to use. *Id.*

40. Walsh et al., *supra* note 35, at 1193.

41. Telephone Interview with Allen Roses, Senior Vice President of Pharmacogenetics,

academic-industry divide appears challenging in this context as well. In the survey by Walsh and his colleagues, academic respondents admitted to failing to fulfill thirty-one percent of requests for materials from industry (as contrasted with only six percent from other academics).[42]

B. Attempts To Bridge the Public-Private Divide

More standardized legal documentation is one obvious mechanism for reducing transaction costs in transfers of drug-related materials between the private sector and academics. In general, standardized contracts can produce positive externalities that reduce transaction costs for users,[43] and efforts in this direction could be helpful. However, because the transactions in question are likely to be of high value, full standardization will be difficult to achieve, or even affirmatively undesirable. Significant benefits may accrue from some level of customization. Moreover, the creation of standardized agreements represents a collective action problem.[44] Given the divergent perspectives of academia and the private sector, solving this problem may not be straightforward.[45]

Even if standardized agreements were successfully created and implemented, the universe of transactions would be limited to those circumstances in which significant work had already been carried out. Drug discovery might be accelerated, but only to a limited extent. To put the point another way, the problem is only partly one of transaction costs in instances where transactions might *currently* occur. More fundamentally, under the existing regime, insufficient numbers of transactions—specifically, screens of potentially interesting assays against large volumes of small molecules—occur in the first instance.

A more comprehensive response to the "valley of death" problem is the Molecular Libraries Initiative (MLI), undertaken by the National Institutes of Health (NIH) several years ago.[46] Although the purposes of the MLI go beyond target

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GlaxoSmithKline, in Research Triangle Park, N.C. (Apr. 18, 2006) [hereinafter Roses Interview] (discussing partnerships that firms sometimes form upon reading of interesting work by academic researchers).

42. Walsh et al., *supra* note 35, at 1191.

43. *See* Marcel Kahan & Michael Klausner, *Standardization and Innovation in Corporate Contracting (or "The Economics of Boilerplate")*, 83 VA. L. REV. 713, 720-30 (1997) (discussing learning benefits conferred on later users and "network benefits" conferred on contemporaneous users).

44. *Id.* at 736-40 (discussing "coordination" problems).

45. In some cases, implementation of standardized agreements can also represent a collective action problem. *See* Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 306 (2003) (discussing failure of collective action in university implementation of the standardized Uniform Biological Materials Transfer Agreement).

46. *See generally* Austin et al., *supra* note 8 (describing the background and goals of the MLI).

validation, one key goal is to use public funding to advance research on targets to a stage that would elicit industry interest. The MLI reflects NIH's recognition of three key technological changes: first, that recent research in genomics (e.g., the Human Genome Project) has produced many new potential drug targets; second, that enormous increases in high-throughput screening power make the screening of hundreds of thousands of molecules a day possible for academic centers; and third, that academic centers now have the capacity to efficiently synthesize large numbers of chemical molecules.[47]

The MLI has created a "Molecular Libraries Small Molecule Repository" at the San Francisco facilities of Discovery Partners International.[48] It has been paying, and will continue to pay, academic researchers with expertise in medicinal chemistry to generate molecules to populate this public domain repository.[49] Currently, the repository contains about 100,000 small molecules (some of which may duplicate molecules held in pharmaceutical firm libraries). This repository consists of four molecular classes: "specialty sets," including compounds with known biological activity, such as drugs and toxins; natural products; "targeted libraries" for specific, high-profile proteins; and diversity compounds.[50] Ten academic centers have received funding to use this repository to perform high-throughput screening on assays submitted by the research community.[51]

The assays pertinent to this effort encompass more than simply proteins that are potential drug targets.[52] As NIH recognizes, small molecules available in the public domain for all researchers are likely to be extremely valuable as research tools that will further basic understanding of biological pathways not necessarily related to direct drug development. Nevertheless, one of NIH's goals is to encourage target validation, so as to narrow the gap between academic outputs and commercial investment and produce more breakthrough drugs.[53]

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47. *See* Nat'l Insts. Health, Overview, Molecular Libraries and Imaging, http://nihroadmap.nih.gov/molecularlibraries/ (last visited Oct. 30, 2007). In addition to the MLI, various individual public institutions offer some HTS capability. For a list, see Solomon Nwaka & Alan Hudson, *Innovative Lead Discovery Strategies for Tropical Diseases*, 5 NATURE REVS. DRUG DISCOVERY 941, 947 (2006). However, the MLI is the most ambitious effort.

48. Molecular Libraries Initiative, General Information, http://mli.nih.gov/mlsmr/general-information (last visited Oct. 30, 2007).

49. *Id.*

50. NIH Molecular Libraries, A Roadmap Initiative, MLSMR Project, http://mlsmr.glpg.com/MLSMR_HomePage/identify.html (last visited Oct. 30, 2007). Targeted libraries include modulators of prominent protein families, such as proteases, kinases, ion channel proteins, and nuclear receptor sets. Diversity compounds include all other compounds. *Id.*

51. Nat'l Insts. Health, New Paradigm Will Help Identify Leads for Drug Discovery, http://www.nih.gov/news/pr/july2006/nhgri-24.htm (last visited Oct. 30, 2007).

52. Other assays will include "protein-protein interactions, splicing events, and diverse cellular and even organismal phenotypes." Austin et al., *supra* note 8, at 1139.

53. *Id.* at 1138 (noting goal of target validation).

In assessing the more directed goal of generating validated targets, it is important to recognize that the molecules in the public repository are likely to be of lower quality (in terms of target specificity, metabolic attributes, toxicity and other relevant features) than those held by pharmaceutical firms. Although academics and the public sector more generally are beginning to achieve some expertise in medicinal chemistry,[54] they still do not possess the level of expertise available in the pharmaceutical industry. This handicap may make the MLI target validation goal harder to attain. More comprehensive validation may await confirmation by a private firm's screening against a more "drug-like" molecule in its own library.

One might argue that private firms should be willing to undertake this additional work. Under the default rules of the Bayh-Dole Act of 1980 (which gave universities broad discretion to secure patents on federally funded research),[55] as well as NIH rules specific to the MLI program,[56] universities may patent targets or associated assays. Thus, following the conventional vision of Bayh-Dole,[57] a private firm might hedge the risk involved in this additional work by obtaining an exclusive license to the patented target or assay. However, given venture capitalists' current reluctance to invest in relatively early-stage patents,[58] these exclusive licenses may not suffice.

In any event, experimentation with another alternative—direct screening of academic assays against a pool of the small molecule libraries held by pharmaceutical firms—would eliminate some unnecessary intermediate work and could also reduce the transaction costs associated with licensing targets. To the extent that such a pool encompassed distinct contributions from several firms,[59] it might

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54. Thus, it appears that the NIH Chemical Genomics Center, which is part of the MLI, has identified three classes of molecules that might be useful in treating Gaucher's disease and is currently working on optimizing their activity and reducing toxicity. *See* Press Release, Nat'l Insts. Health, Novel Approach Targets an Inherited Disorder: NIH Chemical Genomics Center Jumpstarts Drug Development in Public Sector (July 23, 2007), *available at* http://www.genome.gov/2552214. In addition, according to Center director Chris Austin, the Center's specific use of quantitative high-throughput screening techniques, which allows chemical compounds to be tested at different concentrations, is likely to reduce false positives and false negatives. *Id.*

55. Bayh-Dole Act of 1980, Pub. L. No. 96-517, 94 Stat. 3015 (codified as amended at 35 U.S.C. §§ 200-212 (2000)).

56. *See* NIH MLSCN Project Team Position on Data Sharing and IP in the MLSCN Program (Oct. 15, 2005) (on file with authors).

57. *See, e.g.*, Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1698-99 (1996) (discussing motivations behind the Bayh-Dole Act); Arti K. Rai, *Regulating Scientific Research, Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77, 95-97 (1999).

58. *See supra* text accompanying notes 30.

59. For a discussion of questions regarding overlap in molecular library contents, see *infra* Section III.A.

contain considerably more molecules than the current group of 100,000 held in the public-domain repository.

In sum, the impasse in genomic science presents the following underlying characteristics. First, too few qualified researchers are able to use screening assays against the small molecule libraries held as trade secrets by discovery-oriented pharmaceutical firms.[60] In particular, academic scientists with the talent to design assays lack access to these libraries. Second, to the extent that the libraries held by individual, discovery-oriented pharmaceutical firms differ from each other, it would be advantageous for academics to conduct screening assays against a pool that contains portions of *all* the libraries held by discovery-oriented firms.[61]

If such a pool were created, it is unlikely that pharmaceutical firms would contribute molecules about which they already possessed significant information (let alone molecules they considered potential lead compounds). Even so, a pool that included some substantial subset of pharmaceutical firms' compounds—for example, "diversity" compounds about which little was known—could prove extremely useful.

II. MODELS FOR MULTI-FIRM, PUBLIC-PRIVATE COLLABORATION

As a supplement to current approaches such as the MLI and to possible future efforts, including standardized contracts, we suggest a novel, large-scale public-private model. This collaborative approach would draw upon some recent experimentation that pharmaceutical firms are already conducting in this area. Moreover, it would respond to the advice that analysts have been giving the pharmaceutical industry for years—that it must "fundamentally review [its] R&D business models."[62] In this Part, we describe inter-firm, public-private collaborations in the areas of safety and efficacy upon which our proposed approach would draw. Part III describes our proposed collaboration in detail.

A. Existing Collaborations on Toxicity and Efficacy

Until recently, pharmaceutical companies paid insufficient attention to optimizing particular characteristics of small molecules, such as toxicity and "pharmacokinetics" (i.e., absorption, diffusion, metabolism, and excretion), which are

60. Our research suggests that pharmaceutical firms may conduct fewer than one hundred screens per year against their whole library. *See* Roses Interview, *supra* note 41.

61. Molecule libraries held by firms that do not seek to discover new targets would be much less useful, as those libraries would primarily contain molecules that work against existing, already validated targets.

62. DataMonitor, *supra* note 10.

important for drug safety and efficacy in the human body.[63] For example, firms sometimes designated a "lead" compound, and assembled a full team around it, solely because the compound had shown significant activity (affinity and selectivity) in a high-throughput laboratory screen against an assay containing a target protein.[64] Thus, firms were making a substantial investment without any good information about how the body would respond to the potential drug. In recent years, analysts have recognized that the lack of early attention to pharmacokinetic and toxicity-related characteristics of proposed small molecules was a factor in the growing number of pipeline failures, including costly failures at late stages of clinical testing or even after FDA approval for commercial marketing.[65]

Pharmaceutical firms have worked diligently to address this problem. As an initial matter, they purged their libraries of molecules that are likely to be "grit"—for example, molecules that are non-selective inhibitors of many different targets or that have well-known pharmacokinetic or toxicological liabilities.[66] Firms are also enhancing the quality of their libraries with the help of specialized suppliers of small molecules. Moreover, prior to selecting lead compounds for optimization, pharmaceutical firms have been supplementing high-throughput screening with another stage of focused inquiry into properties necessary for safety and efficacy in the human body.[67]

The pharmaceutical industry is also advancing safety and efficacy goals by means of public-private collaborative partnerships. Specifically, in establishing at least two such consortia, firms have recognized that an optimal level of inquiry into safety or efficacy may require knowledge not contained within the boundaries of a single firm. To the extent that any participating pharmaceutical firm finds standard, early biological signs (also known as biomarkers) of drug toxicity or efficacy, all the other firms in the consortium could use this information for a variety of efficiency-enhancing functions.

For example, biomarkers might help to provide expedited preclinical drug safety evaluation as well as early indicators of clinical safety and efficacy.[68] They

63. *See* GAO REPORT, *supra* note 4, at 87 (finding that failure rates in human clinical trials based on lack of safety or efficacy were eighty-two percent in the 1996-99 period and ninety-one percent in the 2000-03 period).

64. Bleicher et al, *supra* note 19, at 370 ("It was not uncommon for a single [hit] compound to be considered a 'lead' structure.").

65. *Id.*

66. Telephone Interview with Allen Roses, Senior Vice President of Pharmacogenetics, GlaxoSmithKline, in Research Triangle Park, N.C. (Dec. 19, 2006) (on file with authors). *See also* Lipinski, *supra* note 9, at 381 (discussing the use of the Lipinski "rule of 5" to filter out compounds that are unlikely to be absorbed orally).

67. *See* Andrew L. Hopkins, Michael J. Witty & Solomon Nwaka, *Mission Possible*, 449 NATURE 166, 168 fig. (2007) (discussing steps such as cell-based or animal model testing).

68. *See, e.g.*, Toxicogenomic Cross-Validation Consortium Agreement § 2.1 (Jan. 20, 2006)

could also be used to troubleshoot compounds that fail preclinical drug safety testing.[69] Whenever the Food and Drug Administration approved a particular biomarker as a reliable indicator of safety or efficacy for a variety of drugs, it might become an industry standard around which all competing firms could converge. As the National Academy of Sciences noted in a recent report endorsing horizontal biomarker consortia, these "precompetitive projects (most likely unrelated to a particular drug) would be enabling to the field."[70]

In one recently formed collaboration, the Predictive Safety Testing Consortium (PSTC), all of the major pharmaceutical firms have committed to sharing internally-developed laboratory methods that predict the safety of new treatments.[71] They have also committed to performing validation experiments on laboratory methods developed by other consortium members.[72] As a result, under the PSTC, experts from multiple firms work on sequential phases of the same project to develop tests of drug safety.

The PSTC agreement relies heavily on a non-profit, trusted intermediary, Critical Path, of which the FDA is a founding member. Critical Path is responsible for consortium management. For example, it collects membership fees from pharmaceutical firm participants, coordinates the selection of research projects, and (with the assistance of an advisory committee composed of Critical Path and pharmaceutical firm representatives) manages the flow of any confidential information.[73] If the PSTC advisory committee deems it appropriate to seek patents on technology generated by the consortium, Critical Path will own the patent rights.[74]

(on file with authors) [hereinafter Consortium Agreement] (discussing the use of "safety biomarkers" for expediting preclinical and clinical drug development).

69. *See id.* § 2.1(c) (discussing such troubleshooting).

70. NAT'L ACAD. OF SCIS., CANCER BIOMARKERS: THE PROMISES AND CHALLENGES OF IMPROVING DETECTION AND TREATMENT 6 (2007), *available at* http://books.nap.edu/catalog/11892.html.

71. Consortium Agreement, *supra* note 68, § 3.2 (stating that members "must be willing and able to contribute one or more nominated exploratory Safety Biomarkers or other information or Materials for use in Consortium research activities"). Note that the Predictive Safety Testing Consortium was formerly known as the Toxicogenomic Cross-Validation Consortium.

72. *See id.* (stating that members must "perform validation work with respect to one or more Safety Biomarkers . . . and have the capability to cross-validate Safety Biomarkers").

73. *See id.* §§ 5.2, 6.1 (discussing various aspects of Critical Path's management role).

74. *See id.* § 8.2(a) (noting the role of the advisory committee in determining whether to pursue formal patent rights); *id.* § 8.2(b) (stating that "[e]ach Member performing any activities under a Research Project hereby assigns to C-Path all of such Member's right, title, and interest in and to any and all Consortium Technology"). The PSTC recently submitted twenty-three proposed biomarkers that could be used to identify kidney toxicity in preclinical animal testing. *See* Bernadette Toner, *Predictive Safety Testing Consortium Submits First Biomarkers to FDA for Qualification*, GENOME WEB DAILY NEWS, June 21, 2007, http://www.genomeweb.com/issues/news/140703-

While the PSTC focuses on tests for safety, the recently-formed Biomarkers Consortium aims to encompass research that identifies good biomarkers of both drug safety and efficacy.[75] Like the PSTC, the Biomarkers Consortium includes all of the major pharmaceutical firms, and it allows scientists at competing firms to contribute their expertise to the development of specific biomarkers. As with the PSTC, public sector agencies—most prominently the non-profit Foundation for the NIH, which manages public-private partnerships for NIH—play a major role in selecting research projects and in managing the flow of funding.[76]

Research on biomarkers will ultimately yield products, such as safety assays, that are beneficial to multiple pharmaceutical firms, but are unlikely to represent a core product for any firm. For this and other reasons, both of these consortia require ex ante commitments to relatively liberal licensing agreements for any intellectual property their common efforts may generate.

In the case of the PSTC, members agree that the objective of the consortium is to achieve "broad public dissemination of the results of the research and development projects conducted pursuant to this Agreement."[77] Patents are to be sought only in cases where the advisory committee determines that they would promote dissemination of discoveries.[78] Moreover, Critical Path is obligated to license any patents it may own to all comers on commercially reasonable terms.[79]

In contrast with the PSTC, the Biomarkers Consortium does not assign intellectual property rights to a trusted intermediary. Rather, inventorship is governed by the default rules of U.S. law, and ownership is defined by the policies of the inventor's employer.[80] Nonetheless, for all new data and inventions arising out of a particular project, all participants that have an ownership interest in the intellec-

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1.htm. It is unclear whether any patent rights have been sought.

75. Press Release, Foundation for the NIH, Public-Private Partnership Forms the Biomarkers Consortium To Advance the Science of Personalized Medicine (Oct. 5, 2006), *available at* http://www.fnih.org/news/TBC_Press_Release.shtml (noting that "the FDA can use biomarkers to determine whether drugs can safely and effectively treat disease"). The Biomarkers Consortium also plans to identify biomarkers for early disease detection. *See id.* That research goal is not directly relevant here.

76. *See* FOUND. FOR THE NIH, THE BIOMARKERS CONSORTIUM, TWO-PHASED PROJECT APPROVAL PROCESS: CONCEPT CLEARANCE AND PROJECT PLAN APPROVAL 3 (2006), *available at* http://test.fnih.org/Biomarkers%20Consortium/Project_Clearance.pdf (showing a flowchart that details responsibilities of the FNIH Board). While the PSTC funds its research projects from membership fees, the Biomarkers Consortium agreement requires the Foundation for the NIH to seek specific funding for each new project. *Id.*

77. Consortium Agreement, *supra* note 68, § 8.2(a).

78. *See id.*

79. *Id.* § 8.3(b).

80. FOUND. FOR THE NIH, THE BIOMARKERS CONSORTIUM, GENERAL INTELLECTUAL PROPERTY AND DATA SHARING PRINCIPLES 5 (2006), *available at* http://test.fnih.org/Biomarkers%20Consortium/IP_Policies.pdf.

tual property generated must grant to all other participants a "non-exclusive, remuneration-free license."[81]

B. Expanding the Collaborative Approach

The formation of collaborative horizontal partnerships to address safety and efficacy raises the question of whether other, somewhat analogous, but more ambitious forms of collaboration could successfully address problems of translation. Specifically, we ask whether large-scale collaboration might improve translation by the academic sector of large volumes of upstream biological information into "validated targets" and potential drug candidates that would be of interest to industry. Like safety and efficacy, translation arguably entails further improvement of relatively undifferentiated trade secret information held by multiple firms. This improvement process may be greatly enhanced through evaluation by multiple parties.

Like the PSTC and the Biomarkers Consortium, our proposed partnership would use a trusted intermediary to facilitate firm participation. Additionally, like the Biomarkers Consortium, it could use the lure of public funding to stimulate greater participation by the private sector. Unlike these other consortia, however, our partnership would produce outputs—potential drug candidates—that engender fierce inter-firm competition. Thus, while the PSTC does not link inventive contribution and ownership, our proposal would maintain a tight link between the two. Additionally, whereas the PSTC and the Biomarkers Consortium mandate relatively liberal licensing practices, our proposal would have no such mandate.

In our proposed partnership, the trusted intermediary would necessarily play a more vigorous role in handling confidential information. As discussed further in Part III, the intermediary would itself conduct the high-throughput screening of the pharmaceutical firms' molecules against assays contributed by academics. It would thus be the only party to the collaboration that possessed full knowledge of all of the assays and molecules that academics and pharmaceutical firms, respectively, had contributed.

By merging academic talent in assay design with the high-quality but underutilized research resource represented by the pharmaceutical firms' libraries, our proposed public-private partnership aims to help the parties traverse the valley of death that currently impedes research on drugs that address new targets. As contrasted with the alternative of complete vertical integration—for example, subsidizing discovery-oriented pharmaceutical firms to hire academics with assay design skills—the public-private partnership we envision would allow assay designers access not simply to one firm's library but instead to a larger, pooled library consisting of small molecule collections that a number of firms had contributed. Unlike complete vertical integration, a public-private collaboration

81. *Id.*

would not require academics to change career paths, which would make it more likely to succeed. Pharmaceutical companies contributing portions of their libraries might still be subsidized to the extent that the trusted intermediary consented, at least initially, to bear some of the costs associated with establishing the pool and of providing academic researchers relevant grants.

Pharmaceutical firms that contributed compounds to the pool would profit directly from any commercial drug that emerged from molecules they contributed. As we discuss in Part III, ordinary patent rules would deliver this result. Additionally, participating firms might find it in their interest to allow those who contributed molecules to the pool to receive a small share of the patentee's profits when one or more of their molecules fell within a subset of initially promising molecules identified by the screening process. In the latter instance, profit would be derived from a predetermined royalty stream to the contributing firms under an automatic license, as discussed in Section III.B below.

III. THE PROPOSED MULTI-FIRM PARTNERSHIP

In this Part, we outline the institutional framework and intellectual property strategies that could help stakeholders in both the private and public sectors to make better and more productive use of the aggregate stock of small molecules available for high-throughput screening. These proposals attempt to bridge the gap between patents and the public domain, which is currently regulated only by the application of trade secret law (or actual secrecy), to the private sector's large hoards of small molecules.

The ultimate objectives of our approach are to:

1) Create a research regime in which qualified public-sector participants explore a larger and higher quality pool of molecules than is currently possible.

2) Design a contractually-constructed framework in which publicly funded university research could identify potential lead compounds without compromising patents on those compounds.

3) Administer this voluntarily-adopted framework within a public-private partnership that would more effectively translate upstream research into truly innovative therapeutic advances, thereby contributing to overall public health.

A. The Threshold Question of Overlap

An initial question regarding pool formation concerns possible overlap among molecules that participating firms may contribute. If, for example, it turned out that molecules contributed by different firms were substantially identical, then there would be little reason to pool the molecules. In that case, a model of multiple public-private partnerships, each built around contracts with a single firm, would become preferable. This alternative model is discussed in Section III.F below.

Because libraries are held by firms as trade secrets, the amount of overlap among them is currently unknown. More important for present purposes, it is unclear whether the molecules *actually selected and contributed* by participating firms would overlap. Even if we postulate that most firms would contribute so-called "diversity" molecules (because these were the molecules about which they had little specific information), the extent of overlap between the various firms' diversity molecules remains unknown. A trusted intermediary accordingly would need access to structural data on a confidential basis in order to determine the degree of overlap. It could then release this information (in suitably anonymized fashion) to participating firms.

For example, in a situation where three firms had contributed molecular libraries, the intermediary might reveal that, of the total number of molecules contributed, about twenty percent were duplicates owned by two firms and ten percent by three firms. At that point, the participating firms would determine whether the degree of overlap was sufficiently small to justify going forward. If the firms decided to proceed, the pooled molecules would already have been collated and any instances of duplication identified. This collation would, in turn, eliminate duplicative screening.

B. A Two-Tiered Regime

Central to our proposed multi-firm partnership is a two-tiered system. At Tier 1, both academic external researchers and the participating companies could be viewed as operating behind a "veil of ignorance."[82] Although the researcher might possess some information about a potentially interesting assay, and the participating companies might hold some basic information about the molecules they contributed, information on both sides would be relatively inchoate and pre-competitive in nature.

Equally important, only the trusted intermediary would know about the full set of assays and molecules existing at Tier 1. Individual academic researchers and contributing firms would remain unaware of contributions by any other parties. In contrast, research activities conducted at Tier 2, under the custom-made

82. *Cf.* JOHN RAWLS, A THEORY OF JUSTICE (1971).

contractual arrangements described below, would necessarily have moved beyond this veil of ignorance.

The trusted intermediary would host the pool and assume responsibilities for its day-to-day management and administration. The intermediary would also certify and perhaps fund the public-sector academics allowed to explore the molecules held in the pool. Additional financial guarantees from participating universities might become necessary in order to assure pharmaceutical firms that contractual obligations regarding nondisclosure were respected.

1. Tier 1: Behind the Veil of Ignorance

At the first tier of the partnership, researchers in approved academic institutions (that is, institutions that had signed nondisclosure agreements and perhaps put up a bond to guard against misappropriation) would contribute assays. The trusted intermediary would then run these assays against the pooled collection of small molecules made available by participating firms. All molecules contributed to the pool would be tagged with a marker that tracked their corporate origin. The trusted intermediary would, however, code these markers so that researchers receiving information on "hits" resulting from high-throughput screening would not know the pharmaceutical firm owner of the molecules they were using.

Successful high-throughput screening of these molecules would likely identify a subset of molecules as "hits"—in other words, molecules that showed significant activity against the target in question and could lead to new drug candidates. The academic who contributed the assay would receive coded results showing levels of activity for the relevant molecules, and the firms would receive some information as well. This Tier 1 information would be released in a structured way, in order to best facilitate the formation of an academic-pharmaceutical partnership for further target validation and drug development.

Prior to being told that one or more of the molecules it had contributed represented a hit, the firm could withdraw a molecule at any point. In order to forestall opportunistic behavior, however, once the trusted intermediary informed the firm that one of its molecules represented a hit, that molecule could not be withdrawn. On the contrary, after a hit, the contributing firm would have an obligation to provide relevant structural information to the academic via the intermediary.[83] Standardized licenses governing first-tier access would forbid information disclosure or misappropriation.

For its part, the academic laboratory and associated university (communicat-

83. For purposes of collation and determining overlap, the firm would already have provided this structural information to the intermediary. As discussed further in the illustrative example below, *see infra* Section III.E, structural information is probably the primary information the firm would have. In particular, firms would be unlikely to contribute to the pool molecules about which they had significant positive information.

ing through the intermediary) would provide the firms that owned hit molecules with a general statement of the methodology used to develop its target. However, in order to maintain its bargaining position despite the absence of a patent,[84] the academic institution would not identify that target.[85] Therefore, at this point, the academic scientist would know the chemical structure of a number of compounds that showed activity against the target, while the pharmaceutical firm(s) would know that one or more molecules from their libraries had presented interesting research possibilities.

The public-sector scientist, with the assistance of the trusted intermediary, would attempt to determine which firm had the combination of hit molecules most likely to yield a successful drug. The decision would presumably be based on an assessment of liabilities and assets associated with the structures in question. Through the trusted intermediary, a firm could also, if it so desired, share with the scientist on a confidential basis any additional information that it might have. Presumably, it would do so in order to entice the scientist into a second-tier partnership.

A complication in the process would arise if one or more of the chosen firm's hit molecules were duplicates of molecules owned by another firm. In all likelihood, co-ownership of even one molecule should remain a relatively rare occurrence because, as discussed earlier, if molecules contributed by different firms overlapped significantly, there would be little reason to move forward with a multi-firm pool.

In the event of co-ownership, there are several options worth considering, and one to be avoided. The latter is the default route of future *patent* co-ownership (e.g., co-ownership of a patent on a potential lead compound that emerged from the co-owned molecule). Patent law encourages strategic behavior on the part of co-owners by allowing each one to "make, use, offer to sell, or sell the patented invention . . . without the consent of and without accounting to the other owners."[86] Although this default approach has the virtue of facilitating licensing (because the consent of only one co-owner is needed), it also means that disagreement between co-owners undermines the existence of an effective patent monopoly. Under our current system of R&D financing, monopoly rights on drugs are critical for hedging the risk associated with the long and complex preclinical and clinical development process.[87]

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84. University participants in the partnership would be barred from seeking patents on assays or targets prior to participation in the screening program. *See infra* Section IV.B.

85. For further discussion of the university perspective, as well as the perspectives of other stakeholders, see *infra* Part IV.

86. *See* 35 U.S.C. § 262 (2000). *See generally* Robert P. Merges & Lawrence A. Locke, *Co-Ownership of Patents: A Comparative and Economics View*, 72 J. PAT. & TRADEMARK OFF. SOC'Y 586 (1990) (discussing possibilities for opportunistic behavior created by the law of co-ownership).

87. *See, e.g.*, Wesley M. Cohen et al., *Protecting Their Intellectual Assets: Appropriability*

The simplest solution would allow the researcher to continue with the firm he or she had chosen, notwithstanding co-ownership of one or more hits. This option would be particularly useful if (as seems likely, given that the threshold inquiry would presumably have found relatively little overlap in contributions) only one or two molecules out of the chosen firm's set of hits were co-owned. The co-owner might then be entitled to royalty-based compensation if the molecule in question led to a marketable drug, but it would have avoided the cost and risk of follow-on work.

In the rare case where all (or most) of the relevant molecules were co-owned, the co-owning firms could set up a separate joint venture that would hold future patent rights. In order to avoid antitrust concerns in cases where the joint venture occupied a large share of the relevant research space, one of the firms could remain a silent partner that simply held a pre-determined equity stake in the joint venture. Importantly, the initial framework agreement would specify the alternatives available in situations of dual ownership so as to rule out the possibility of co-ownership of patents.

As noted earlier,[88] it appears that some pharmaceutical firms have already formed public-private partnerships with academic researchers whose published work indicates that they are working on interesting targets. They have done so, however, on a limited, ad hoc basis. Our first tier public-private partnership would provide a standardized platform for the systematic formation of many more second tier relationships than currently exist. Not only would the basis for forming such relationships be put in place, but with routine access to a pool of high-quality small molecule libraries guaranteed, one would also expect the public sector to develop many more validated targets that would be of interest to pharmaceutical companies.

Essentially, firms would be outsourcing assay development and target validation to individual academics who are well placed to do this work, but who would otherwise be difficult to integrate into the firm vertically as employees.[89] As contrasted with vertical integration, a public-private partnership would allow assay developers to run their assays against a broad array of molecules held by multiple firms.

Conditions and Why U.S. Manufacturing Firms Patent (or Not), (Nat'l Bureau of Econ. Research, Working Paper No. 7552, 2000), *available at* http://www.nber.org/papers/w7552; *cf.* Tracy R. Lewis, Jerome H. Reichman & Anthony D. So, *The Case for Public Funding and Public Oversight of Clinical Trials*, ECONOMISTS' VOICE, Jan. 2007, http://www.bepress.com/ev/vol4/iss1/art3/ (arguing that clinical trials should be treated as a public good).

88. *See supra* note 41 and accompanying text.

89. *Cf.* Bernard Munos, *Can Open-Source R&D Reinvigorate Drug Research?*, 5 NATURE REVS. DRUG DISCOVERY 723, 723 (2006) (discussing the outsourcing of drug research-related laboratory and clinical studies "to institutions with the requisite capacity through the help of matchmaking software").

2. Tier 2: Beyond the Veil of Ignorance

Once the academic had chosen a prospective partner, second-tier negotiations would commence. Because the terms of such second-tier partnerships are likely to vary quite substantially depending on the type of target at issue, we do not propose standard-form agreements for this tier. Presumably, the negotiated contract enabling Tier 2 research would further specify the expected relations of the parties during the drug development phase, and the distribution of expected royalties from patented lead compounds. Assuming the drug development process proved successful, and the patented drug passed clinical trials and entered the stream of commerce, the patent owner (i.e., the pharmaceutical firm) would obtain patent rents exactly as occurs at present.

A possible complication could arise, however, if the scientist and the pharmaceutical firm could not successfully conclude a second-tier agreement. In that case, we would propose that the scientist retain the opportunity to negotiate with the owners of other molecules that had represented hits at Tier 1. The information obtained by the academic in the negotiations with the first firm would, of course, remain subject to confidentiality and nondisclosure agreements.

If a Tier 2 partnership was formed and *subsequently* dissolved, the magnitude of potential inter-firm information leakage could become sufficiently great as to rule out allowing the scientist to negotiate with other firms. In any event, the framework agreement for the partnership would have to provide for both of these contingencies.

An important question to be addressed in the Tier 2 agreement would concern the timing of any eventual publication by the academic. Although we do not propose standard form agreements at Tier 2, the framework agreement should ensure that the academic can publish his or her findings as soon as appropriate arrangements for patentability had been made. This would represent an improvement over the current situation, where the available empirical evidence indicates that corporate sponsors sometimes require academics to withhold data well beyond the time necessary to file a patent.[90]

C. The Option of a Contractually-Constructed Liability Regime[91]

In addition to the structure outlined above, participating firms might also

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90. *See, e.g.*, David Blumenthal et al., *Relationships Between Academic Institutions and Industry in the Life Sciences—An Industry Study*, 334 NEW ENG. J. MED. 368, 371 (1996) (finding that fifty-six percent of corporate sponsors report that research results are sometimes kept confidential longer than the time required to file a patent).

91. The term "contractually-constructed liability regime" is drawn from J.H. Reichman & Paul F. Uhlir, *A Contractually Reconstructed Research Commons for Scientific Data in a Highly Protectionist Intellectual Property Environment*, 66 LAW & CONTEMP. PROBS. 315 (2003).

agree on a supplementary system of royalties that would govern compensation to any firm that had provided structural information about its molecules to a researcher deciding among promising "hits." In other words, firms would be contracting into a subsidiary set of "take and pay rules," or liability rules, rather than relying entirely on exclusive property rights.[92] As a historical matter, liability rules have always modulated between exclusive property rights, on the one hand, and the public domain, on the other.[93] In modern times, codified liability regimes that provide ex ante entitlements to compensation for certain uses (but not necessarily a right to exclude others from use) have been adopted in some intellectual property systems,[94] and in at least one international treaty.[95]

One feature of liability rules is that, even in the absence of legislative fiat, they may be voluntarily adopted whenever stakeholders seek to obtain a private ordering with outcomes that differ from what the default rules of intellectual property law might otherwise provide.[96] For example, various commentators have discussed patent pools as an example of contractually-constructed liability rules.[97] Similarly, contractually-constructed liability rules are sometimes used by

92. The classic reference is, of course, Guido Calabresi & Douglas Melamed, *Property Rules, Liability Rules, and Inalienability: One View of the Cathedral*, 85 HARV. L. REV. 1089 (1972); *see also* Robert Merges, *Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations*, 84 CAL. L. REV. 1293 (1996).

93. *See, e.g.*, J.H. Reichman, *Saving the Patent Law from Itself: Informal Remarks Concerning the Systemic Problems Affecting Developed Intellectual Property Regimes*, *in* PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT 289 (F. Scott Kieff ed., 2003).

94. *See, e.g.*, J.H. Reichman, *Charting the Collapse of the Patent-Copyright Dichotomy*, 13 CARDOZO ARTS & ENT. L.J. 475, 504-20 (1995) (stressing the need for a new intellectual property paradigm based on liability rules for cumulative and sequential innovation); J.H. Reichman, *Legal Hybrids Between the Patent and Copyright Paradigms*, 94 COLUM. L. REV. 2432, 2477 (1994) (discussing an Italian regime protecting construction designs and technical drawings); *id.* at 2480 (discussing the British Design Law of 1988, since repealed by the E.U. Design Regulation); *see also* Merges, *supra* note 92, at 1308-09 (discussing 17 U.S.C. § 115, a liability regime for sound recordings of copyrighted musical works).

95. F.A.O. Res 3/2001, International Treaty on Plant Genetic Resources for Food and Agriculture, Nov. 3, 2001, http://www.fao.org/ag/cgrfa/itpgr.htm (imposing a compensatory liability regime on those who make commercial applications derived from public-domain seeds).

96. *See* J.H. Reichman, *Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation*, 53 VAND. L. REV. 1743 (2000); *see also* Jerome H. Reichman & Tracy Lewis, *Using Liability Rules To Stimulate Innovation in Developing Countries: Application to Traditional Knowledge*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME 337 (Keith E. Maskus & Jerome H. Reichman eds., 2005).

97. *See, e.g.*, Merges, *supra* note 92, at 1340-52. As Merges discusses, the typical patent pool involves multiple firms agreeing voluntarily to refrain from exercising their rights to exclude. Instead of asserting patent rights, firms contribute the rights to a package license that is available on

patent holders as a mechanism for generating revenue from background property rights. (Indeed, proponents of the "one monopoly profit" thesis would argue that patent holders should generally be indifferent between using liability rules and exploiting their monopoly exclusively.)[98] When Stanford University famously made its Cohen-Boyer patent on DNA manipulation techniques available to all users willing to pay specified royalties under a non-exclusive license, it voluntarily converted the exclusive rights conferred by its patent to a liability regime.[99]

As discussed further below,[100] we believe the possibility of a liability rule payment could induce greater participation by pharmaceutical firms. This compensatory liability payment (say, on the order of three to five percent) would become available to firms if any of their molecules fell within the class of promising "hits" at the initial stage of high-throughput screening. Firms would accordingly benefit from income streams not only in circumstances where they actually undertook the expensive and risky follow-on work that led to a patented marketable drug, but also if they contributed a small amount (in the form of structural information on a hit) to upstream work. In this manner, firms could, to some extent, mitigate the overall risks of drug development.[101]

The framework agreement for our proposed partnership would spell out any ex ante liability rule entitlements that the participating firms had agreed to adopt. The intermediary would also collect and share data concerning the impact of the liability regime as a cost-sharing and risk-reducing technique over time. However, in the event that such obligations triggered antitrust difficulties or deterred participation (perhaps because firms doing the follow-on work resisted the liability rule as an unacceptable "reach-through royalty"),[102] they remain an optional feature of our proposal.

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reasonable terms either to participants in the pool or to all comers. *Id.* In recent years, the pooling of patents around information technology industry standards has become quite common. *See, e.g.*, Carl Shapiro, *Navigating the Patent Thicket: Cross-Licenses, Patent Pools, and Standard Setting*, *in* 1 INNOVATION POLICY AND THE ECONOMY 119 (Adam Jaffe et al. eds., 2001).

98. For an excellent discussion of the implications of the "one monopoly profit" thesis for platform technologies, and of situations where the thesis might not apply, see Joseph Farrell & Philip Weiser, *Modularity, Vertical Integration, and Open Access Policies: Towards a Convergency of Antitrust and Regulation in the Internet Age*, 17 HARV. J.L. & TECH. 85, 104, 105-19 (2003).

99. For a discussion of the Cohen-Boyer licensing strategy, see Rai & Eisenberg, *supra* note 45, at 300.

100. *See infra* Section IV.A.

101. We also believe that the innovation-related benefits of a liability rule scheme (in terms of inducing participation in the pool) are sufficiently large that a small royalty paid to competitors should not be deemed to violate antitrust law. *See infra* Section IV.D.

102. *See supra* note 38.

D. Adding New Participants

The public-private partnership we propose would be most likely to succeed if the founding members were firms with robust libraries that continued to be active in the search for new targets. At the same time, it would be inopportune, counterproductive, and possibly illegal as a matter of antitrust law to foreclose the possibility that other firms might join the pool. The pool members would thus be well-advised to organize from the outset the conditions of future membership.

Because of the manner in which the pool would be structured—specifically, the fact that private-firm researchers would not have any access to the small molecule pool and that even access by academic researchers at Tier 1 would be restricted to information about potentially promising "hits"—adding additional members should be relatively straightforward. New members and their contributions would be protected by the same nondisclosure agreements as pre-existing members. Similarly, hit molecules contributed by new members would be treated in the same manner as hit molecules contributed by founding members.

Notably, existing consortia, such as the PSTC, explicitly provide for the addition of new members. Under the PSTC framework agreement, new members that can contribute to biomarker validation and pay membership fees are allowed into the consortium as a matter of course.[103]

E. An Illustrative Example

Consider the following stylized example of the manner in which our proposed public-private partnership would work.[104] Many researchers believe that Alzheimer's disease is caused by the accumulation of short protein fragments that are formed when certain precursor proteins (known as amyloid precursor proteins) break down.[105] An Alzheimer's researcher (Researcher A) in University B determines that a previously unknown protein (protein C) appears to be centrally involved in the breakdown of amyloid precursor proteins. She creates an assay designed to test whether a small molecule binds to protein C ("protein C binding assay").

Researcher A (and her employer, University B) have previously complied with all the requirements for participation in the screening pool. She and her university have signed the relevant nondisclosure agreements and have posted the bond necessary to reinforce the pertinent nondisclosure rules. Thus, she is eligi-

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103. Consortium Agreement, *supra* note 68, § 3.3.

104. Note that although the facts in this example are generally based on accurate scientific information, they are intended for illustrative purposes only.

105. *See, e.g.*,Vincent T. Marchesi, *An Alternative Interpretation of the Amyloid Aβ Hypothesis with Regard to the Pathogenesis of Alzheimer's Disease*, 102 PROC. NAT'L ACAD. SCI. 9093, 9093 (2005).

ble to submit her assay to the trusted intermediary who will screen it against the aggregate collection of molecules that Companies 1, 2, and 3 have contributed to the pool.

The trusted intermediary will have previously compared the structure of the molecules submitted by these companies and presumably found only a small amount of overlap (e.g., only ten percent of molecules were owned by two firms and one percent were owned by three firms). Based on this small amount of overlap, the companies had decided to go forward with the pool.

The trusted intermediary proceeds to screen the combined molecule libraries of all three companies against the protein C binding assay. The intermediary then gives the results, which include the raw data generated in the experiment, to Researcher A. In consultation with the trusted intermediary, Researcher A determines that there is a group of seven molecules that show significant activity and might lead to promising new drugs. The trusted intermediary informs A that these molecules are owned by Companies 1 and 3—Company 1 owns three of the molecules, and Company 3 owns the other four.

At this point, the trusted intermediary also informs Companies 1 and 3 that they have molecules that represent hits, but the companies do not learn that they are hits on protein C specifically. Companies 1 and 3 can no longer withdraw the relevant molecules from the pool, and they must provide Researcher A with information about the structures of the hit molecules. Researcher A and the trusted intermediary analyze the structures they have been given and the results of the assay, and on that basis decide that Researcher A and University B should attempt to negotiate a Tier 2 agreement with Company 3. If an agreement is reached with Company 3, and subsequently results in a new drug, Company 1 may be entitled to a three to five percent royalty as provided for in the framework agreement. If the negotiations with Company 3 fail, Researcher A and University B have the option of negotiating with Company 1.

In the more complex case where one or a few of the molecules in Company 3's set of hits is also owned by another company (say Company 2), the decision-making process would be governed by the rules upon which the stakeholders had previously agreed. For example, the framework agreement might provide that in most cases, Researcher A could simply continue working with Company 3, while Company 2 might become entitled to some predetermined compensation but would not participate in, or bear any risk associated with, downstream research. In the rare case that the relevant molecules were all co-owned, the framework agreement might enable Companies 2 and 3 to form a joint venture that owned any resulting patent rights.[106]

106. The possibility of using joint ventures in downstream work on a set of promising molecules drawn from different sources would depend on the attitude of the relevant antitrust authorities. We discuss the antitrust implications of these options below. *See infra* Section IV.D.

If this and similar ventures were to succeed, the framework agreement would have maximized opportunities to generate new drugs by multiplying the number of assays that were screened against an expanded chemical space. In this manner, our model would enable complex and risky research that might not otherwise have occurred under existing arrangements. More importantly, it could enable and greatly increase the likelihood of breakthrough therapeutic results on significant diseases.

F. Single Firm Public-Private Partnerships

As previously observed, even if the trusted intermediary determined that the molecules that firms had contributed overlapped substantially, it would still be in the firms' interest to undertake some sort of collaborative approach. In that case, however, a better approach might rely on one or more single firm public-private partnerships. A single-firm partnership would give academic researchers the opportunity to screen their assays against that portion of the firm's library that the firm chose to make available.

Single firm public-private partnerships would not require the level of organizational infrastructure required by a broader pooling approach. A willing firm might simply invite interested academic researchers to submit assays, which it would then screen in-house against some subset of compounds within its proprietary library. However, a trusted intermediary might remain useful in this context, especially if it could assist the firms in identifying potential academic research participants and their associated institutions.

For example, in the context of tropical diseases targets, it appears that the World Health Organization's (WHO) Tropical Disease Network has organized a consortium of researchers who are interested in screening their targets against pharmaceutical firm libraries. Three firms—Pfizer, Merck Serono, and Chemtura—are now allowing this "TDR Compound Evaluation Network" to submit targets for in-house screening against a subset of the firms' respective chemical libraries.[107] The trusted intermediary might also help to fund the academic scientists, guard against misappropriation of unpatented results by participants in the partnership, and set the conditions of eventual publication of research results.

Because the "private" side of the partnership would, at any given time, be limited to a single firm, there would be no need for a two-tiered regime. Rather, qualified academics would simply submit assays to the firm in question. If and when a particular screening assay yielded a group of hits, the academic and the firm would then negotiate the terms of a public-private development partnership. As with the multi-firm partnership, the private firm would be free to withdraw molecules from the screening process up to the point when the molecule yielded a hit.

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107. Hopkins, Witty & Nwaka, *supra* note 67, at 169.

In the event that screening against the library of a given firm yielded no interesting hits, the academic investigator might want to submit the assay to other firms that had made a subset of their libraries available. However, because anonymity could not be preserved in a single-firm arrangement, "sequential" screening would depend on the first firm's willingness to permit it.

IV. ANALYZING THE COLLABORATION: STAKEHOLDER INCENTIVES AND TRADEOFFS

Having outlined the basic principles of our two-tiered proposal, we turn to a detailed discussion of the incentives that would induce stakeholders to enter into such an arrangement. We also briefly discuss salient antitrust issues pertinent to our proposal.

A. The Firms' Perspective

Pharmaceutical firms stand to gain a great deal, and lose little, through participation in our proposal. Current efforts to generate truly novel drugs are failing. Our proposal would leverage the expertise of publicly funded researchers in a manner that redounds to the benefit of the pharmaceutical industry as a whole while limiting aggregate costs and generating considerable efficiencies in the upstream research process.

Firms will be concerned about the risk that potentially important trade secret information (specifically, molecular structure and the fact that a particular molecule shows activity against an assay) might leak over to competitors. For this reason, only academic researchers should be allowed access to such information. Those researchers who identified a promising molecule would be deterred from misappropriation not only by contractual obligations and required bonding, but also by their need to partner with the firm contributing the most promising molecule in order to commercialize the research results.

By contrast, allowing private-sector researchers entry into the pool would create undue risk of misappropriation and industrial espionage. Fear of such misappropriation might deter firms from entering the pool in the first instance. Alternatively, firms might be tempted to contribute only "bad" molecules. Indeed, fear of misappropriation is so great that various efforts to foster even a limited amount of inter-firm information exchange about molecular library contents in the past have foundered on the inability of firms to sufficiently disguise or "mask" information about molecular structure.[108] Restricting participation to aca-

108. *See* Elizabeth K. Wilson, *Is Safe Exchange of Data Possible? Modelers in Need of Proprietary Compounds Seek Ways To Share Information, But Not Structure*, CHEMICAL & ENGINEERING NEWS, Apr. 25, 2005, at 24, *available at* http://pubs.acs.org/cen/science/83/8317sci1.html (describing efforts to enable "safe exchange" of chemical structures).

demic scientists—a prominent feature of our proposal—should prove attractive from the firms' perspective.

Moreover, even with respect to academic researchers, access to molecules would remain quite limited. The trusted intermediary would conduct the high-throughput screening on submitted assays. At Tier 1, academic researchers would receive results (and accompanying structural information) only with respect to molecules that represented hits. In exchange for this information, firms would be rewarded with the possibility of a collaboration as well as a potential royalty even if their firm was not chosen to undertake downstream development.

However, leakage of some structural information between firms might occur in certain circumstances, namely, when an assay revealed hit molecules from two different firms. If an academic moved on to a Tier 2 collaboration with one firm, there is some concern that he might inappropriately use information about the other firm's molecule(s). Similarly, if Tier 2 negotiations with one firm fell through, the researcher might take information derived from those negotiations into conversations with a second firm.

To forestall these possibilities, the framework agreement for the partnership should explicitly prohibit researchers from using information derived from one firm in their dealings with another firm. Enforcement of such a provision might prove difficult, however. Thus, the firm that was not chosen might be best rewarded for the risk of some level of leakage through the contractually-constructed liability scheme discussed above.[109]

B. The Academic Researchers' Perspective

Researchers, and their universities, should be motivated to participate in the collaboration through financial incentives and the potential for groundbreaking discoveries. If academic researchers succeeded in validating a target, they, and their universities, would find themselves in a strong position to negotiate a favorable Tier 2 agreement with one of the companies contributing hit molecules.

The academics would bring to the table their substantial knowledge of the assay and target, and the pharmaceutical firm would bring its information concerning the relevant molecule, its expertise in medicinal chemistry, as well as all of its downstream development resources. If the resulting partnership yielded a commercially successful drug, the researcher and his university would secure a share of the revenues.[110] They would also secure a reputational gain through

109. *See supra* Section III.C.

110. Note that this is a different claim from the argument that technology *licensing* (e.g., patent licensing) is likely to bring in substantial revenue. As many observers have noted, university patent licensing generally involves upstream technology with uncertain payoffs and therefore revenues are typically quite small. Only in the relatively unusual circumstance where the university sells rights to a drug is the revenue payoff substantial. *See, e.g.*, Press Release, Emory University, Gilead Sci-

eventual publication of the breakthrough research.

In our view, these financial and reputational benefits to the public research community should help to offset delays in publication that participating firms might deem necessary to protect commercially valuable information. Specifically, as noted earlier, the researcher exploring chemical space at Tier 1 would have to sign a nondisclosure agreement with respect to any structural data on molecules that he or she received.[111] Additionally, at Tier 2, the researcher must be willing to forego publication of commercially valuable information until relevant patents (e.g., on promising lead compounds) had been filed.

The ultimate financial benefits should also mitigate certain limitations on university patenting that are likely corollaries of our proposed public-private partnership. Under current law, universities are entitled to seek intermediate patents on validated targets. In the proposed collaboration, universities would forgo such patents in exchange for a transactional commitment at Tier 2 by the pharmaceutical company to a revenue stream from any drug that was ultimately developed. This revenue stream would recognize the significant research contribution of the university and its researcher.

C. The Perspective of the Trusted Intermediary

In order for the proposed public-private partnership to take off, the trusted intermediary would probably have to provide some seed funding. Specifically, the intermediary might, at least initially, bear the cost of funding researchers to develop assays, of conducting high-throughput screening, and of general pool administration. However, once the concept of pooling small molecule libraries had proved to be scientifically and economically viable, the firms themselves should be willing to subsidize many, if not all, of the activities in the collaboration.

If the trusted intermediary were the NIH, or an NIH-funded proxy, our proposal could be seen as complementary to its Molecular Libraries Initiative. While the MLI is likely to prove very useful in advancing basic knowledge about biological pathways, lack of access to small molecule libraries held by pharmaceutical firms may limit its success in target validation. At a minimum, the MLI will not typically result in potential lead compounds. More generally, two of the three themes highlighted in the current NIH Roadmap for Medical Research—encouraging "new pathways for discovery" and supporting "research teams of the

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ence and Royalty Pharma Announces $525 Million Agreement with Emory University To Purchase Royalty Interest for Emtricitabine (July 18, 2005), *available at* http://www.news.emory.edu/Releases/emtri/ (describing payment of $525 million for sale of royalty rights to anti-AIDS drug). Our proposal similarly would involve partnerships dealing with end-product drugs; therefore, revenue payoffs could be substantial.

111. *See supra* Subsection III.A.2.

future,"[112] (including interdisciplinary work and public-private partnerships)—are specifically promoted by the terms of our proposal.

The pharmaceutical companies could, of course, foot the bill for the entire initiative and establish their own trusted intermediary. We believe, however, that participation of a public entity remains desirable, even if the operation were totally funded by the private sector. For example, the presence of a public-sector player would greatly simplify relations with academia and add a layer of indirect enforcement of nondisclosure rules that would reassure the participating firms. Likewise, a public sector presence would reinforce the academic scientists' expectations that the public interest in shared research results would ultimately be respected, without compromising either side's intellectual property rights. Finally, the presence of a public-sector player would greatly facilitate negotiations between the trusted intermediary and the antitrust authorities over time.

D. Antitrust Concerns and the Public Interest

If successful, our proposal would necessarily entail some level of collaboration between firms that represent a significant percentage of the pharmaceutical industry. For the most part, only limited *inter-firm* R&D coordination or exchange of information would occur–largely confined to contexts where complementary assets had to be deployed in order to maximize research potential. Thus, we believe that our proposal should pass muster from the standpoint of both normative economic analysis and antitrust doctrine.

The question of whether a competitive or concentrated (perhaps even monopolistic) market structure best promotes innovation has long been mooted in the economic literature. Joseph Schumpeter famously argued that concentration promotes risky innovation by allowing firms to limit diffusion of knowledge to competitors and thus appropriate more fully the benefits of their innovative efforts.[113] In contrast, Kenneth Arrow and others have asserted that monopoly power can dull incentives to innovate, particularly in situations where a new product would displace a product already produced by the monopolist.[114]

As antitrust doctrine has expanded its focus beyond end product markets, it too has examined the relationship between competition and innovation. Influenced by Arrow's work, in the mid-1990's the Federal Trade Commission (FTC) and the Antitrust Division of the Department of Justice (DOJ) adopted an "innovation markets" analysis, which looks at competition in the R&D processes that

112. NAT'L INSTS. OF HEALTH, NIH ROADMAP FOR RESEARCH (2006), http://nihroadmap.nih.gov/pdf/NIHRoadmap-FactSheet-Aug06.pdf.

113. *See* JOSEPH A. SCHUMPETER, CAPITALISM, SOCIALISM AND DEMOCRACY 81-106 (1942).

114. *See, e.g.*, Arrow, *supra* note 32. For a summary of these arguments, see Rai, *supra* note 26, at 824-25.

produce end products.[115] Under innovation markets analysis, a joint venture, licensing agreement, or merger is suspect if it unduly limits the number of competing innovators and yields no offsetting innovation-related efficiencies.

Although innovation markets analysis might imply a relatively strict review of R&D collaborations, the DOJ and FTC have emphasized how difficult it is to define an innovation market.[116] In practice, the overriding focus in most cases is not market definition but whether the collaboration is likely to accelerate or slow the pace at which R&D efforts are pursued.[117] The agencies specifically recognize that "[t]hrough the combination of complementary assets, technology, or know how, an R&D collaboration may enable participants more quickly or more efficiently to research and develop new or improved goods . . . ."[118]

In the case of our proposed collaboration, the reality that R&D on new drug targets is very expensive and risky should make antitrust authorities more disposed towards a Schumpeterian perspective on the resulting pharmaceutical innovation. Nonetheless, two aspects of our model might concern antitrust regulators. First, the optional liability rule scheme we have proposed might be seen as a reach-through royalty that dulled incentives on the part of the firm enjoying the royalty to innovate independently. However, we think it is unlikely that a small royalty stream would significantly affect such incentives. The situation where *no one* works on a molecule that modulates a new target is much more likely. Indeed, it is the status quo.

The second antitrust difficulty might involve the situation where co-ownership of molecules required a substantial compensatory royalty or even a joint venture. In both cases, the argument in favor of allowing collaboration would rest on the fact that the assets in question were co-owned and therefore complementary.

To address antitrust concerns expeditiously, we would propose that the initial framework agreement expressly address questions of co-ownership (and, if desired, liability rules), and that this agreement be vetted by the antitrust authorities before any collaborative work began. The PSTC framework agreement pro-

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115. DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY § 3.2.3 (1995) [hereinafter DOJ, INTELLECTUAL PROPERTY], *available at* http://www.usdoj.gov/atr/public/guidelines/0558.htm (defining innovation markets); *see also* DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST GUIDELINES FOR COLLABORATIONS AMONG COMPETITORS § 3.32(c) (2000) [hereinafter DOJ, COLLABORATION], *available at* http://www.ftc.gov/os/2000/04/ftcdojguidelines.pdf (discussing innovation markets).

116. "The Agencies will delineate an innovation market only when the capabilities to engage in the relevant research and development can be associated with specialized assets or characteristics of specific firms." DOJ, INTELLECTUAL PROPERTY, *supra* note 115, § 3.2.3; *see also* DOJ, COLLABORATION, *supra* note 115, § 3.32(c).

117. DOJ, COLLABORATION, *supra* note 115, § 3.31(a).

118. *Id.*

vides an instructive example. It contains an "antitrust statement" that limits inter-firm sharing of information to that necessary for purposes of biomarker validation and allows consortium members to pursue independent biomarker validation projects.[119] We would envision a similar statement addressing antitrust concerns in our framework agreement.

CONCLUSION: BROADER IMPLICATIONS OF THE COLLABORATIVE APPROACH

In developing our proposal for greater access to small molecule libraries, we have drawn upon models of inter-firm collaboration that the pharmaceutical industry is currently using for biomarkers. However, our approach is designed to work in settings different from the creation of biomarker standards, where rights in collaborative outputs must be tightly protected.

For example, a similar approach may be useful in advanced materials engineering research. Such research represents a context where inter-firm transfer of inchoate and unpatented, but nonetheless valuable, information is desirable.[120] Contract-based exchange can be implemented so long as the connection between the inchoate information put in ex ante and the codified, differentiated information that emerges ex post is reasonably clear. The presence of a trusted intermediary that polices contract breaches and prevents undesirable spillovers is also important.

Our proposal attempts to embody all the features that are likely to facilitate contract-based exchanges of pre-patentable, but nonetheless valuable, information. If academics and pharmaceutical firms are interested in truly innovative drug discovery, they should experiment with this effort to forge new and viable pathways across what has hitherto proved to be a largely impassable "valley of death."

119. *See* Consortium Agreement, *supra* note 68, at exhibit A.

120. Professor Krishna Rajan, Iowa State University, Presentation at the University of Tokyo Conference on Designing Global Information Commons for Innovation in Frontier Sciences (Nov. 8, 2007) (conference notes on file with authors).

Proxy Consent to Research: The Legal Landscape

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I. INTRODUCTION

When an adult suffers from a disorder that impairs his or her capacity to consent, may another person enroll that individual in research? The answer, it appears, is not a simple "yes" or "no," but rather "it depends."

The lack of clear legal answers to this question has significant ramifications for the conduct of important research on disorders that affect many individuals. A growing population in our country suffers from illnesses that may affect decision-making, such as dementia, mental retardation, or, in certain instances, severe neuropsychiatric disorders. To illustrate this point, consider Alzheimer's disease ("AD"). As the most common cause of dementia, the current and projected impact of AD is immense. An estimated four to fifteen million people are expected to suffer from Alzheimer's disease by the year 2047.[1] Beyond the quantitative impact of AD, the personal and relational costs of the disease are staggering. Patients in later stages may not recognize family members and often lose many of their core human traits and abilities. Many patients face institutionalization because of the common, yet extremely challenging, behavioral and psychiatric expressions of the disease. The financial costs are also significant. Current annual costs, both direct and indirect, approach $100 billion in the United States alone.[2] It is urgent that research on this disease be strongly encouraged and facilitated.

A person who may consent on behalf of another to participate in research is referred to as a "proxy" or "surrogate." Proxy consent for research on disorders such as AD has been called "a gray zone of law and ethics."[3] Early bioethics documents such as the Nuremberg Opinion—not binding law but historically important—required consent from the subject himself,[4] and thus proxy consent would never be allowable. However, later documents concerning scientific research, including the influential Belmont Report,[5] did allow for proxy consent

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1. Ronald Brookmeyer et al., *Projections of Alzheimer's Disease in the United States and the Public Health Impact of Delaying Disease Onset*, 88 AM. J. PUB. HEALTH 1337 (1998).

2. Bernard S. Bloom et al., *Cost of Illness of Alzheimer's Disease: How Useful Are Current Estimates?* 43 GERONTOLOGIST 158 (2003); Glen T. Schumock, *Economic Considerations in the Treatment and Management of Alzheimer's Disease*, 55 AM. J. HEALTH-SYS. PHARMACY, S17 (1998).

3. Paul S. Appelbaum, *Involving Decisionally Impaired Subjects in Research: The Need for Legislation*, 10 AM. J. GERIATRIC PSYCHIATRY 120 (2002).

4. *See* United States v. Brandt, 2 TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS 1 (1947).

5. Nat'l Com'n for the Prot. of Human Subjects of Biomedical and Behavioral Research, The Belmont Report: Ethical Principles and Guidelines for Research Involving Human Subjects, 44 Fed. Reg. 23,192 (Apr. 18, 1979).

to research.[6] Despite the promulgation of codes of ethics and statements by professional societies, clear guidelines are still lacking regarding the conditions under which proxy consent for research is acceptable.

Currently, federal regulations governing research allow proxy consent for research involving adults who lack decision-making capacity if a "Legally Authorized Representative" (LAR) gives permission.[7] Under these regulations, however, an LAR is defined as "an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research."[8] The federal regulations presume that each state has law concerning research involving mentally impaired adults that will guide the decisions of researchers, institutional review boards (IRBs), and surrogates when they are called upon to make decisions. Unfortunately, the states' "applicable laws" regarding who can serve as an LAR (and under what conditions) are often unclear.[9] While proxy decision-making is permissible in theory, in practice it may not be allowed because the states have not created clear laws governing its use.

States allow for different types of proxies, such as courts, guardians, people with Durable Powers of Attorney (DPAs) for health care, and family members. Of particular interest to researchers are states that allow families to be proxies in the research context. Allowing family members to be proxies for research may be the best solution to this problem because it allows both for autonomy of the patient—families are likely to know best what the patient would have wanted—and for much needed research to continue. Obtaining proxy consent from family members uses far fewer resources than going to court to seek a decision or appointment of a guardian. The latter method can be so taxing and time-consuming that researchers may simply stop trying to conduct research that involves incompetent patients.

There is no empirical data regarding the amount of research currently being conducted with decisionally impaired subjects, and therefore there is also no data showing how the lack of clear guidelines affects the supply of subjects. Despite the lack of statistics, there is anecdotal evidence that the research community has been burdened by the lack of clear regulations and that the absence of clarity has, at times, adversely affected the amount of research being performed. In 2002, for instance, the Executive Vice Chancellor of UCLA, concerned about the lack of

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6. *See* Bernard A. Fischer, IV, *A Summary of Important Documents in the Field of Research Ethics*, 32 SCHIZOPHRENIA BULL. 69 (2006); Scott Y.H. Kim et al., *Proxy and Surrogate Consent in Geriatric Neuropsychiatric Research: Update and Recommendations*, 161 AM. J. PSYCHIATRY 797 (2004).

7. 45 C.F.R. § 46.102(c) (2006).

8. *Id.*

9. *See* Kim et al., *supra* note 6, at 799-800.

clear regulatory guidance on how to handle the issue of surrogate consent for research involving people with diminished capacity, issued a university-wide moratorium on approval of human subjects research involving decisionally impaired participants unless the consent of a court-appointed conservator was obtained.[10] After a divisive legislative session California's legislature passed A.B. 2328,[11] a law that took effect in January 2003 and allowed informal surrogates to consent on behalf of incompetent patients.[12] Data has not been collected to measure whether this law has encouraged research efforts involving decisionally impaired people with diseases such as AD. The topic of surrogate consent has also been highlighted by researchers who study the critically ill, who very often cannot provide their own informed consent.[13] Further evidence that the research community considers these issues of consent to be timely can be found in the convening of a National Institutes for Health (NIH) group in Washington, DC, in July 2002 to discuss this type of proxy consent. The Office for Human Research Protections (OHRP), a federal agency, has also convened a committee to address this issue.[14]

This Article aims to enhance the clarity of existing guidelines and highlight the need for further regulation. In a more predictable legal environment we expect that research with decisionally impaired subjects will increase and improve. Not least, clarifying the legal landscape would encourage research by reducing researchers' fears of criminal and civil prosecution. Without reform, research on disorders that impair mental abilities likely will be encumbered. Because many states do not have "applicable laws" that guide LAR designation, the current state of the law may put research on disorders that impair decisional abilities at risk.[15]

We seek in this review to examine the legal landscape concerning LARs in the various states. After reviewing our methodology in Part II, we turn to the

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10. Memorandum from Daniel M. Neuman, Executive Vice Chancellor, Univ. of Cal., L.A., to the Faculty of Univ. of Cal., L.A., RE: Moratorium on IRB Approval of Surrogate or Proxy Informed Consent for Human Subjects Research (Sept. 30, 2002), *available at* http://www.oprs.ucla.edu/human/news/item?item_id=127481.

11. 2002 Cal. Legis. Serv. 489 (West) (codified at CAL. HEALTH & SAFETY CODE § 24178 (West 2006)).

12. *See* John M. Luce, *California's New Law Allowing Surrogate Consent for Clinical Research Involving Subjects with Impaired Decision-making Capacity*, 29 INTENSIVE CARE MED. 1024 (2003).

13. John M. Luce, *Research Ethics and Consent in the Intensive Care Unit*, 9 CURRENT OPINION CRITICAL CARE 540 (2003).

14. For more information on the OHRP, see OHRP Fact Sheet, http://www.hhs.gov/ohrp/about/ohrpfactsheet.htm (last visited Nov. 30, 2007).

15. *See, e.g.*, Scott Y.H. Kim et al., *What Do People at Risk for Alzheimer Disease Think About Surrogate Consent for Research?*, 65 NEUROLOGY 1395 (2005).

existing law in this area in Part III. Section A briefly reviews direct references to LARs in state statutes. Section B provides an overview of state laws directly relevant to inferring proxy consent in the research context. Section C examines the two most detailed statutes on proxy consent to research, passed in California and Virginia. Section D discusses formal letters issued between 2000 and 2006 by the Office of Human Research Protections (OHRP) which provide insight into federal interpretations of state laws. Section E reviews relevant case law on proxy consent to research and Section F reviews explicit limits placed on proxy decision-making in the research context. Appended to this Article are three tables that show our findings by state.16 Table 1 lists state statutes regarding proxy consent to research. Table 2 lists those statutes addressing family proxy consent to treatment. Table 3 classifies statutes by the powers that are given to substitute decision-makers.

After presenting our results, we discuss them in Part IV. In Section A—the "Positive Side"—we explore some meta-issues, such as the implications of using treatment proxies to define LARs in the research context. In Section B—the "Normative Side"—we discuss what the law *should* be in this area. As a matter of positive law, we believe that reasonable inferences from related statutes could support a finding that families may serve as proxies for research. As a normative matter, we believe that families often will be the best decision-makers and should therefore be authorized to make proxy research decisions, although some limits should be placed on when they may give proxy consent. Finally, in Part V, we note the limitations of our research and the need for further studies on various aspects of proxy consent issues.

II. METHODS

An important preliminary definitional issue must be addressed: the distinction between proxy consent to research and proxy consent to treatment. When applicable, we defer to the language of the state statutes. Statutes speaking of consent to "treatment" are classified as statutes regarding proxy consent to treatment. Where statutes speak of "research," or "experimental treatment," we classify them as concerning proxy consent to research.[17]

Federal regulations define research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."[18] In contrast, treatment does not aim to lead to generalizable knowledge, but aims to ameliorate a specific patient's medical

16. To view the tables online, please visit www.yale.edu/yjhple.

17. We also are conservative about other locutions—e.g., "health care"—taking them to refer to treatment, though they could reasonably be interpreted to include both treatment and research.

18. 45 C.F.R. § 46.102(d) (2006).

condition. "Experimental treatment" may have both aims. It is "experimental" because it has not been established as part of the ordinary standard of care. In practice, this distinction can become blurry because something that is clearly "Human Subject Research" according to the definition in the regulations can offer subjects the prospect of direct benefit. The research is not individualized to the subject, so what he or she receives in the way of "treatment" is not individualized to his or her needs. Because the objective is to obtain generalizable knowledge, this intervention would be classified as research, even if it is helpful to the individual.

For the positive law sections and tables of this Article, we conducted an extensive search for statutes on proxy consent adopted by the legislatures of the fifty states.[19] We did not research regulations promulgated by state agencies to effectuate statutes. We also conducted a thorough review of the case law created in judicial decisions interpreting statutes or addressing issues not encompassed in statutes.

In researching the statutes, we first located every direct reference to the term "Legally Authorized Representative." Second, we conducted a broad search in the fifty-state statutory databases of Lexis and Westlaw.[20] We also did more focused searches examining family consent in particular.[21] We looked specifically for guardian and conservator consent through another search.[22] We then searched for statutes on "durable powers of attorney" and related statutes.[23] Since many states do not have research proxy statutes, we designed our search to encompass laws concerning proxy consent in treatment-related contexts. Such statutes, while not directly on point, often allowed us to draw valuable inferences. For example, analyzing these statutes allowed us to review statutorily-imposed limits on proxy consent powers in the states.

We also reviewed letters issued by the Office of Human Research Protections during the years 2000-2006 that addressed proxy consent to research issues. This review provided insight into how the federal government office that

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19. The ABA legislative update on the Commission on Law and Aging has tables with some information replicated in our three tables. Some of that information is dated; the tables do not address many of the items we address (e.g., the different routes for proxies in the research context or the standards by which proxies must make decisions). Our tables are organized in a way that aims to be helpful for making inferences about proxies in the research context. *See* Comm'n on Law & Aging, Am. Bar Assoc., Legislative Updates, http://www.abanet.org/aging/legislative updates/home.shtml (last visited Nov. 30, 2007).

20. Search terms were: (health or medic!) & consent & (treatment research) & (surrogate or proxy or "durable power of attorney" or guardian or conservator).

21. Search terms were: (health medic!) & consent & (spouse parent "next of").

22. Search terms were: ((guardian conservator) /p consent) & (health! medic!).

23. Search terms were: (DPA or "durable power of attorney") or surrogate or (substitute /2 decision /2 mak!).

oversees research conceptualizes this issue. We reviewed all letters issued by the OHRP for this time period and identified those relevant to proxy consent to research on adults. Finally, we did a thorough search of relevant case law to see if courts have addressed the interpretive difficulties that the statutes sometimes raise or if they have created their own guidelines on who qualifies as an LAR.

Of course these different approaches are not equally helpful in determining the extent to which individuals can give proxy consent to research. Methodologically, a statute which purports to define "Legally Authorized Representative" in the context of proxy consent to research is most on point. A statute which lists kinds of proxies who may consent to research (without mentioning the term LAR) is also extremely helpful. Beyond that, we are left to make more or less secure inferences from laws that concern other contexts and use these inferences to create a model. This issue is addressed further in Part IV.

III. RESULTS

A. Direct Mentions of "Legally Authorized Representative"

The term LAR occurs in state statutes approximately 295 times, not including multiple mentions of the term in the same section of a statute. The contexts in which LAR is mentioned include not only statutes about consent to treatment or research, but also whom medical information may be disclosed to and when agents of government officials may perform various activities. Indeed, the overwhelming majority of references (180) to the term concern the Legally Authorized Representative of state auditors examining the accounts of the books of various public agencies.[24]

The statutes also sometimes use language qualifying the LAR language, giving some suggestion of what the term might mean. Examples are "the [LAR] or agent,"[25] "[LAR] or family,"[26] "a spouse or domestic partner of the individual absent other [LAR],"[27] "parent or [LAR],"[28] "next of kin or [LAR] or other legal representative,"[29] "conservator, guardian, or other [LAR],"[30] and "a guardian, conservator, or guardian ad litem authorized by the court, or other [LAR]."[31]

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24. *See, e.g.*, IOWA CODE ANN. § 16.31(1) (West 2005); MISS. CODE ANN. § 43-33-747(1) (2007); N.J. STAT. ANN. § 12:11A-22(d) (West 1979); N.M. STAT. § 58-18-20(A) (1978).

25. *See, e.g.*, CONN. GEN. STAT. ANN. § 21a-8a(b) (West 2006).

26. *See, e.g.*, CAL. WELF. & INST. CODE § 4905(a) (West 1998).

27. *See, e.g.*, CAL. UNEMP. INS. CODE § 2705.1 (West 1986).

28. *See, e.g.*, KY. REV. STAT. ANN. § 214.468 (LexisNexis 2007).

29. *See, e.g.*, VA. CODE ANN. § 54.1-2961(E) (2005).

30. *See, e.g.*, CAL. WELF. & INST. CODE § 5622(b) (1998).

31. *See, e.g.*, MINN. STAT. ANN. § 245B.02(15) (West 2007).

In the specific context of consent to medical treatment or research, the term LAR is used twenty-nine times. The contexts include emergency treatment (California), treatment for developmental disability (California), HIV testing (Illinois, Michigan), predictive genetic tests (South Dakota), and treatment by telehealth (Nebraska).[32] Texas statutes refer to the concept multiple times in numerous medical contexts: appropriate care settings,[33] mental retardation community placement,[34] information provided regarding long-term support,[35] consumer direction of services,[36] do not resuscitate orders,[37] and facilities and services for clients with mental retardation.[38]

There are some thirty other references to LAR in the medical context that do not involve consent to treatment or research. These statutes discuss issues such as access to medical records or their disclosure to others,[39] and disclosure of results of tests for HIV.[40] In the research context in particular, there is a statute on the right to receive copies of signed consent forms and on the permissibility of disclosing a research record in individually identifiable form without the prior written consent of the person or his or her LAR.

Finally, the term LAR occurs specifically in the context of consent to participate in research in at least three jurisdictions: Guam, New York, and Virginia. Only a very small number of jurisdictions discuss or mention the meaning of LAR in a context that is relevant to this Article. Two statutes do not define LAR and simply refer to other state laws, at least on certain issues (Guam and Washington). The other two laws (Texas and Virginia) list people who may serve as LARs. Virginia does so explicitly in the context of consent to research, as discussed in detail in Subsection III.C.2.

Looking directly at the uses and definitions of LAR in statutes, then, is at most modestly useful. Most of these references concern matters other than research or treatment, and they do not provide helpful descriptions or definitions even when they are on point. Hence, we must survey related statutes and other legal materials to determine the answers to our questions about the permissibility of proxy consent.

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32. CAL. HEALTH & SAFETY CODE § 24177.5 (West 2006); MICH. COMP. LAWS ANN. § 333.5133 (West 2001); NEB. REV. STAT. § 71-8505 (2003); S.D. CODIFIED LAWS § 34-14-22 (2007).

33. *See* TEX. GOV'T CODE ANN. § 531.0244 (Vernon 2004).

34. *See* TEX. GOV'T CODE ANN. § 531.02442 (Vernon 2004).

35. *See* TEX. GOV'T CODE ANN. § 531.042 (Vernon 2004).

36. *See* TEX. GOV'T CODE ANN. § 531.051 (Vernon Supp. 2007).

37. *See* TEX. HEALTH & SAFETY CODE ANN. § 166.081(6)(A) (Vernon 2001).

38. *See* TEX. HEALTH & SAFETY CODE ANN. § 533.038 (Vernon 2003).

39. *See, e.g.*, 735 ILL. COMP. STAT. ANN. 5/8-2001 (West 2007).

40. *See, e.g.*, FLA. STAT. § 381.004(3)(e) (2007); 410 ILL. COMP. STAT. 305/9 (West 2007).

B. Inferring LAR Status by Examining State Laws Defining Proxies Per Se

We examined state statutes to see who is authorized to consent to research for someone who cannot consent for herself. The proxies appointed by statutes range from family members to guardians to courts. We are most interested in jurisdictions that explicitly allow families to consent in the research context. Many jurisdictions do not speak directly to this issue, and therefore we are forced to make inferences based on descriptions of the proxy's authority to provide consent for purposes other than research. For instance, what sorts of procedures are proxies permitted to decide upon in the treatment context? For which procedures are proxies precluded from giving consent, and how do these procedures compare with those used in various kinds of research? We cannot presume that absence of a statute necessarily means that proxy consent to research is not permitted.

Because analysis of the laws is not straightforward, we compiled our data about the statutes in three tables, appended to this Article and described below.

1. Statutes on Proxy Consent to Research

We turn now to when proxies may consent specifically to research participation. Table 1, Column 3 lists those states where family members are explicitly mentioned as individuals who can give proxy consent on behalf of their incompetent family members to participate in research. Nine jurisdictions have statutes that specifically allow this. Some of these jurisdictions restrict the use of proxy consent to certain populations, e.g., psychiatric patients (Montana), nursing home patients (Washington), developmentally disabled patients (D.C. and Montana), or terminally ill patients (Oklahoma). Others only allow its use in specific kinds of research, e.g., psychiatric (Delaware). Others impose certain limits on when such proxy consent is permissible, e.g., the research will assist the ward to develop or regain his abilities (Florida). But other statutes are fairly broad and general. Thus, practically speaking, even those researchers and Institutional Review Boards (IRBs) that are in states with these statutes must carefully consider the specific provisions of their state's laws.

Table 1, Column 4 lists those jurisdictions in which other persons are explicitly authorized to consent on behalf of an incapable subject without having been appointed by a court to do so. There are five statutes in this category. Listed here are those jurisdictions that allow a proxy to consent to research if there is an advance directive (North Carolina); or allow an agent with a health care DPA to consent to research (Missouri, Montana, and Oklahoma). Two of the three states that provide for DPAs' consent also allow consent to be obtained from others individuals, such as family members (Missouri and Oklahoma). One jurisdiction does not allow the DPA to consent to experimental mental health treatment, among other things, unless the DPA form provides otherwise (Wisconsin).

Again, even when non-court-appointed surrogates are allowed, there are specific restrictions that make generalizations across states difficult.

Column 5 contains information about when legal guardians may consent to research on behalf of their incompetent wards. Fourteen jurisdictions explicitly mention guardian consent in the research context and do not require court authorization (e.g., Alaska, Missouri, and New Mexico). Some require court authorization only if there is no IRB approval for the research (e.g., Florida). Some jurisdictions put limits on when guardians can consent—e.g., only if the research is intended to preserve life or prevent serious injury, or only if it is intended to assist the ward to develop or regain abilities (e.g., Alaska and Connecticut). A number of them apply only to specific populations, such as developmentally disabled patients, psychiatric patients, or involuntarily committed patients (e.g., Colorado, Connecticut, D.C., Georgia, and New Mexico). And some refer to alternate routes for volunteering people for research (e.g., Connecticut and Missouri).

Column 6 has information about states where courts can consent to research on behalf of incompetent patients, where the courts' consent is required, and where courts may authorize a guardian to engage in proxy consent. In some cases, a requirement of court approval applies only to certain groups, e.g., psychiatric patients (D.C.) or developmentally disabled patients (e.g., Connecticut and North Dakota); in others, it applies to every incompetent subject. Certain jurisdictions put limits on when the courts can provide consent, e.g., only if the procedure is intended to preserve the life of the potential subject, or only if it is related to the specific goals of the patient's treatment program (e.g., Connecticut, Florida, Illinois, Nevada, New Jersey, and North Dakota).[41]

In total, nine states explicitly allow family members to give proxy consent to

41. It should be noted that there are at least three states whose statutes raise interpretive difficulties. Florida seems both to allow guardians to decide, *see* FLA. STAT. ANN. § 394.4598 (West 2007); FLA. STAT. § 765.113 (1994), and to require court approval before guardians may consent, *see* FLA. STAT. § 744.3215(4)(b) (1994) (requiring court authorization for an "experimental biomedical or behavioral procedure"). Illinois seems to allow guardian or family consent without court approval, *see* 410 ILL. COMP. STAT. 50/3.1 (2005), but then requires court approval for "[u]nusual, hazardous, or experimental services or psychosurgery" if the patient "is under guardianship." 405 ILL. COMP. STAT. 5/2-110 (2005). These may be reconciled in that the latter is found in the chapter relating to rights of recipients of mental health and developmental disabilities services. North Dakota seems both to allow guardians to consent, *see* N.D. CENT. CODE § 25-03.1-40 (2002), and guardians to consent only with a court order. N.D. CENT. CODE § 25-01.2-11 (2002). These may be reconciled by the fact that the first only applies in the context of the "civil commitment of patients" while the second applies "to an institution or facility that provides residential care." In those cases where there seems to be a conflict, we have included the statutes in both columns of our table as they may need to be interpreted by case law.

research. Twenty-seven states[42] have an explicit statute on proxy consent to research in general (e.g., guardian consent, DPA consent, etc.).

2. The Treatment Context

Even if a state does not have a specific law regulating proxy consent for research, it may have proxy laws for other contexts that shed light on, or have direct implications for, proxy consent for research in that state. For health care decisions, every jurisdiction has a guardianship statute that empowers the "courts to appoint guardians for decisionally incapacitated people."[43] Another survey found that, while far from uniform, all states have enacted some form of advanced health care directive that allows the declarant to specify treatment and to designate a health care proxy in the document.[44]

Of most interest to us are states in which proxy consent by family members for treatment is explicitly allowed. Table 2 lists statutes that authorize family members to make proxy in the treatment context. Column 3 contains statutes regulating decisions by family proxies in the treatment context in general. Fifteen states have these types of statutes. Column 4 contains statutes regulating decisions by family proxies about life-sustaining treatment—whether to consent to or refuse it. Ten states, seven of which are not among the fifteen states listed in Column 3, have these types of statutes. Column 5 contains statutes regulating mental health, developmental disability or substance abuse treatment decisions, or decisions in the case of these kinds of patients. Fifteen states, six of which are not included in the first two columns, have these types of statutes. Column 6 contains statutes regulating other specific interventions as well as other miscellaneous proxies. Ten states, five of which are not listed in the other columns, have statutes that fall into this category. In total, thirty-four states fall into one (or more) of these categories.

3. General Standards for Proxy Decision-making

We now move to consider the statutory schemes that specify standards for proxy consent and set limits on proxy consent to certain interventions. This inquiry may be important in states where there is not an explicit authorization for

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42. There are twenty-seven states that have laws regarding which proxies may consent to research, i.e., states that have any item in any column. It should be noted that some jurisdictions are listed in more than one category.

43. *See, e.g.*, Marshall B. Kapp, *Legal Basis of Guardianship*, *in* GUARDIANSHIP OF THE ELDERLY: PSYCHIATRIC AND JUDICIAL ASPECTS 18 (George H. Zimny & George T. Grossberg eds., 1998).

44. *See* Bretton J. Horttor, *A Survey of Living Will and Advanced Health Care Directives*, 74 N.D. L. REV. 233 (1998).

proxy consent to research or treatment, or for states that have a treatment statute but do not appear to allow it to serve as precedent for proxy consent to research.

There are three places to look for laws of this type: first, at statutes that generally describe the kinds of proxy decision-making that are allowable; second, at statutes that specify how the proxy decision shall be made; and third, at statutes that prohibit proxy decision-making in certain contexts.

Table 3, Column 3 describes in general terms the kinds of decisions proxies can make. For example, one statute describes the decision-maker's power to include "[a]ny medical decision the subject can make,"[45] while another covers "any decision a parent could make for her child."[46] One could argue that research decisions fall into any of these general categories. It should be noted, however, that we did not catalog the many jurisdictions that say, for example, that DPAs can make all "health care" decisions for their principal. The question, again, would be whether decisions to participate in research are "health care" decisions. A case can be made in either direction.

Column 4 describes the standard by which proxies are to decide—which may have implications for when proxy decisions are allowed. At least twenty-nine jurisdictions require a "substituted judgment" standard: what the patient would have decided if competent, provided his or her wishes are known. Seven other states require a "best interests" standard. Most states also say to use this standard if the patient's wishes are not known.

Another approach to answering questions about proxy consent is to consider what kinds of decisions DPAs and guardians are *not* permitted to make, at least without court approval. Column 5 catalogs these statutes. Five jurisdictions require court approval for proxy consent to abortion; nine require court approval for sterilization; six require court approval for electroconvulsive therapy; and seven require court approval for psychosurgery. Particularly relevant is that eight states require court approval for experimental treatment.

Although we do not review the case law that has been generated by court approval statutes in this Article, it is worth noting that there are also a number of state laws that require a judicial finding of incompetence before a person may lose his right to refuse psychotropic medication. These cases differ from the research context however, in that most commentators believe that a subject's dissent should serve as an absolute bar to research (despite a finding of incompetence and surrogate consent), whereas refusal of psychotropic medication for treatment purposes can be overridden.

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45. We cannot imagine any decision a proxy could make that a person himself could not make.

46. For an example of a decision a parent cannot make for his or her child, imagine the situation where a parent is unable to give permission for an extremely risky procedure intended to primarily benefit another child, or, where a parent is unable to refuse a treatment necessary to save a child's life. *See* Table 3 for further information on these and related standards.

In short, this approach to reviewing laws governing proxy consent to research looks at statutes which are permissive in the treatment context (statutes that, when read reasonably, seem to allow proxy consent for treatment) and at statutes which are limiting in this context (statutes that, when read reasonably, may prohibit proxy consent for treatment). Later we discuss how these statutes may or may not help to answer questions about the availability of proxy consent in the research context.

C. The Two Most Detailed State Laws

1. The California Law

In 2002, California passed a law, A.B. 2328, allowing proxy consent to be given for research.[47] There are several key features of this law. First, it allows proxy consent only to medical experiments that "relate to the cognitive impairment, lack of capacity, or serious or life-threatening diseases and conditions of research participants." Second, it applies only if subjects are "unable to consent" and, third, if they do not dissent. Fourth, the proxy must have "reasonable knowledge" of the research participant. Fifth, the proxy is required to exercise "substituted judgment" if possible, and use a "best interests" standard when it is not possible.[48]

The possible proxies, in order of priority, are as follows: DPA, conservator, spouse, a domestic partner as defined by section 297 of the Family Code, adult son or daughter, custodial parent, adult sibling, adult grandchild, or an adult relative with the closest degree of kinship to the person. If there is more than one proxy in a given category—such as two siblings—then each member of the proxy group must consent to the proposed research. Note that both a DPA and a guardian come before family members. If there is no DPA or guardian, however, family members may consent. In practice, there will often be no DPA or guardian and the most frequent surrogates will be family members. An important aspect of the law is that it does not limit proxy consent to research that falls under some threshold risk/benefit ratio. Presumably, as long as the relevant IRB approves, research involving significant risk but without any potential to directly benefit the subject is possible in California. Another significant feature of the law is that it appears to be inapplicable to subjects who are involuntarily committed, voluntarily admitted, or admitted on a conservator-request to a psychiatric hospital.

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47. 2002 Cal. Legis. Serv. 489 (West) (codified at CAL. HEALTH & SAFETY CODE § 24178 (West 2006).

48. *Id.*

2. The Virginia Law

The Virginia law[49] appears to have been modeled after the federal regulations governing children's research[50] with some modifications for the adult surrogate consent context. The statute defines a LAR by listing the order of priority for proxy decision-makers: parents having custody of a minor; an agent appointed in an advance directive (provided the directive authorizes research decisions); a guardian; a spouse; an adult child; a parent when the subject is an adult; an adult brother or sister; and any other judicial or other body authorized by law. LAR status flows down from group to group—so if a person does not exist at the highest category, the power is then vested in a person (or persons) in the second highest category. The statute also says that an attorney-in-fact[51] may serve as a proxy to the extent that the Durable Power of Attorney instrument grants the authority to make this decision. The law states that if there are two or more individuals in any given category at issue, then each member of the proxy group must consent for the subject to be enrolled.

The LAR may not consent if he knows or should know that a procedure is contrary to the religious beliefs or values of the prospective subject. The LAR also may not consent to research involving non-therapeutic sterilization, abortion, psychosurgery, or admission for research purposes to certain kinds of facilities or hospitals. And unlike the California law, the law stipulates a maximum level of risk that a LAR may consent to for non-therapeutic research.[52] Furthermore, the risk must be deemed by the human subjects review committee to represent no more than a "minor increase over minimal risk."[53]

D. Federal Law: The OHRP Letters

The federal government has weighed in on how to use state statutes about proxy consent in a general medical context to interpret the notion of an LAR in the research context. The OHRP is a federal regulatory body that oversees research with human subjects.[54] Issues of interest to the research community

49. VA. CODE ANN. § 32.1-162.18 (2004).

50. *Compare* VA. CODE ANN. § 32.1-162.18 (2004) *with* 45 C.F.R. § 46(D) (2006).

51. An attorney-in-fact is essentially a Durable Power of Attorney—someone appointed to make decisions for the person when he is incapable.

52. Non-therapeutic research is essentially research that offers no prospect of direct benefit (today this research would be called no-direct-benefit research).

53. For a discussion of what this means, see, for example, David Wendler & Ezekiel J. Emanuel, *What Is a "Minor" Increase over Minimal Risk?,* 147 J. PEDIATRICS 575 (2005), and David Wendler et al., *Quantifying the Federal Minimal Risk Standard: Implications for Pediatric Research Without a Prospect of Direct Benefit,* 294 JAMA 826 (2005).

54. *See* OHRP Fact Sheet, *supra* note 14.

reach the OHRP, which issues opinion letters, in a variety of ways—e.g., investigators submit questions to them, whistle blowers contact them, or the OHRP itself uncovers them when "spot checking" different institutions.[55] We reviewed all letters from the OHRP written between 2000 and 2006, uncovering eighteen letters written during that time that discuss the concept of who may serve as an LAR in the (adult) research proxy context.[56] These letters addressed specific cases. Generally, what was at issue were studies involving incapacitated ICU patients whose participation in research seems to have been based on family consent. As we noted in the Introduction, the federal regulations defer to states on the issue of who is a proper LAR. Thus, the OHRP asks investigating institutions to explain the legal grounds on which they claim that family members are able to give proxy consent. The OHRP considers who has made the judgment, giving most authority to state Attorneys General but also looking, for instance, to hospital counsels' justifications. Sometimes the OHRP suggests that hospitals seek the advice of their state Attorney General's office.

A number of the OHRP letters seem to interpret the existence of a family proxy consent to treatment statute as also authorizing family proxy consent to research.[57] These letters may be interpreted in different ways:

(1) if a family member can give proxy consent to any reasonable treatment,

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55. *See* Telephone Interview with Susan L. Rose, Executive Director, Office for the Protection of Research Subjects, University of Southern California, in L.A., Cal. (Oct. 1, 2007).

56. There are other letters from the OHRP about LARs in the context of proxy consent for children to participate in research. The scope of this Article is limited to adult subjects and thus we do not discuss the different set of issues that arise in the context of proxy consent for children. (While the regulations applicable to adults defer to the states, there are specific federal regulations regarding proxy consent in the case of children and thus these OHRP letters discuss issues irrelevant to our discussion.)

57. Letter from Office for Human Research Prot. to Richard M. Cagen, Adm'r, LDS Hosp. (Feb. 4, 2002) (on file with author), *available at* http://www.hhs.gov/ohrp/detrm_letrs/YR02/feb02e.pdf; Letter from Office for Human Research Prot. to Regis B. Kelly, Executive Vice Chancellor, Univ. of Cal., S.F. (Apr. 11, 2002) (on file with author), *available at* http://www.hhs.gov/ohrp/detrm_letrs/YR02/apr02p.pdf; Letter from Office for Human Research Prot. to Alvin W. Kwiram, Vice Provost for Research, Univ. of Wash. (Feb. 4, 2002) (on file with author), *available at* http://www.hhs.gov/ohrp/detrm_letrs/YR02/feb02g.pdf; Letter from Office for Human Research Prot. to Ralph Snyderman, President, Duke Univ. Health Sys. (Feb. 1, 2002) (on file with author), *available at* http://www.hhs.gov/ohrp/detrm_letrs/YR02/feb02a.pdf; Letter from Office for Human Prot. to Fazwaz T. Ulaby, Vice President of Research, Univ. of Mich. (Feb. 11, 2002) (on file with author), *available at* http://www.hhs.gov/ohrp/detrm_letrs/YR02/feb02n.pdf; Letter from Office for Human Research Prot. to Donald E. Wilson, Dean, Sch. of Med., Univ. of Md. (Feb. 4, 2002) (on file with author), *available at* http://www.hhs.gov/ohrp/detrm_letrs/YR02/feb02f.pdf.

he can also give proxy consent to any reasonable research;

(2) if a family member can give proxy consent to treatment, he can also give proxy consent to this type of intervention in the research context;

(3) if a family member can give proxy consent to treatment, he can also give proxy consent to any research procedure which carries the same degree of risk;

(4) if a family member can give proxy consent to treatment by a particular, mentioned intervention (e.g., ventilation), he can also give proxy consent to this particular intervention in the research context (this is different from number (2), which analogizes research to whatever particular treatment is at issue, e.g., a medication, a particular surgery; while this interpretation compares research to the *particular treatment mentioned here*, e.g., ventilation); and

(5) if a family member can give proxy consent to treatment by a particular, mentioned intervention, he can also give proxy consent to any research with a degree of risk similar to that posed by the specified intervention.

It seems that all of these letters can be interpreted consistent with these five ways. The language of the letters, however, is, to us, most consonant with interpretation (2). This intuition is probably based on a literal reading of the relevant federal regulation, which refers to a "subject's participation in the *procedure(s)* involved in the research."[58] Although this is a reasonable parsing of the actual words of the regulations, it does create some tensions. If someone can give proxy consent to a spinal tap to discover whether the patient has a disease, can he also give proxy consent to a spinal tap in the research context, particularly when it is no-direct-benefit research? Clearly the risk/benefit ratio is different because of the absence of direct benefit to subjects in this example. Perhaps, then, the better position would be to allow proxy consent when the interventions in the different contexts (treatment versus research) have the same degree of risk compared to direct benefits.[59]

The research teams mentioned in these letters sometimes could not rely on a general treatment-proxy statute, because they did not exist in their respective

58. *See* 45 C.F.R. § 46.102(c) (2006).

59. *See* Letter from Office for Human Research Prot. to Richard M. Cagen, *supra* note 57; Letter from Office for Human Research Prot. to Donald C. Harrison et al., Senior Vice President and Provost for Health Affairs, Univ. of Cincinnati (Dec. 20, 2001) (on file with author), *available at* http://www.hhs.gov/ohrp/detrm_letrs/dec01h.pdf.

states. Many of them instead cited laws permitting proxies in different contexts—lifesaving treatment or treatment of the terminally ill,[60] interventions with people in persistent vegetative states (PVS),[61] interventions in emergency situations,[62] and autopsies and organ donation statutes.[63] In most cases, the OHRP did not allow such statutes to be used as precedents for proxy consent to research. They found that because the subjects are not in a PVS or are still living, autopsy and PVS cases are not analogous.

One letter does explicitly note that basing proxy consent to research on proxy consent to treatment is most apposite when the research is "therapeutic"—when there is direct benefit to participants.[64] The letter nevertheless suggests that more could conceivably be allowed if the intervention is in the subject's best interests, or even in the placebo context when the risk is small and the potential benefit great.

Another question is what happens if there is no family-proxy in the treatment or other relevant context? In one letter, a law provides for proxy consent by the guardian, DPA, or other "legal authority."[65] In two other letters, the investigators say—and the OHRP agrees—that Pennsylvania law permits a "legally responsible person" to give proxy consent, although this person is nowhere defined.[66] Conversely, in a letter to researchers at Vanderbilt, the OHRP

60. *See* Letter from Office for Human Research Prot. to Donald C. Harrison et al., *supra* note 59; Letter from Office for Human Research Prot. to Donald C. Harrison et al., Senior Vice President and Provost for Health Affairs, Univ. of Cincinnati (Feb. 5, 2002) (on file with author), *available at* http://www.hhs.gov/ohrp/detrm_letrs/YR02/feb02i.pdf; Letter from Office for Human Research Prot. to Floyd D. Loop, Executive Vice President and Chairman, Cleveland Clinic Found. (Feb. 7, 2002) (on file with author), *available at* http://www.hhs.gov/ohrp/detrm_letrs/YR02/feb02k.pdf.

61. Letter from Office for Human Research Prot. to Gerald Litwack, Assoc. Dean for Scientific Affairs, Thomas Jefferson Univ., (Jan. 30, 2002) (on file with author), *available at* http://www.hhs.gov/ohrp/detrm_letrs/YR02/jan02m.pdf.

62. *Id.*

63. Letter from Office for Human Research Prot. to Lee E. Limbird, Assoc. Vice Chancellor for Research, Vanderbilt Univ., (Feb. 4, 2002) (on file with author), *available at* http://www.hhs.gov/ohrp/detrm_letrs/YR02/feb02h.pdf.

64. Letter from Office for Human Research Prot. to Donald E. Wilson, *supra* note 57.

65. Letter from Office for Human Research Prot. to John R. Sladek, Jr., Vice Chancellor for Research, Univ. of Colo. (Jan. 31, 2002) (on file with author), *available at* http://www.hhs.gov/ohrp/detrm_letrs/YR02/jan02o.pdf.

66. Letter from Office for Human Research Prot. to Gerald Litwack, Thomas Jefferson Univ. (Jun. 10, 2002) (on file with author), *available at* http://www.hhs.gov/ohrp/detrm_letrs/YR02/jun02a.pdf; Letter from Office for Human Research Prot. to Neal Nathanson, Vice Provost for Research, Univ. of Pa. (Jun. 10, 2002) (on file with author), *available at* http://www.hhs.gov/ohrp/detrm_letrs/YR02/jun02b.pdf (referring to Letter from Office for Human Research Prot. to Gerald Litwack, *supra* note 61).

concludes that there is no non-guardian, non-DPA authority to consent to treatment in Tennessee, and so the same is true of research as well.[67] Finally, in one correspondence, researchers cite statutes showing that a non-LAR may consent to research in their state and the OHRP explicitly disallows it.[68] This may be the only kind of case in which the OHRP does not defer to the states on the question of who is an allowable proxy.

In conclusion, the OHRP seems to allow general treatment proxy statutes that permit family consent to serve as authority establishing that family members can also serve as proxies for research. However, it generally does not consider more specific, treatment-focused proxy statutes to provide grounds for proxy consent to research. The interpretive difficulties noted above will need to be worked out to clarify exactly what it is that individuals should infer about proxy consent to research from the general, somewhat ambiguous statutes.

E. Relevant Case Law

Some of the interpretive issues regarding who should be deemed a proxy decision-maker in the research context could be answered by case law. In deciding cases about DPAs, courts may have interpreted the relevant federal and state statutes and articulated their own views about who should be allowed to provide proxy consent. A review of the case law, however, uncovered only two cases that deal explicitly with proxy decision-making in the research context, and only one of these cases involved adult subjects. In each, the court assumed that family may give proxy consent. The issue they addressed was whether family can consent to a particular kind of research. We address this issue both positively and normatively in our discussion Section below.

The first case, *T.D. v. N.Y. State Office of Mental Health*,[69] occurred in the mental health context. The plaintiffs included six involuntarily committed psychiatric patients who were deemed incapable of giving or withholding informed consent and were fearful that they would be entered into research protocols by proxies. The state regulations, discussed in two decisions by the appellate division, contained provisions regarding volunteering incapable subjects to participate in research, including "'more than a minimal risk' nontherapeutic and possibly therapeutic experiments."[70] These studies involved

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67. Letter from Office for Human Research Prot. to Lee E. Limbard, Assoc. Vice Chancellor for Research, Vanderbilt Univ. (Jun. 26, 2002) (on file with author), *available at* http://www.hhs.gov/ohrp/detrm_letrs/YR02/jun02e.pdf.

68. Letter from Office for Human Research Prot. to John S. T. Gallagher, President, North Shore Univ. Hospital (Jan. 14, 2002) (on file with author), *available at* http://www.hhs.gov/ohrp/detrm_letrs/YR02/jan02f.pdf.

69. 690 N.E.2d 1259, 1260 (N.Y. 1997).

70. T.D. v. N.Y. State Office of Mental Health, 228 A.D.2d 95, 97 (N.Y. App. Div. 1996); *see*

approved and experimental antipsychotic and psychotropic drugs, "which are capable of causing permanent harmful or even fatal side effects and/or highly invasive painful testing procedures."[71] Several involved a "medication-free or placebo phase in which subjects, who are being successfully treated with approved drugs, are taken off the medication for a period of time before the experimental medication is introduced, during which time they may relapse and suffer the adverse symptoms of their particular illnesses or disorders."[72]

The decision of the state's highest court contains some ambiguities, but does say that that the regulations were promulgated beyond the authority of the Office of Mental Health because that authority was exclusively granted to another agency. The court went on to say that the regulations violated the state's constitutional and common law as well as the Federal Constitution.[73] The opinion is far-ranging and introduced concerns about the lack of notice and review of capacity decisions and surrogate decisions. It seemed to express concerns about the entire idea of this kind of research being decided by a proxy. And it plainly affirmed the court below.

The appellate division explicitly set forth a proxy consent standard. It held that:

> When the proposed medical course does not involve an emergency and is not for the purpose of bettering the patient's condition, or ending suffering, it may be doubtful if a surrogate decisionmaker—a guardian, a committee, a health-care proxy holder, a relative, or even a parent could properly give consent to permitting a ward to be used in experimental research with no prospect of direct therapeutic benefit to the patient himself.[74]

The second case, *Grimes v. Kennedy Krieger Institute*, involved a lead abatement intervention study, with parents consenting on behalf of their children.[75] This case is outside the scope of our review because the holding was limited to children. However, it should be noted that, in deciding the case, the court cited the exact language used in the *T.D.* case.[76]

Cases addressing proxy consent outside the research context mostly fall into two categories. The first category consists of cases involving life-sustaining or

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also T.D. v. N.Y. State Office of Mental Health, 626 N.Y.S.2d 1015, 1020 (N.Y. App. Div. 1995).

71. *T.D.*, 228 A.D.2d at 97-98.

72. *Id.* at 98.

73. The Court of Appeals offered the view that the appellate court should not have gone beyond the holding about the regulatory body's authority, but dismissed the appeal because this argument was not actually made by the defendants. *See* T.D., 690 N.E.2d at 1260.

74. *T.D.*, 626 N.Y.S.2d at 1020.

75. 782 A.2d 807 (Md. 2001).

76. *Id.* at 855-56.

life-saving treatment.[77] The second category consists of mental health cases, e.g., civil commitment, conditional release, refusal of medication, and refusal of electroconvulsive therapy.[78] There are also cases in the context of emergency care,[79] nursing homes,[80] kidney donation,[81] sterilization,[82] and abortion.[83] Other specific issues discussed in these cases are the standard of proof;[84] and whether a public agency can refuse to be appointed a guardian in certain cases.[85] None of these cases discuss whether it is legitimate to look at the existence of proxy consent in other contexts when attempting to make decisions about proxy consent in the research context.

Indeed, many of the interpretive questions regarding the statutes, such as

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77. *See, e.g.*, Rasmussen v. Fleming, 741 P.2d 674 (Ariz. 1987); Dep't of Insts., Grand Junction Reg'l Ctr. v. Carothers, 821 P.2d 891 (Colo. Ct. App. 1991); *In re* Tavel, 661 A.2d 1061 (Del. 1995); *In re* Gordy, 658 A.2d 613 (Del. Ch. 1994); *In re* Browning, 568 So. 2d 4 (Fla. 1990); *In re* L.H.R., 321 S.E.2d 716 (Ga. 1984); *In re* Lawrance, 579 N.E.2d 32 (Ind. 1991); Woods v. Commonwealth, 142 S.W.3d 24 (Ky. 2004); DeGrella v. Elston, 858 S.W.2d 698 (Ky. 1993); *In re* Doe, 583 N.E.2d 1263 (Mass. 1992); Rosebush v. Oakland County Prosecutor (*In re* Rosebush), 491 N.W.2d 633 (Mich. Ct. App. 1992); *In re* Torres, 357 N.W.2d 332 (Minn. 1984); Murphy v. Wheeler (*In re* Warren), 858 S.W.2d 263 (Mo. Ct. App. 1993); Jason S. v. Valley Hosp. Med. Ctr. (*In re* L.S.), 87 P.3d 521 (Nev. 2004); *In re* Conroy, 486 A.2d 1209 (N.J. 1985); *In re* AB, 768 N.Y.S.2d 256 (Sup. Ct. 2003); *In re* Univ. Hosp. of the State Univ. of N.Y. Upstate Med. Univ., 754 N.Y.S.2d 153 (Sup. Ct. 2002); *In re* Crum, 61 Ohio Mis. 2d 596 (1991); *In re* Fiori, 673 A.2d 905 (Pa. 1996); San Juan-Torregosa v. Garcia, 80 S.W.3d 539 (Tenn. Ct. App. 2002); *In re* Infant C., 37 Va. Cir. 351 (Cir. Ct. 1995); *In re* Grant, 747 P.2d 445 (Wash. 1987); *In re* Hamlin, 689 P.2d 1372 (Wash. 1984); Belcher v. Charleston Area Med. Ctr., 422 S.E.2d 827 (W. Va. 1982); Lenz v. Phillips Career Dev. Ctr. (*In re* L.W.), 482 N.W.2d 60 (Wis. 1992).

78. *See, e.g.*, Myers v. Alaska Psychiatric Inst., 138 P.3d 238 (Alaska 2006); Von Luce v. Rankin, 588 S.W.2d 445 (Ark. 1979); *In re* L.H.R., 321 S.E.2d 716 (Ga. 1984); Harada v. Hatsuye T. (*In re* Hatsuye T.), 689 N.E.2d 248 (Ill. App. Ct. 1997); *In re* Boyle, 674 A.2d 912 (Me. 1996); Cohen v. Bolduc, 760 N.E.2d 714 (Mass. 2002); *In re* Foster, 547 N.W.2d 81 (Minn. 1996); *In re* Welch, 686 N.W.2d 54 (Minn. Ct. App. 2004); *In re* A.A., 885 A.2d 974 (N.J. Super. Ct. Ch. Div. 2005); Sanders v. N.M. Health & Env't Dep't (*In re* Sanders), 773 P.2d 1241 (N.M. Ct. App. 1989); *In re* S.A., 582 A.2d 137 (Vt. 1990).

79. *See, e.g.*, Stafford v. La. State Univ., 448 So. 2d 852 (La. Ct. App. 1984); Miller v. R.I. Hosp., 625 A.2d 778 (R.I. 1993).

80. *See, e.g.*, Rains v. Belshé, 38 Cal. Rptr. 2d 185 (App. 1995).

81. *See, e.g.*, Hart v. Brown, 289 A.2d 386 (Conn. Super. Ct. 1972); Little v. Little, 576 S.W.2d 493 (Tex. Ct. App. 1979); Lausier v. Pescinski (*In re* Pescinski), 226 N.W.2d 180 (Wis. 1975).

82. *See, e.g.*, Wirsing v. Mich. Prot. & Advocacy Serv. (*In re* Wirsing), 542 N.W.2d 594 (Mich. Ct. App. 1995); *In re* Grady, 405 A.2d 851(N.J. Super. Ct. Ch. Div. 1979).

83. *See, e.g.*, *In re* Doe, 533 A.2d 523 (R.I. 1987).

84. *See, e.g.*, Sabrosky v. Denver Dep't of Soc. Serv., 781 P.2d 106 (Colo. Ct. App. 1989).

85. *See, e.g.*, *In re* D.A., 100 P.3d 650 (Mont. 2004).

whether those authorizing treatment proxies also authorize research proxies, are not resolved by court decisions. They simply do not address this question. In fact, the cases themselves ask these questions regarding the statutes. Hence, the force of treatment proxies as exemplars of proxies in the research context remains unclear in the cases no less than the statutes.[86]

F. Limitations on Proxy Decision-making in the Research Context

We have discussed whether proxies are allowed and who may serve as proxies. Another important question remains: Are there any limits on proxy decision-making in the research context? We briefly noted limitations built into various statutes regarding research and we have identified some general limitations on proxy decision-making in Table 3. Our more extensive description of the California and Virginia laws showed different approaches to this question, and the *T.D.* case suggested a bar on proxy consent for no-direct-benefit research.

In this section we focus on statutory provisions that prescribe limits on what research proxies may decide. The only two family proxy statutes that put limits on proxy consent are California and Virginia.[87] Only seven other states (in eight different statutory sections) prescribe limits on guardian decision-making, court decision-making, or authorization of guardian decision-making.[88] A number of jurisdictions allow proxy consent only if, among other things, the intervention is intended to preserve the life of or prevent serious impairment or injury to the subject. There are additional requirements in these states too, as well as alternate ways to obtain consent. In Alaska, for example, the intervention must also not involve significant risk of physical or psychological harm.[89] In Connecticut, a guardian may consent if the intervention is intended to preserve the life of or prevent serious impairment to the ward (the statute also provides other routes, e.g., approval by an IRB); the ward's primary care physician approves; and the ward is developmentally disabled. For court approval in Connecticut for the developmentally disabled, the standard is not "preserving life, etc.," but the procedure must be "intended to assist the ward to regain the ward's abilities."[90] In Florida and Nevada, a court may permit a guardian to consent if the intervention is "of direct benefit to, and intended to preserve the life of or prevent serious impairment to the physical or mental health of the ward; or it is intended

86. We do not catalog the treatment proxy cases simply in the interests of space. In essence, the same arguments we make in the statutory context would apply in the case context. And since most states have some treatment proxy statute, those states also having cases on treatment proxies does not appreciably clarify our question.

87. See Table 1.

88. *Id.*

89. *Id.*

90. Conn. Gen. Stat. § 45a-677 (Supp. 2007).

to assist the ward to develop or regain his abilities." In New Jersey, the experiment must be necessary and directly related to the goals of treatment. In North Dakota, no hazardous or intrusive experimental research is allowed unless it is directly related to specific goals of a person's treatment program.[91]

In short, the limitations imposed on proxy decision-makers encompass a number of requirements that are put together differently in the different jurisdictions. The three key standards are:

(1) intended to preserve the life of or prevent significant injury/impairment to the physical or mental health of the ward;

(2) intended to assist the ward to develop or regain his or her abilities; and

(3) directly related to the goals of treatment.

Additional requirements are imposed in some states. For instance, some states have rules stating that an intervention cannot be done if it involves significant risk of physical or psychological harm or that interventions must be of direct benefit to the participant. It is important to note, however, that most jurisdictions do not give a standard that applies uniquely to the research context.

Table 3 shows that there are other standards governing a substituted decision-maker's treatment decisions in different contexts; for example, a standard that permits a proxy to make any decision that a parent could make for his child. In this Article we do not explicitly draw inferences from these other laws for limitations on proxy consent to research. The kind of reasoning from treatment to research that we have applied to the question of who may consent may also be applied to limitations on consent.

IV. DISCUSSION

Because federal regulations have left the issue of proxy consent for research to the states, we planned for this review to be a comprehensive survey of state statutes bearing on that issue. After reviewing all state statutes that may have a bearing on the question of proxy consent for research, we found that there is relatively thin guidance from state statutes. Although nine states theoretically allow family consent for research, the scope and restrictions particular to each state make generalizations impossible, even among those states. Moreover, while there is considerably more state statutory guidance in the treatment context, it is far from clear how such statutes might be used to justify proxy consent for research. Considering that many states lack even de facto surrogate consent laws

91. *See* Table 1.

for treatment contexts, the issues become even murkier.

In considering how we might attempt to clarify this complex matter, at least three key questions arise: first, whether proxy consent for research is permitted at all; second, who may serve as proxies; and third, what kinds of research may they consent to—i.e., should there be limitations on what proxies may decide on behalf of another person? In this Part's first Section we interpret what is currently allowed as a matter of positive law, and in the second Section we discuss what type of regulation would be optimal.

A. The Positive Side of the Law

1. Is Proxy Research Permitted?

The first issue is to what extent proxy consent for research is currently allowed by the law. While the Nuremberg Opinion did not seem to allow proxy consent, it may be that the issue simply was not contemplated at the time it was written. The horrors of Nazi research were perpetrated on people who were decisionally capable. Later ethics documents allowed proxy consent. The federal regulations concerning research allow any Legally Authorized Representative to give proxy consent. This, of course, does not answer the question as to whether proxy consent is allowed in any given state. Instead, each state is expected to provide the answer for its particular jurisdiction.

Our survey of the states addresses whether the states allow proxy consent for research at all. Twenty-seven states explicitly allow at least some type of proxy consent for research. But what about the states that do not explicitly mention proxy decisions for research? A statute that is silent on this point could be read as not permitting proxies to agree to research, on the ground that being placed into a study is unlike any other medical decision made on a patient's behalf. On the other hand, instead of implicit prohibition, silence may mean that the legislature simply regarded research as analogous to other medical contexts, so proxies have the authority to consent, at least to research that does not involve major risks (most treatment decisions that proxies will be authorized to make will not involve major risks, or their benefits will offset their risks). It is worth remembering that OHRP allows analogizing from the treatment to the research context, and all states allow proxy consent for treatment. Still, because OHRP seems to require a positive reference to state or local law defining LAR, an absence of relevant laws (e.g., family surrogate treatment laws), from the federal perspective, may mean that that kind of surrogate-based research is not allowed in those states.

If a court wants to address this issue as a matter of state law, one place it should look for guidance is to prohibitions on proxy consent to treatment in a particular jurisdiction. For instance, some jurisdictions prohibit proxy consent for certain types of irreversible sterilization or psychosurgery. Such constraints make

two kinds of argument possible. First, one could argue that it is also impermissible for proxies to consent to these particular interventions in the research context. Second, and more interestingly, one could argue that these limitations on proxy consent in the treatment context may support analogies to the research context. Is consent to research more like consent to sterilization or consent to another kind of surgery? Is a research protocol more like a mental health treatment to which a proxy may consent, or one such as psychosurgery, to which some proxies may not consent? Considered in these terms, one clearly relevant factor is the seriousness of the research intervention.

Another possible approach that jurisdictions that do not have relevant statutes could take is to ask whether research decisions fall into one of the general kinds of decisions proxies are empowered to make. For instance, does "any medical intervention" include research? Does "any decision a parent could make for his child" include research? Certainly, "any decisions the patient could have made for himself" would seem to include decisions authorizing participation in research. The point is that when a state gives a general categorization of kinds of decisions proxies may make, that implies that a proxy may make them. Indeed, giving the general categorization only makes sense on the theory that a proxy will decide, so these laws necessarily envision proxy consent. So, if a decision is in one of the general categories (e.g., "any medical decision the subject could make"), then a proxy decision-maker may be appointed to make that decision. Still, there is often no direct statement about who may serve as that proxy. Moreover, asking whether research is a "medical decision" simply repeats our initial question.

The examples listed in Table 3, Column 4 are even less helpful. Requiring decisions based on substituted judgment or best interests seems to countenance proxy decisions, but doing so does not determine who may serve as proxies or when proxies should be allowed to decide issues—e.g., can they consent to a particular course of research for a particular patient? That a proxy may make a decision, say, in your best interests, surely does not mean that he can decide for you *anything* that is in your best interests. For example, can one make her incompetent nephew travel to Timbuktu because she determines that it is in his best interests? Within a health care context, allowing or requiring decisions of certain kinds (e.g., "best interests," "substituted judgment") seems to countenance research that meets those standards. But a number of assumptions are necessary for these statutes to be understood as authorizing proxy consent, and the statutes are even less helpful in authorizing particular kinds of decisions made by proxy decision-makers.

Hence many state statutes seem to countenance proxy consent but sometimes do not state, first, whether specific types of research fall into the general categories within which proxies are authorized to make decisions, and, second, who is an allowable proxy. As we saw earlier, the "prohibiting" statutes may be

clearer because they put specific limits on proxy consent to research.

Positively, then, it would seem that many places do allow consent to research by certain kinds of proxy. We also believe that—while non-appointed, non-court proxies are the most important—most jurisdictions, if push came to shove, would allow a court itself to make many proxy decisions, even if provision for this were not made explicitly in the statutes. Consider that proxy consent to research is sometimes in the best interests of a person; if the person cannot make the decision herself, it seems that *someone* must be authorized to decide. Of course, the federal regulations seem to contemplate that some entity has the power to decide—namely, whomever the states designate as LARs. Since courts are widely perceived as the optimal default decision-makers, it is hard to imagine that a court would not be allowed to make proxy decisions.

2. Who Can Serve as Proxies?

Our second question—targeted at those jurisdictions that allow proxy consent to research—involves what categories of individuals are allowed to be proxies for research decisions, and in what order of priority these categories of individuals stand. Again, we are most interested in informal proxies and, in particular, families. Many statutes are silent on this issue. As in the case of whether to allow proxies at all, one may read this silence in different ways: One may think the statutes forbid informal proxies to decide or that they allow any plausible proxy to decide. An intermediate position is to look again at other contexts, and to allow informal research proxies in some situations, but not others.

In any event, we should be clear that a statute mentioning one kind of proxy need not be read, at least in certain circumstances, as forbidding others that are not mentioned. Failure to mention family may not be decisive. A statute listing all the decisions a guardian may make does not necessarily imply that no one other than a guardian may make them (e.g., that a guardian may consent to antibiotics for her developmentally disabled ward does not mean that family members may not make this decision). Of course, if a statute says that *only* guardians may decide certain things; or if a fair reading of the guardianship statute is that guardians will be the exclusive decision-makers in a given context; or if a given statute purports to list *all* permissible research proxies, then such statutes may indeed exclude informal proxies. Determining the specific implications of each rule must be done on a state-by-state basis.

Also, we may draw inferences from proxy laws in contexts other than research. As a matter of positive law, it is of interest that all but sixteen states allow families to give proxy consent to treatment in general or to certain treatments in particular (although the latter may be too specific to be taken as precedents here). Again, the OHRP does rely on treatment proxies to argue for

the permissibility of family research proxies. On the other hand, one may see the "glass-half-empty" here too: In at least sixteen states there is *no* basis for using a reference to family proxies in the treatment context to justify using them in the research context. There are also the "general categorizations" statutes that provide a basis for arguing in favor of family proxies, but again, though they may entitle us to countenance proxy decisions to research, these statutes explicitly limit the ability of the proxy to give consent.

Our principal question, however, is whether, as a result of statutory interpretation, we *should* take the existence of family proxies in the treatment context to mean that family proxies are also allowable in the research context. Again, there are arguments on both sides. Some arguments in favor of the broad interpretation are the following: First, many of the interventions in the research context are also found in routine medical care. If proxies are allowable in the latter context, then they should also be allowed in the former. At least in some cases, it seems unlikely that the interventions will be particularly dangerous. Second, if the research is potentially helpful, then it may be in the subject's best interests to enroll in the program. In this sense, a proxy research decision is very similar to a proxy treatment decision. Finally, proxies are allowed to decide upon treatments that are very risky, if the potential benefit compensates for the risk. Many research decisions are less risky than some of these decisions.

There are also considerations in favor of a more conservative approach. The fact that an intervention is allowed in the treatment context does not mean that it is or should be allowable in the research context. For instance, as we noted, the risk/benefit ratio for a procedure like a spinal tap is very different in the treatment than the no-direct-benefit research context. Second, one might argue that research should not be conceived as being in individual subjects' best interests in the way that clinical treatment aims to be. Research is not primarily designed to meet an individual patient's needs, whereas treatment is. To conceive of the research as a treatment designed for a particular patient would be a "therapeutic misconception."[92] Finally, the rare treatment decisions that are extremely risky may justify only some research decisions at best; in addition, in really rare high-risk cases, it already is often the case that some formal decision-maker is called upon to review the proxy decision.

Perhaps the answer is to suggest again that family proxy consent to research be allowed in the case of some research—e.g., research that is most like treatment—and be prohibited in others. That is, we need not say either that

92. *See generally* Paul S. Appelbaum et al., *False Hopes and Best Data: Consent to Research and the Therapeutic Misconception*, 17 HASTINGS CENTER REP. 20 (1987); Paul S. Appelbaum et al., *The Therapeutic Misconception: Informed Consent in Psychiatric Research*, 5 INT'L J.L. & PSYCHIATRY 319 (1982); Charles W. Lidz & Paul S. Appelbaum, *The Therapeutic Misconception: Problems and Solutions*, 40 MED. CARE V55 (2002).

family proxy consent to research is allowed or that it is not allowed depending solely on whether there is a proxy treatment statute. Other considerations may be important, such as whether the research is like treatment in some significant way. Again, though, it may make sense to be more expansive than this: One may read silence as a complicit way of allowing inferences to be drawn from statutes allowing treatment proxies to the research proxy context.

3. What Are the Limits on Proxy Consent?

The third question in our positive discussion concerns when a proxy is authorized to consent.[93] That is, if a proxy is authorized to decide, can he decide "yes" to *this particular* piece of research? Only nine states speak directly to this question in their research statutes and only one court has addressed this issue directly. Earlier, we noted the different positions that the states took. When a state does not speak to the issue of when proxy consent can be given in its research statutes, then one can reach a variety of different conclusions about which standard governs the proxy's decision-making ability: One could assume that the broadest standard in such cases applies—the substituted judgment of the patient, or, if that is not known, her best interests; one could infer that the general standard used in the treatment context also applies in the research context (e.g., that one may decide as a parent may decide for his or her child); or one could look at specific, analogous treatment contexts and argue that the standard from those situations should apply to the current one.

There are a number of considerations, of course, that will feed into a decision about the appropriateness of proxy consent to different kinds of research. These include the risks of the research intervention, the degree of the patient's incapacity, the ability to ascertain the patient's competent wishes, the likely benefit to the patient, the absence of other promising non-research interventions that will offer similar benefits, as well as other considerations. Below we address the normative question of whether we should limit proxy choices, and, if so, how.

It will be clear that our three questions interact in a variety of ways. To say that proxy consent should be allowed does not say when it should and should not be allowed. And empowering proxies to make decisions does not say which proxies should be making decisions, or when they should have this power. We may want more protective proxy policies under certain circumstances, e.g., when the risks inherent in a research program are high. However, it is only by thinking about each of these three questions that one can arrive at a comprehensive statute.

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93. *See* Diane E. Hoffman & Jack Schwartz, *Proxy Consents to Participation of the Decisionally Impaired in Medical Research–Maryland's Policy Initiative*, 1 J. HEALTH CARE L. & POL'Y 123 (1998).

B. The Normative Side of the Law

Thus far this Article has looked at the positive law that exists addressing questions related to the permissibility of proxy consent to research. We have examined explicit laws regarding proxy consent to research and we have asked whether we may infer a legal position on its legality based on how states have dealt with proxy consent issues in other contexts.

We now turn to the normative dimension of our three questions. Specifically, we look at the following: First, should proxy consent to research be allowed? Second, who should be designated to serve as proxies and in what order? Third, under what conditions should proxies decide "yes" to proposed research?[94]

One important note before we begin: Our positive law interpretation and normative discussion interact in important ways. Our answers to the normative questions may provide reasons to interpret positive law in particular ways. If it is right or better that *X*, then perhaps we should interpret a law to mean *X* when such an interpretation is plausible. It is also the case that the inferences can go in reverse: if there is a lot of positive law that *X*, then there may be a societal consensus that *X* is right or good.[95]

1. Should Proxy Research Be Permitted?

The first normative question is whether we should allow proxy consent for research at all. We think the answer is a clear "yes." More than half of the states explicitly allow proxy consent to research of some kind and all states have some kind of treatment proxies. The widespread existence of proxy consent—both as a

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94. For discussion of the normative issues, see Jessica Wilen Berg, *Legal and Ethical Complexities of Consent with Cognitively Impaired Research Subjects: Proposed Guidelines*, 24 J. L. MED. & ETHICS 18 (2001); Richard J. Bonnie, *Research with Cognitively Impaired Subjects: Unfinished Business in the Regulation of Human Research*, 54 ARCHIVES GEN. PSYCHIATRY 105 (1997); Dallas M. High, *Advancing Research with Alzheimer Disease Subjects: Investigators' Perceptions and Ethical Issues*, 7 ALZHEIMER DISEASE & ASSOCIATED DISORDERS 165 (1993); Dallas M. High et al., *Guidelines for Addressing Ethical and Legal Issues in Alzheimer Disease Research: A Position Paper*, 8 ALZHEIMER DISEASE & ASSOCIATED DISORDERS 66 (1994); Kim et al., *supra* note 15; Henry J. Silverman et al., *Protecting Subjects with Decisional Impairment in Research: The Need for a Multifaceted Approach*, 169 AM. J. RESPIRATORY & CRITICAL CARE MED. 10 (2004); Dave Wendler et al., *Views of Potential Subjects Toward Proposed Regulations for Clinical Research with Adults Unable to Consent*, 159 AM. J. PSYCHIATRY 585 (2002).

95. An example of the latter type of reasoning occurs in the "cruel and unusual punishment" context, which turns on prevailing norms of decency. For example, the Supreme Court took there to be a consensus that executing people with mental retardation was wrong because most states had passed statutes forbidding it. *See* Atkins v. Virginia, 536 U.S. 304, 313-16 (2002).

matter of law and of practice—may be evidence that there is a societal consensus that proxy consent is a permissible and desirable phenomenon.

This position can also be justified normatively. While forbidding research on the decisionally incapable would ensure that we would not exploit vulnerable persons, such a prohibition would have unfortunate consequences. Most importantly, in cases where the only way to learn about an illness that affects the decisionally impaired is to study decisionally impaired people, a ban against such research would mean that we could never learn about the illness. For example, studying severe dementia requires researchers to enroll the severely demented—a group who are inherently a class of decisionally impaired people. Or consider people with particular kinds of late-stage cancer who are necessarily decisionally impaired (e.g., patients suffering from late-stage brain cancer); we can only study their condition by enrolling decisionally impaired people in research.

Certainly there are limits to this kind of consequentialist argument. Some studies may provide too little potential benefit to subjects while placing them at significant risk; these studies should not be done even if they are the only feasible way to research a condition. But to forbid *all* research with decisionally impaired people would sweep so broadly that it could cripple research into certain illnesses.

In addition, one can imagine many cases of research with decisionally impaired people that would not be controversial to most people. Take the case, for example, of a person giving an advance directive consenting to a particular research study, prior to becoming decisionally impaired. Assume that the study involves known procedures and risks that have not changed over time and that the subject clearly understood when giving the advance consent. Or take the case of a study with substantial potential benefit and very limited risk. If we forbid all research consented to by proxies, we prevent studies that most people would think are perfectly acceptable. Finally, there are justice concerns in the sense that we deprive the group of decisionally impaired patients of the possible benefits of research, which they may be unable to get in any other way.

There are three possible answers to the question of whether we should allow proxy consent for research at all. The first is to forbid it altogether. The second is to allow it potentially in all research decisions. And the third is to acknowledge limits on proxy decision-making by only allowing it in some cases. We will begin by discussing the first of these options, leaving our discussion of the second and third options to the following section on proxy decision-making.

There are contexts in which we flat-out forbid proxy consent. For example, we do not let guardians volunteer their wards to be married. On the other hand, the rationale in these cases is probably that the decision is too personal for someone else to make, ought to involve understanding on the ward's part, and is not essential. For example, a guardian's belief that a marriage would be in someone's interest should certainly not trump what the person *wants,* no matter

whether the person is competent. Even if the guardian and the person agree about the marriage, we may require a competent choice by the person himself to enter into a marriage. Additionally, a marriage decision is also clearly optional in a way that some medical decisions are not.

There are other examples of this kind of flat-out ban on someone else deciding something for her ward. For instance, a guardian or other proxy cannot write a will for a person, nor can he volunteer his incompetent ward to engage in a boxing contest. Rules with parents are even stricter—e.g., a parent cannot volunteer his child to work when the child is underage. Each example has its own complexities, but each shows that there are some things guardians and proxies are simply forbidden to decide.

Research choices, however, are more like medical choices and less like choices to marry. Research choices are less personal, and they involve the *kind* of decisions that proxies already make all the time in the medical arena. In addition, the subject's competency is not crucial in research—you need to understand what you are doing when you get married for the marriage to have meaning, but such understanding is not necessary when a doctor gives you medicine or performs surgery. Finally, some research decisions are not optional, so to speak: for example, a research study that is a subject's only hope for treatment may be one where we want *someone* to make the decision. That is, the decision is not optional in the same way a decision to marry is, and not deciding in this situation becomes a de facto decision to exclude the person from the study.

Normatively, then, the answer to the question of whether we should have proxy consent to research at all seems to be yes. Entirely eliminating proxy research appears to be quite an undesirable option. If all research involving people who are incompetent to decide for themselves is disallowed, then we exclude a whole population from the advantages of research and research participation, and we severely curtail research advances for their conditions. Moreover, such a ban would preclude people from altruistically consenting to research. Finally, such a rule would frustrate the desires of individuals who may have wanted to participate in this research, and who might have even expressed this clearly in an advance directive.

2. Who Should Serve as Proxies?

Our second normative question is who should be allowed to serve as proxies and in what order we should designate potential proxies. As with the question of whether there should be proxy consent to research at all, the existence of family proxy statutes, together with the widespread practice of family consent in the treatment context, suggests that there is a broad, societally sanctioned consensus that proxy consent is permissible and appropriate for the research context as well as for treatment.

As a normative matter, then, we argue that family proxies should be allowed in the research context. A guardian or court need not be involved. Families generally know their family members best and care about them most. And, unlike in the context, say, of psychiatric treatment for unwilling patients—where we might not want to pit family member against family member—in the research context the patient must agree to the intervention. Hence, we believe that families should be considered LARs for purposes of the law in this arena.

Indeed, family proxies in the research context may be less problematic at times than those in the treatment context. In the research context there will *always* be a thorough committee review of the decision, unlike in the treatment context where the proxy's will gets implemented without further review. Further, in the research context an IRB exists to ensure that the risk/benefit ratio of the research is favorable, that the investigators have considered every possible safeguard for subjects, and that other requirements have been fulfilled.

When there is more than one person available to serve as a proxy, (e.g., a named person who has a DPA for research decision-making, a DPA for treatment, and a family member), then who should serve as the proxy? If there is a DPA for research, this is a relatively easy case: if a person, while competent, chooses a particular person to make decisions for her, and if that selection included decisions in the research context, there is good reason to accept that proxy's decisions. In these cases, the potential subject herself has selected a particular person and asked us to respect that proxy's judgment in the research context. Each potential subject should know best whom to trust with these decisions. If a DPA for research has been selected, that proxy's judgment should have first priority.

A DPA for treatment should be recognized next. Again, the potential subject has personally pre-authorized a trusted person to look after her medical needs. Some research implicates the medical interests of its subjects. Even when it offers no prospect of direct benefit, it may have the same degree of consequentiality as certain medical decisions. Finally, the subject has endorsed the DPA as someone who can be trusted to best discern her wishes and interests.

Whether a guardian or an informal family proxy should be next in line is a vexing question. One solution is that family proxies should come first. They are likely the most available, know the potential subject better, and care deeply about him or her. On the other hand, what should we make of the fact that family members, if there is a guardian available, are not the guardians themselves? One might think that if they truly cared about the potential subject, they would have volunteered or been chosen to be a guardian. There are arguments on the other side, however. First, if the guardian is a guardian of the estate, family members may have declined to participate because they were not competent to make financial decisions. Indeed, it seems like we might prefer family proxies to guardians of the estate whenever the latter have been chosen for their financial

expertise, as that base of knowledge is not inherently salient to research decisions. Second, even if the guardian is a guardian of the person, family members may not have volunteered because of the time-intensive nature of looking after that person. But this does not mean that these family members do not still care for the potential subject, and they may still want to be consulted about important decisions.

Even if we accept that a person's refusal to volunteer to be a guardian does not rule that person out as a proxy, we still must ask who is the most likely to be the best decision-maker in the research context. Guardians have a fiduciary duty to make the best choice for their wards. But in certain circumstances, family proxies may also bear a similar duty, even if it is not as plain as in the case of a guardian.[96] Guardians may be more impartial, as a non-guardian family member's own interests may be more involved in the ward's outcome. For instance, family members are likely to benefit more if the research helps the subject. Or, more pessimistically, a family member may be concerned about receiving the potential subject's inheritance. It is not difficult to imagine a case where an adult child of a person with Alzheimer's disease might not be very concerned about his parent's well-being, but may be concerned about the depletion of his inheritance due to the costs of care for his parent. On the other hand, it seems wrong to presume that family members will not try to make the very best decision for the ward; as much as their own interests are implicated in treatment decisions, they probably care about the ward more than a non-family guardian. Finally, regarding "knowledge of the ward," it would seem that family members typically have the upper hand over a fiduciary guardian who is not bound by familial ties. But, then again, because they lack intimate knowledge of the ward, a non-family guardian may make more efforts—do more "due diligence"—to find out what the ward would have wanted and what would be best for him.

Given all of these considerations, we believe the following would be the best protocol. If a family member is the guardian, the researcher should go to him or her (assuming no DPA exists). If not, we should look at the treatment proxy laws to determine who should come next. If most treatment proxy statutes put guardians before families, for example, we would follow this, but would allow one exception: when the guardian is very hard to find—if it will take

96. *See, e.g.*, 37 C.J.S. *Fraud* § 6 (2007) (stating that a fiduciary is "a person, having a duty . . . to act primarily for another's benefit," and that "the primary question" in determining whether a fiduciary relationship exists in a family "is whether one family member has dominion over the other family member in regard to the transaction involved"); Tamar Frankel, *Fiduciary Law*, 71 CAL. L. REV. 795, 808 (1983) (stating that when a parent "substitutes for a child who is unable to take care of himself," this substitution "fall[s] into a status category but is not automatically fiduciary"); Elizabeth S. Scott & Robert E. Scott, *Parents as Fiduciaries*, 81 VA. L. REV. 2401, 2401-03 (1995) (characterizing parents as fiduciaries of their children, but acknowledging that the parent-child relationship differs from most traditional fiduciary relationships).

considerable effort to find and consult her—family members should be permitted to serve as proxies.

Our main point is that family should be allowed to serve as proxies. In what order they should be consulted is a difficult question. We believe that DPAs should come first, but that whether family or guardians should come next remains open to debate. It also seems important to collect empirical evidence about what is actually happening—e.g., the frequency of each kind of proxy actually being consulted in the context of research projects. This could help give a sense of what the societal consensus is about who may serve as proxies and in what order.

3. What Should Be the Limits on Proxy Consent?

The third normative question concerns when proxies should be able to consent. There are two general positions one can take on this issue. First, IRBs now struggle with the task of making sure that research with decisionally incapable people (indeed, all research) has a favorable risk/benefit ratio—that the risks are justified by the potential benefit. In weighing these factors, IRBs may take into account the potential benefits to society that the research may provide. Once an IRB has made an initial positive determination, a proxy may volunteer his ward for the research provided it meets some general standard that applies to all proxy decisions—e.g., that the intervention is what the person would have wanted if competent, or is in the person's best interests (not necessarily best medical interests), or some combination thereof.

The second position would be to argue that IRBs and proxies must apply a standard above and beyond the substituted judgment and best interests standards. That is, the first position is that IRBs and proxies are given no standard in addition to a general risk/benefit inquiry and best interests/substituted judgment standard in order to decide; and the second position is that their decision must meet some further specified standard.

It is important to note one complication that exists with any standard that is used—proxies generally do not seem to know how to apply them. For instance, proxies—even when given a substituted-judgment-if-known standard—appear to use a combined standard of substituted judgment and best interests.[97] Laws specifying *how* proxies *should* make decisions may be pointless because there is no way to ensure that this is what is happening and it seems idealized, based on the fairly limited evidence we have on how proxies make decisions. On the other

97. *See, e.g.*, Jason H.T. Karlawish et al., *How Do AD Patients and Their Caregivers Decide Whether To Enroll in a Clinical Trial?*, 56 NEUROLOGY 789 (2001); Greg A. Sachs et al., *Ethical Aspects of Dementia Research: Informed Consent and Proxy Consent*, 42 CLINICAL RES. 403 (1994).

hand, a similar point in an analogous situation has not led us to abandon our legal standards. We do not use the fact that juries seem often to make insanity determinations based on how deranged the person seemed, rather than whether he met the criteria for the insanity defenses to recommend that we jettison the criteria for insanity.[98] It may be that the standard binds discretion in some ways. And we do not want people to think that they should feel free to ignore the interests protected by the legal standard and to make arbitrary decisions concerning their wards. Indeed, perhaps the combined standard that people seem to use in this context is a result of proxies *trying* to apply the legal standard. If they just decided however they wished, we might get worse quality decisions than we currently have. In short, there may be good reasons to articulate a proxy decision-making standard even if it does not seem as though proxy decision-makers are conscientiously applying it.

Again, the second possibility is to propose a standard for what research should be allowed. We discussed a number of suggestions regarding potential standards earlier. The three key standards mentioned were: intended to preserve life or prevent significant injury/impairment to the physical or mental health of the ward; intended to assist the ward to develop or regain his or her abilities; and directly related to the goals of treatment. Additional requirements have been imposed in some states. For instance, a ban on interventions that involve significant risk of physical or psychological harm, or a requirement that the research be of direct benefit to the participant.

We suggest that, even if we do not follow the first tack, the second should allow more room for research that is not necessarily intended to benefit the subject. We would propose considering a kind of risk/benefit calculation which would allow some no-direct-benefit research. This is in contrast to some of the standards above, which require the possibility of some benefit. In the end, we focus on the hardest case, suggesting that the only risk/benefit ratio that might conceivably be forbidden out of hand—or be presumed to be forbidden—should be very high risk, no-direct-benefit research. If we allow proxy consent in the hardest of cases, it will also obviously be permissible in easier cases when the risk is lower and/or the prospect of benefit greater.

Let us first consider the kinds of interventions with decisionally impaired people that we might want to forbid. Three historical cases serve as examples.[99]

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98. For discussion of the literature on how juries make insanity judgments, including original research, see, for example, Norman J. Finkel & Sharon F. Handel, *How Jurors Construe "Insanity,"* 13 LAW & HUM. BEHAV. 41 (1989); Jennifer L. Skeem & Stephen L. Golding, *Describing Jurors' Personal Conceptions of Insanity and Their Relationship to Case Judgments*, 7 PSYCHOL., PUB. POL'Y & L. 561 (2001).

99. These are not exactly on point in that one involves children, the second involves coercion and not capacity, and the third involves kidney donation and not research. Still, they are all

The first is the Willowbrook study.[100] Developmentally disabled patients in a hospital for the mentally retarded were infected with hepatitis to study its natural course in an institutional setting. These were institutionalized people who did not have the capacity to consent to the intervention. They were, then, doubly incapacitated: because of their mental state and because of the coercive nature of institutionalization.

In this case, the experimenters solicited the proxy consent of the patient's parents or family members. However their family members' consent was invalid, as the proxies were under undue influence because their consent was a precondition to admission. This form of coerced consent is uniformly considered to be invalid. It is true that this disease is more of a problem for the institutionalized than it is for people in non-institutionalized communities, so studying the disease course perhaps required having institutionalized participants. However, the developmentally disabled people included in the Willowbrook study were arguably not necessary to the experiment, as other institutionalized individuals would obviously have had a greater capacity to consider the risks and benefits of being a part of the study, and provided their own personal consent. Yet without knowing the details of the study we cannot know if there was something special about the disease that merited a specific focus on people with developmental disabilities. But, even if studying them were "necessary," we may not want such studies done, or at least not in situations where coercive means are used upon proxy decision-makers. In short, this appears to be a case of exploiting vulnerable people. Whether family proxies could consent if given proper understanding and a real choice is at least questionable. In the end, the study has been viewed as a model of mistreatment of the vulnerable in the research context.[101]

The second example occurs in the *Kaimowitz* case,[102] which concerns experimental psychosurgery on a prisoner who was informed that he was unlikely to be able to leave the institution without the psychosurgery, but that he might be able to leave if it was performed. The court considered the inmate's diminished capacity, as well as the extreme paucity of knowledge about the risks of the procedure. It focused mostly, though, on the coercive nature of the

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examples of cases where we might—or perhaps should not be allowed to—subject the ward to the intervention on the basis of a proxy decision.

100. David J. Rothman, Were Tuskegee & Willowbrook 'Studies in Nature'?, 12 Hastings Center Rep. 5, 5-7 (1982).

101. *See* Chez Josephine v. Columbia Univ., No. 101362-2002, 2004 NY Slip Op 51006U at *8 (N.Y. App. Div. June 29, 2004) (describing the legislative reaction in New York to the Willowbrook experiment); *see also* ROBERT J. LEVINE, ETHICS AND REGULATION OF CLINICAL RESEARCH 70-71 (2d ed. 1988); Rothman, *supra* note 100.

102. Kaimowitz v. Dep't of Mental Health, 13 Crim. L. Rep. (BNA) 2455 (Mich. 1973); *see also* ALEXANDER D. BROOKS, LAW, PSYCHIATRY AND THE MENTAL HEALTH SYSTEM 902-24 (1974).

inmate's situation. Most interesting for us, the court held that "although guardian or parental consent may be adequate when arising out of traditional circumstances, it is legally ineffective in the psychosurgery situation. The guardian or parent cannot do that which the patient, absent a guardian, would be legally unable to do."[103] It is not made clear why proxies may consent when their ward is legally unable to consent in other circumstances—e.g., when they are incompetent to consent to a hernia operation—but may not provide consent here. Still, the bottom line is that there could be no proxy consent to the psychosurgery. The court adverted to the extreme risk and very low possibility of benefit of the psychosurgery as one of the factors in its decision. The fact that this case has more to do with coercion than capacity is unimportant; the important thing is that the court has placed limits on proxies even when the subject him or herself, for whatever reason, could not consent.

The third example does not concern a research study, but is similar in that a medical procedure was done for the benefit of someone else and not for the medical interests of the person undergoing the procedure. In this case, *In re Pescinski*,[104] a long-institutionalized man with schizophrenia was volunteered by his guardian-sister to be a kidney donor for his other sister. Here, as in no-direct-benefit research, the man would be acting in the interests of his sister, as the medical intervention would not advance his interests at all. Of interest in the case is that there were several other family members who, from a medical point of view, were potentially eligible donors. Each of the potential donors, however, had a reason to say no—one was too old, one was too young, one was a farmer with many children, etc. The court decided that the guardian-sister could not volunteer her incompetent brother for the surgery. The case seemed too much like it was a case of "harvesting" the organs of a person who could not consent. While in one sense the risk of the procedure was relatively low—major surgery always carries risks, but complications in kidney donations are uncommon—in another sense the risk was high: if the incompetent brother should have an accident and need another kidney, he could potentially lose his life.

We should also note that in this case, the potential patient did not belong to a class of individuals that would eventually benefit, in a medical sense, from the procedure. The case is most relevant when we think of the possible situations in which proxy consent could be provided for procedures that would harm the patient, but aid third parties. Particularly in the case of kidney donation, the "necessity" requirement is implicated, as many potential kidney donors exist.

These three cases raise the question of the permissibility of proxy consent to research. We should arguably never allow proxy consent to research with these kinds of risk/benefit ratios. In each case the subjects could not consent

103. BROOKS, *supra* note 102, at 914.

104. 226 N.W.2d 180 (Wis. 1975).

themselves. In each case a proxy decision seemed problematic, whether because of the risk/benefit ratio or the exploitation of incompetent people when others could have participated equally as easily. We have already given cases where most people find proxy consent to be acceptable and a few hard cases should not convince us to ban proxy consent altogether. But the argument here is different—certain kinds of proxy consent are so problematic that perhaps we should characterize them in a particular way and wholly rule them out.[105]

Let us focus, then, on the hardest case—medical research that is high risk and offers no prospect of direct benefit to its subjects. While the psychosurgery case could conceivably have had direct benefit for the subject, it is still true that the risks were exceedingly high. The developmentally disabled patients in the Willowbrook case, on the other hand, would not have benefited themselves from the study as it focused on the impact the disease has as it goes untreated. The kidney donation case also provides a good example of this type of situation as it involved risks for the patient and provided no potential direct medical benefit.

What should we do in these hard cases? One possibility is to say that in any case that falls in the category of high risk and no direct benefit, proxy consent should be forbidden. We believe this is problematic for two reasons. First, we think the most important issue in deciding on research for an incompetent person is what he would have wanted if competent. If such a patient, while competent, had signed an advance directive that he wanted to participate in high risk, no-direct-benefit research—indeed, the case becomes even stronger if he identified a particular research project, whose risks and benefits he fully understood—then his enrollment in the study would be appropriate. We might even say that if there is clear evidence that the person would have wanted this research—through letters, public statements, etc.—then we should permit such research on a substituted judgment basis as well. While it is highly unlikely that this kind of evidence will be available in most cases,[106] in those cases where it does exist, proxies should be permitted to consent to high risk, no direct benefit research.

The second point is that some interventions of this kind are justified even when they are not in the medical interests of the ward. As a counterpoint to the *Pescinski* case there is the case of *Hart v. Brown.*[107] In this case the court

105. If we wish to put it in risk/benefit terms, we believe that most people would overwhelmingly agree that minimum risk research is perfectly acceptable, as is a minor increase over minimum risk but with potential benefit. Perhaps more controversial—but still acceptable—would be research with more than a minor increase over minimum risk if there is a prospect of direct benefit, or with a minor increase over minimum risk even if there is no direct benefit. The latter two may be more controversial, and the ability to apply these standards of "minimum risk," "minor increase over minimum risk," and is extremely problematic.

106. *See* Wendler et al., *supra* note 94, at 590.

107. 289 A.2d 386 (Conn. Super. Ct. 1972).

approved the donation of a kidney by a seven-year-old for the sake of her twin sister. The court required that the parents' reasoning, as well as the state of the child, be evaluated. It also noted that, quite apart from her medical interests, it was in the general best interests of the healthy twin to save her sister, whom she loved and wanted to help. In other words, the court countenances that the girl's gratification at being altruistic and her interest in saving her sister were enough to justify this procedure. It will be noted that the necessity requirement is arguably not met here—other kidneys might be available—yet we still may want to grant the twin the right to donate her kidney to her sister.

The point is that if we have an inflexible, bright-line rule, the healthy sister in *Hart* would not have been allowed to save her twin. Of course high risk/no-direct-benefit research can also be like this. A person may want to participate in such research because he recognizes that future generations of his family may benefit; because being a self-sacrificing, altruistic person gives the person great utility; because her caregivers may benefit and be better caregivers (on non-medical measures) to the person; because the person is dying and wants his life and illness to serve a higher purpose or have meaning, in the way the individual constructs that meaning. In other words, if, in the best interests scenario, we focus only on medical benefit, we prevent decisions to participate in research that are, broadly speaking, in the interests of the person as she perceives them.

If we do not want to simply rule out proxy consent to these types of research, there remain two possibilities. First, given that there is always a full ethics committee review by an IRB, we could simply let the proxy decide using a substituted judgment or best interests standard without further direction. Or, second, we could raise a presumption that "high risk, no-direct-benefit research" is impermissible, but allow the presumption to be rebutted if the IRB or proxy can establish that other factors support going ahead with the research. Essentially, there are two issues here: whether there should be a presumption against such research and, if one does exist, what agent should be able to decide if the presumption has been overcome—the IRB and/or the proxy?

As for whether a presumptive standard should be used, there are a number of considerations. Consider a different context: imposing medication on an incompetent patient. Some jurisdictions allow the guardian to require medication if the guardian finds that it is either what the patient would have wanted if competent or that it is in the patient's best interests. Other jurisdictions allow involuntary medication only if it will help the patient recover from a significant illness in a much shorter time than if other interventions are used. Clearly the former gives the proxy greater discretion in deciding. But the latter may prevent decisions from being made that many people would not want to prevent.

In other words, a standard guides discretion and this may useful so long as the standard is good and if it covers most cases that will occur. It is undesirable if there are often cases where we want decisions that depart from the ex ante rule,

and it is hard to rebut the presumption. It is also undesirable if the standard is too hard to apply. A standard that bases decision-making authority in terms of degrees of risk, for instance, has been shown to be difficult to apply.[108] The same is likely true of standards that discuss different degrees of benefit to the patient.

In short, the choice between no rule and a presumptive rule probably turns on, and should turn on, how much we want to guide the discretion of the decision-maker.

Which brings us to the next issue: if we do use a presumptive rule, both the IRB and the proxy must apply it, albeit in different ways. The IRB will *always* make the initial decision in reviewing the protocol. They will ask whether there are circumstances in which the presumption against this research could conceivably be rebutted. IRBs are important to involve, as they will have more experience than individual investigators. And giving them a central decision-making role will also be likely to lead to greater consistency, as boards' compositions tend to be stable over time.

On the other hand, individual proxies are more likely to be able to spend time on specific issues, with a more finely grained understanding of the complexities presented by particular situations. Once an IRB has decided to approve a research project, it remains for the proxy to look at the individual for whom she is making the proxy decision and decide whether this person would have wanted to be involved in the research and whether it is in her best interest. In short, we could have regulatory language that sets a presumption against involving decisionally impaired individuals in certain types of research, but allow IRB and proxy decision-making to possibly rebut this presumption.

In the end, given all the considerations we have discussed, we believe that the best approach is to maintain current IRB functions and allow proxies to consent to any research which they think the subject would have wanted, or, if this is not sufficiently known, to any research that would be in his best interests (as conceived in a broad sense). That is, we would not lay out a presumption against certain research which the IRB and the proxy would have to rebut. The presumptive rules themselves only give illusory guidance because applying them is fraught with difficulty. And giving proxies the highest level of authority to decide for their loved ones what they think best is probably the best way to protect subjects.

In concluding, we note that we would impose three further requirements on

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108. *See, e.g.*, Seema Shah et al., *How Do Institutional Review Boards Apply the Federal Risk and Benefit Standards for Pediatric Research?*, 291 JAMA 476 (2004); Helen M. Sharp & Robert D. Orr, *When "Minimal Risk" Research Yields Clinically-Significant Data, Maybe the Risks Aren't So Minimal*, 4 AM. J. BIOETHICS W32 (2004); Henry Silverman et al., *Variability Among Institutional Review Boards' Decisions Within the Context of a Multicenter Trial*, 29 CRITICAL CARE MED. 235 (2001).

research with the decisionally impaired. First, the participation of decisionally impaired individuals should, generally, be necessary—fulfilling the so-called "necessity requirement" as discussed in the kidney donation case.[109] Second, their dissent from any research participation should always be honored. Finally, we should require a heightened degree of proxy understanding before we accept their consent. If the first requirement is not met—if non-decisionally impaired people are available to do the study—then we have no good reason to volunteer the decisionally impaired in the study. We would have a caveat even to this, though. If the research is potentially very beneficial to the subject and the subject could not get such benefit unless he participates, then his participation perhaps should be allowed. As to the second requirement, we believe that forbidding dissenting people to be volunteered makes sense even if the research is potentially beneficial. Being studied primarily for the benefit of other people should not be something a person is forced to do even if she is considered incapable of effectively refusing. Finally, given the risks inherent to research, and the fact that the proxy decision-maker herself is not assuming the risk, we should make sure she truly understands the risks and benefits of the research. Dispelling any "therapeutic misconception" is particularly important here. Indeed, for research that poses the very highest risk with no benefit we may want to assure ourselves that the proxy understands and is considering the appropriate factors in making her decision. This is a question that deserves greater study.

In considering the various laws examined here, we believe that the California law comes closest to setting a reasonable example. We believe that the law is a little narrow—e.g., we might want to allow proxy consent to research for diseases that are not "serious or life-threatening" but nevertheless substantially affect the lives of those affected. On the other hand, it does not use standards in terms of risks that are hard to understand and apply. Moreover, it explicitly does allow family proxies, thereby reassuring investigators.

V. LIMITATIONS OF OUR RESEARCH AND DIRECTIONS FOR FUTURE RESEARCH

The biggest limitation regarding the positive part of our study is our focus on state statutes and six years of OHRP letters, and not on other sources of law. State statutes are typically the most important source for this kind of study because they have the full force of law and, at times, directly set forth the legal standards that govern an issue. Some states, however, have regulations and letters from their Attorney General—sources of law that were not discussed in this Article—that bear on our question. While we did look at relevant case law, we found little guidance in court opinions regarding the appropriate answers to our questions. Thus, this study looks primarily at just a few pieces of a much larger

109. *See Hart*, 289 A.2d at 386.

puzzle. Future research into these other sources of law would be helpful.

The normative part of our study is a first step in a bigger project of justifying normatively a proxy consent protocol in the research context. We need further analysis of these issues and more research into what researchers, subjects, and citizens think about this issue. For example, empirical studies are needed that look at how proxies are actually used in the research context in different jurisdictions—and how adequate proxies are at meeting statutorily-imposed standards. Do most jurisdictions use informal family proxies in the research context, despite the fact that doing so lacks clear state law authorization?[110] Is there a consensus among stakeholders of all kinds about who should serve as proxies and in what order? Is there also a consensus among stakeholders about which sorts of research should be allowed in this context, and which not—e.g., seriously risky research? While there are some empirical studies of such issues, more would be worthwhile.[111]

Other evidence should be gathered on whether the current system works in the case of decisionally vulnerable populations—are IRBs making the normatively correct judgments? Is there evidence on whether decision-makers consistently understand different levels of risk and benefit? Is there a difference in decisions which use a presumptive rule and those which do not?

VI. CONCLUSION

In conclusion, we have surveyed the current state of the law on the question of who may serve as a proxy in different research contexts. This is an important question because there is anecdotal evidence that an unclear answer has hindered important research and left investigators and IRBs to seek guidance from state and federal agencies.

Our results show that nine states specifically allow family members to serve as proxies in the research context, at least in some cases, and that twenty-seven states allow some kind of proxy decision-making in the research context. In the treatment context, there are seventeen states that explicitly allow family proxy decision-making for general treatment decisions. We also looked at general proxy decision-making standards. The two most detailed laws on proxies in the research context do allow families to make decisions on behalf of a decisionally impaired individual. And the OHRP appears to allow general treatment proxy statutes to authorize family proxies in the research context. There are also

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110. *See, e.g.*, Jason H.T. Karlawish et al., *Informed Consent for Alzheimer's Disease Clinical Trials: A Survey of Clinical Investigators*, 24 IRB: ETHICS & HUMAN RES. 1, 3-5 (2002).

111. *See* Scott Y.H. Kim et al., *Impaired Decision-Making Ability in Subjects with Alzheimer's Disease and Willingness to Participate in Research*, 159 AM. J. PSYCHIATRY 797 (2002); *see also* Kim et al., *supra* note 15, at 1395-1400.

statutes that place limitations on when proxies may make these types of decisions (e.g., only if the intervention is intended to preserve the life of or prevent serious injury to the subject).

In addition to discussing how to interpret unclear or ambiguous laws, we also looked at the three central normative questions in this arena: whether proxies should be allowed; who should serve as proxies; and what limits should exist on the types of things to which proxies can consent?

Conclusively answering all the questions we have raised would be impossible in a brief paper. Developing a model statute is arguably desirable, given the amount of multi-site research being done on these issues. In addition, the factors playing a role in deciding a number of issues—e.g., whether family proxies should be allowable—would not seem to differ depending on the patient's home state. However, it may also be the case that we prefer that different states experiment with such issues.

Whether or not a model statute is desirable at this point, however, it is certainly desirable that states adopt clear, well thought out statutes that specify who may serve as a Legally Authorized Representative. We suggest that laws similar to California's be adopted. In any event, such statutes should address our three main questions—whether proxies may consent to research, and, if so, which individuals should serve as proxies, and for which sorts of research they can provide consent. Finally, future research is needed on a variety of issues. Rules on proxy consent are necessary to allow important research to be done in an ethically appropriate manner.

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TABLE 1: STATE STATUTES ADDRESSING PROXY CONSENT & RESEARCH

Discussed in text supra III.B.1

State	Cite	Family as Legally Authorized Representative	Non-Guardian Surrogate	Guardian	Court
Alabama					
Alaska	ALASKA STAT. §§ 13.26.150, 47.30.830 (2006)			§ 13.26.150(e)(4) *Only if intended to preserve life or prevent* serious impairment § 47.30.830 Not if it involves significant risk of physical or psychological harm (limit applies to all experimental procedures, not just guardian-made decisions)	
Arizona					
Arkansas	ARK. CODE ANN. § 28-65-302 (1987)				Guardian, only with court order approval, for abortion, sterilization, psychosurgery, or removal of bodily organs
California	CAL. HEALTH & SAFETY CODE § 24178 (West 2006)	Detailed law discussed in text, *supra* Subsection III.C.1			
Colorado	COLO. REV. STAT. § 27-10.5-114 (2002)			§ 27-10.5-114 For developmentally disabled ("DD") persons	
Connecticut	CONN. GEN. STAT. § *45a-677(e)(6)* (2007)			For the mentally retarded, a guardian may not *consent to experimental biomedical or* behavioral procedures or participation in any biomedical or behavioral experiment, unless it (A) is intended to preserve life, (B) is intended to assist in regaining abilities and has been approved for the ward by the court or (C) has been (i) approved by a recognized institutional review board or (ii) endorsed or supported by the Department of Mental Retardation, and (iii) approved for the ward by such ward's primary care physician	*See* entry in guardian column
Delaware	DEL. CODE ANN. tit. 16, §§ 1121, 1122, 5176 (2003)	§§ 1122, 5176 Rights devolve to next of kin, guardian, or representative in mental health pharmacological research Consent may be waived if in patient's best interest, and there is prior written approval of guardian, or if none, of next of kin, and court approves on affidavit		§§ 1121, 1122 Guardian or representative may consent if patient adjudicated incompetent	§ 5176 Court must approve of pharmaceutical research
District of Columbia	D.C. CODE §§ 7-1305.09, 21-2047(c)(2) (Supp. 2007)	§ 7-1305.09 Consent of mentally retarded or of guardian or parent		§ 7-1305.09 For DD, patient's consent or consent of parent or guardian is required before involvement in experimental research	§ 21-2047(c)(2) Guardian in the case of the mentally ill only if the power is expressly set forth in the order of appointment or after subsequent hearing and order of the court

Florida	FLA. STAT. §§ 394.4598, 744.3215(6)(e), 765.113 (2006)			§§ 394.4598, 744.3215(6)(e), 765.113 Guardian advocate cannot consent to research without IRB approval or without court order		§§ 394.4598, 765.113 Guardian consent is acceptable for research that lacks IRB approval so long as court approval exists §744.3215(4)(b) Court may permit guardian to consent if "[i]t is of direct benefit to, and is intended to preserve the life of or prevent serious impairment to the mental or physical health of the ward; or it is intended to assist the ward to develop or regain his or her abilities"
Georgia	GA. CODE ANN. § 37-3-162 (2006)			If a treatment is not a standard psychiatric treatment, patient or guardian must consent		If not standard psychiatric treatment and consent is given by someone other than the patient or guardian, court must approve
Hawaii						
Idaho						
Illinois	405 ILL. COMP. STAT. 5/2-110 (2005); 410 ILL. COMP. STAT. 50/3.1 (2005)	50/3.1 Looks to prior consent of the patient, but if that is unavailable, then to guardian, spouse, parent or authorized agent				5/2-110 In case of mental health, if minor or under guardianship, a parent or guardian can provide consent only with a court order of approval and if treatment is in best interest of ward
Indiana						
Iowa						
Kansas	KAN. STAT. ANN. § 59-29b78 (2006)					For people with alcohol or substance abuse problems, consent is required from a legal guardian who has obtained authority to consent from a court
Kentucky						
Louisiana						
Maine						
Maryland						
Massachusetts						
Michigan	MICH. COMP. LAWS § 330.1629 (1999)					Guardian-provided consent, but only with a court order of approval for extraordinary procedures
Minnesota	MINN. STAT. § 524.5-313 (Supp. 2007)					Guardian-provided consent, but only with a court order of approval
Mississippi						
Missouri	MO. REV. STAT. §§ 431.064, 630.115 (Supp. 2007)	Consent to experimental treatment by attorney-in-fact, legal guardian, or family in order of priority given; patient may dissent Limitations when patient has expressly withheld consent	Durable power of attorney	Guardians may consent as well as others		

Montana	MONT. CODE ANN. §§ 53-20-147, 53-21-147 (2007)	No research without informed consent of the resident or patient, or the resident/patient's parents or guardians or a responsible person appointed by the court after consultation with specialists; Consent must be obtained by the patient if competent *and* the guardian or parents or responsible person or "friend"; Statutes apply to people with "developmental disabilities" or "serious mental illness"			
Nebraska					
Nevada	NEV. REV. STAT. § 159.0805 (2003)				Guardian shall not consent to experiment unless specifically empowered by the court, which shall authorize it only if it is of direct benefit to the patient and intended to preserve the life or to prevent serious impairment to the mental or physical health of the ward or assist in developing or regaining abilities
New Hampshire	N.H. REV. STAT. ANN. § 464-A:25 (2006)				Guardian-provided consent, but only with a court order of approval
New Jersey	N.J. STAT. ANN. §§ 30:4-24.2(d)(2), 30:4-27.11d (West 1997)				For patients an institutions governed by the State Department, if patient is incompetent, court determines if the experiment is necessary. Requires direct relationship between goals of treatment and goals of experiment
New Mexico	N.M. STAT. § 43-1-15 (2003)			Petition for guardian for civilly committed patient if he is incapable of consenting to research	
New York	N.Y. MENTAL HYG. LAW § 80.01 (McKinney 2006); N.Y. PUB. HEALTH LAW § 2442 (McKinney 2002)	PUB. HEALTH LAW § 442 If subject is incapable, consent to research "shall be subscribed to in writing by such other person as may be legally empowered to act on behalf of the human subject"; Language vague, but may include family For instance, a note in MENTAL HYG. LAW § 80.01 states that the legislature wishes to "strengthen the surrogate decision-making role of parents and other family members"			
North Carolina	N.C. GEN. STAT. § 122C-57 (2005)		Durable power of attorney/advance directive		

North Dakota	N.D. CENT. CODE §§ 25.01.2-09(4), 23-03.1-40(12) (2002); N.D. CENT. CODE § 30.1-28-12 (Supp. 2007)			§ 25-03.1-40(12) Right not to be subjected to experimental research without informed consent of patient or guardian (note that this appears under section regarding commitment procedures; may apply to patients adjudicated and found not incapacitated)	§30.1-28-12 Guardian-provided consent, but only with a court order of approval (for guardians of incapacitated persons) § 25.01.2-09(4) At institutions for the DD, no medical behavioral or pharmacological research without court order; no hazardous or intrusive experimental research unless directly related to specific goals of person's treatment program
Ohio						
Oklahoma	OKLA. STAT. tit. 63, § 3102(6) (2007)	For IRB-approved experimental treatment, test or drug in the case of a terminally ill or persistently unconscious patient: may obtain informed consent of legal guardian, durable power of attorney, or family member in order of priority; these parties cannot consent over a patient's objection	Durable power of attorney may give consent	Guardian may give consent		
Oregon						
Pennsylvania	20 PA. CONS. STAT. ANN. § 5521 (West 2005)			Guardian-provided consent, but (d) requires a court order of approval for experimental biomedical or behavioral medical procedure or participation in biomedical or behavioral experiment	*See* entry in guardian column
Rhode Island						
South Carolina						
South Dakota						
Tennessee						
Texas						
Utah						
Vermont						
Virginia	VA. CODE ANN. § 32.1-162.18 (2005)	Detailed law discussed in text, *supra* Subsection III.C.2				
Washington	WASH. REV. CODE § 74.42.040 (2001)			In case of residents in nursing homes, residents and guardians, if any, have a right to give informed, written consent before participating in experimental research		
West Virginia						

Wisconsin	WIS STAT. ANN. §§ 51.61(1)(G), 155.05(3) (1), 155.05(3) (West 2006)		§§ 51.61(1)(G), 155.05(3) (1), 155.05(3): Health care agent may not consent to experimental mental health research unless durable power of attorney form expressly provides.	§§ 51.61(1)(G), 155.05(3): Persons receiving services for mental illness, developmental disability, or alcoholism or drug dependency: right not to be subjected to research without patient and guardian consent after consultation with independent specialists and patient's legal counsel; must first be approved by institution's research and human rights committee and by department.	
Wyoming					

TABLE 2: STATE STATUTES ADDRESSING FAMILY PROXY CONSENT & TREATMENT

Discussed in text supra III.B.2

State	Cite	Treatment	Life-Sustaining Treatment	Mental Health/Developmental Disabilities Treatment	Other Interventions
Alabama	ALA. CODE § 22-8A-11 (2006)		If a patient has not executed a do not resuscitate order and he or she is incompetent, physician may execute one together with guardian or durable power of attorney or family, taking into consideration what the patient would have wanted and where there is no hope that patient will regain ability to make decisions		
Alaska					
Arizona	ARIZ. REV. STAT. ANN. § 36-3231 (2003)	If no guardian or durable power of attorney, family in order of priority			
Arkansas					
California	CAL. HEALTH & SAFETY CODE § 121020 (West 2006)				Consent for HIV testing and disclosure of test results if patient is not competent, in order of priority
Colorado	COLO. REV. STAT. §§ 15-14-401, 27-10-114 (2002)				Families may request protective services
Connecticut	CONN. GEN. STAT. §§ 17a-238, 19a-582 (2007)			§ 17a-238(f)(3) For mental patients	§ 19a-582 Consent for HIV testing if patient is incapable in order of priority; families may request protective services
Delaware	DEL. CODE ANN. tit. 31, § 3908 (2003)				Families may request protective services in emergency contexts
District of Columbia					
Florida	FLA. STAT. §§ 415.105; 415.1051 (2006)				No protective services without patient's consent, or—if patient lacks capacity—that of his or her caregiver, guardian or family
Georgia	GA. CODE ANN. §§ 31-9-2, 31-36A-6, 37-4-21 (2006)	§ 31-36A-6 Also must consent specifically to admission, transfer and discharge	§§ 31-9-2, 31-36A-6 Families may consent to do not resuscitate order		§ 37-4-21 Families may request protective services (for non-emergency mental health services)
Hawaii	HAW. REV. STAT. § 327E-5 (2004)	If surrogate is not designated or unavailable, go to other family members			
Idaho					
Illinois	755 ILL. COMP. STAT. 5/11a-17; 40/20 (2007)		Including do not resuscitate order, but not for mental health		
Indiana					

Iowa	IOWA CODE § 144A.7 (2005)		If patient has not executed a do not resuscitate and he or she is incompetent, physician may execute one together with guardian or durable power of attorney or family			
Kansas						
Kentucky						
Louisiana	LA. REV. STAT. ANN. § 28:223 (2007); LA. REV. STAT. ANN. §§ 40:1299.53, 40:1299.58 (2001)	§ 40:1299.53 List of individuals able to consent			§§ 28:223, 40:1299.58 For mentally retarded persons	
Maine	ME. REV. STAT. ANN. tit. 18-A, § 5-806 (1998); ME. REV. STAT. ANN. tit. 18-A, § 5-805 (Supp. 2006)		If a patient has not executed a do not resuscitate order and is incompetent, physician may execute one together with guardian or durable power of attorney or family; surrogate may withdraw life-saving treatment if guardian has not been appointed or is not available			
Maryland						
Massachusetts	MASS. GEN. LAWS ch. 201D, §§ 5, 16 (2004)	§ 16 If no proxy appointed, may rely on informed consent of responsible parties to the extent permitted by the law	§ 5 Agent's authority subject to limitations on proxy			
Michigan						
Minnesota	MINN. STAT. § 144.651(10)(b) (2003); MINN. STAT. § 253B.03(6) (Supp. 2007)	§ 144.651(10)(b) When a patient is admitted and is unconscious, comatose, or unable to communicate, family may participate in treatment, unless it is known that patient does not want treatment			§ 253B.03(6) For civilly committed patients, if they are incompetent and have no guardian, then their nearest relative holds the power to consent; if a guardian exists, then the guardian controls consent	
Mississippi	MISS. CODE ANN. §§ 41-30-21, 41-41-211 (1972)	§ 41-41-211 By surrogates, i.e., agents other than guardians, including family			§ 41-30-21 Request for discharge from voluntary inpatient treatment recognized if the patient is incompetent and the request is made by parent, legal guardian or other representative	
Missouri						
Montana	MONT. CODE ANN. § 50-5-1201 (2007)					For safety devices, patient or legally appointed representative may consent
Nebraska						

Nevada	NEV. REV. STAT. §§ 449.613, 449.624, 449.626 (2005)		If a patient has not executed a do not resuscitate order and he or she is incompetent, physician may execute one together with guardian or durable power of attorney or family			
New Hampshire						
New Jersey						
New Mexico						
New York	N.Y. MENTAL HYG. LAW §§ 80.01-13 (McKinney 2006)				State establishes state-wide quasi-judicial surrogate decision-making process which aims to strengthen the role of parents and other family members	
North Carolina	N.C. GEN. STAT. § 90-21.13(a) (2005)	No informed consent action where certain conditions are met if proxy does not get consent from patient, or spouse, parent, guardian or nearest relative				
North Dakota	N.D. CENT. CODE § 23-12-13 (2007)	Family may give informed consent for incapable person; excludes consent for sterilization, abortion, psychotherapy but does not mention research				
Ohio	OHIO REV. CODE ANN. §§ 2133.08B, 5123.86 (LexisNexis 2007)		§ 2133.08B If a patient has not executed a do not resuscitate order and he or she is incompetent, physician may execute one together with guardian or durable power of attorney or family	§ 5123.86 For major procedures, if patient is incapable due to mental illness, a natural or court-appointed guardian may give informed consent; in case of an emergency decision-making ability flows in order of priority; for surgery for DD or electro-convulsive therapy, consent can come from resident's guardian, spouse, next of kin		
Oklahoma	OKLA. STAT. tit. 36, § 6804 (1999)	If a patient is incapable, then their representative decides			Mental health patients, before major operation, must inform family	
Oregon	OR. REV. STAT. §§ 127.540, 127.635 (2005)		If a patient has not executed a do not resuscitate order and he or she is incapable, physician may execute one together with guardian or durable power of attorney or family			
Pennsylvania						
Rhode Island	R.I. GEN. LAWS § 40.1-26-3 (2006)				For mental patients and the DD, any medical decision; if incompetent, guardian or relative must consent to invasive treatment or surgery	

South Carolina	S.C. CODE ANN. § 44-20-440 (2002)			Admission of DD on request of the DD, if competent, or family, among others	
South Dakota					
Tennessee	TENN. CODE ANN. § 33-3-219 (2001)			For DD and mental health patients: surrogate, including family, may decide on dental, psychological or routine medical or psychiatric treatment	
Texas	TEX. HEALTH & SAFETY CODE ANN. §§ 313.004; 462.009; 597.041 (Vernon 2001)	§ 313.004 Treatment decisions, including those concerning life-saving treatments, made by people in order of listed priority, including family	§ 313.004 Family consent to treatment including life-saving treatment	§ 597.041 For DD: list of family members who may consent to treatment on their behalf	
Utah					
Vermont	VT. STAT. ANN. tit. 18, § 7708 (2002).			In mental health cases, consent of patient, attorney, guardian, or next of kin is required for any form of surgery	
Virginia	VA. CODE ANN. §§ 18.2-76(A), 54.1-2970, 54.1-2986 (2005).	§ 54.1-2986 If a patient is incompetent, doctors may provide or withdraw treatment including life-prolonging treatment, based on the consent of listed people, including family, in order of statutorily created priority		§ 54.1-2970 For a mental health or retardation patient in a facility or receiving case management: emergency treatment without informed consent permitted, if no legally authorized guardian or committee, reasonable efforts are made to advise parent or next of kin of need for action, and no reasonable objection raised on behalf of patient, and two physicians have cause to believe patient unable to consent	§ 18.2-76(A) An incapable woman may be given an abortion only if consent is provided by a parent, guardian, other person standing in loco parentis, or a committee
Washington	WASH. REV. CODE § 7.70.065 (2007); WASH. REV. CODE §§ 70.96A.110(1), 70.96A.120(6) (2002)	§ 7.70.065 If patient is incompetent, statute lists who may consent, in order of priority, including family		§ 70.96A.110(1) If minor or incompetent, parent, among others, may apply for treatment for alcoholism or drug addiction §70.96A.120(6) Automatic notification of family or next of kin of patient's admission to alcoholic/drug addict treatment program unless a non-incapacitated adult patient requests no notification	

West Virginia	W. VA. CODE §§ 16-3C-4(a), 16-30-3, 16-30-8 (2006)	§§ 16-30-3, 16-30-8 If adult surrogate reasonably available and willing to make health care, then can consent on behalf of the patient; if not, proxy selected by attending physician; statute lists persons, including family, from whom the physician may select				§ 16-3C-4(a) Consent for HIV testing of incapacitated patients may be provided by other individuals, in order of statutorily created priority list
Wisconsin	WIS. STAT. ANN. § 50.06 (West 2006)	Lists the order of priority, including family, by which proxies can consent to the admission of incapacitated people to facilities, though proxies do not apply to people diagnosed as mentally ill, DD, or adjudicated incompetent; proxies may also make health care decisions to the same extent as a guardian				
Wyoming	WYO. STAT. ANN. §§ 35-20-105, 35-22-406 (2007)	§ 35-22-406 In absence of designation or if a designee is not reasonably available, consent flows to family in statutorily-defined order of priority				§ 35-20-105 Self, caregiver, conservator, guardian, guardian ad litem or families may request protective services; no protective services can be provided without patient consent, or—if patient lacks capacity—that of the above persons

TABLE 3: STATE STATUTES ADDRESSING POWERS OF SUBSTITUTE DECISION-MAKERS & LIMITATIONS ON POWERS
Discussed in text supra III.B.3

State	Cite	Description of Substitute Decision-Maker ("SDM") Power: A) SDM may decide anything subject could decide if competent, subject to limitations imposed by subject B) SDM may take actions that are expressly authorized by power of attorney C) SDM has same rights as parent with respect to child D) SDM may take actions not limited by power of attorney E) None noted	Standard for Substitute Decision-Makers: A) Substituted Judgment (if wishes known) B) Best Interest(s) C) Not noted	Explicit Court Approval Necessary: A) Abortion B) Sterilization C) Experimental Treatment D) Convulsive Therapy E) Psychosurgery F) Not necessary for any of A-E
Alabama	ALA. CODE § 22-8A-6 (2006)	A (limited by specific instructions of the individual, if any)	C	F
Alaska	ALASKA STAT. §§ 13.26.116, 13.26.150c (2006)	§ 13.26.150 C (when guardian is SDM)	C	F
Arizona	ARIZ. REV. STAT. ANN. § 14-5312 (2005)	§ 14-5312(A) C (for guardian may be modified by guardianship order) § 14-5312(13) A (for mental health)	§ 14-5312(13) A	F
Arkansas	ARK. CODE ANN. § 20-9-602 (1987)	A Note: "to any surgical or medical treatment or procedure"	C	F
California	CAL. PROB. CODE § 45A-656 (West 2007); CAL. PROB. CODE § 2355 (West 2002)	§ 45A-656 A; C (for guardian)	§ 2355 A (guardian)	F
Colorado	COLO. REV. STAT. § 15-14-314(1) (2002)	A	A	F
Connecticut	CONN. GEN. STAT. §§ 45a-656 (West Supp. 2007)	E	C	F
Delaware	DEL. CODE ANN. tit. 12, § 3922 (2001)	A; C (for guardian, but may be modified by guardianship order)	A	F
District of Columbia	D.C. CODE § 21-2047 (2001); D.C. CODE § 21-2047 (Supp. 2007)	§ 21-2047(b)(4) (2001) A Note: "Consent to medical examination and medical or other professional treatment"	§ 21-2047(a)(6) (Supp. 2007) A	F
Florida	FLA. STAT. §§ 394.4598, 765.401 (2006)	§ 394.4598(6) A; B (guardian advocates are subject to the same restrictions as proxies)	§ 765.401 A	§ 394.4598(6) A; B; C; D; E
Georgia	GA. CODE ANN. § 29-4-23 (2006)	A	C	F
Hawaii	HAW. REV. STAT. § 327E-6 (2004)	A	C	F
Idaho	IDAHO CODE ANN. §§ 15-5-312, 66-606 (2001)	§ 15-5-312 A; C (for guardian)	§ 66-606 B	F
Illinois	755 ILL. COMP. STAT. 5/11a-17 (2007)	A (for mental health treatment); B (guardian abilities limited by the Health Care Surrogate Act)	A (guardian)	F
Indiana	IND. CODE § 16-36-1-7 (1993); IND. CODE § 29-3-8-2 (2000).	§ 29-3-8-2(b) C	§ 16-36-1-7(h)(1) B	F
Iowa	IOWA CODE § 144B.6 (2005); IOWA CODE § 633.635 (2003)	§§ 144B.6, 633.635 A	§ 144B.6 A	§ 633.635(2)(b) F

Kansas	KAN. STAT. ANN. § 59-3075 (2005)	§ 59-3075 B (guardian's abilities subject to the control and direction of the court for all things)	§ 59-3075(e)(2) B	F
Kentucky	KY. REV. STAT. ANN. § 387.065 (1999)	C	C	F
Louisiana	LA. REV. STAT. ANN. § 28:227 (2007)	A	A	F
Maine	ME. REV. STAT. ANN. tit. 18-A, §§ 5-312, 5-806 (1998)	§ 5-312 C (for guardian, except as modified by court)	§§ 5-312, 5-806 A (guardian)	F
Maryland	MD. CODE ANN. EST. & TRUSTS § 13-708 (LexisNexis Supp. 2006)	B (guardian's powers limited to those approved by court)	C	F
Massachusetts	MASS. GEN. LAWS ch. 201D, § 5 (2004)	A	A	F
Michigan	MICH. COMP. LAWS § 330.1602 (West 1999)	A	A	A; B; C
Minnesota				
Mississippi		A	B	F
Missouri	MO. REV. STAT. §§ 431.064, 475.120(2) (2007)	E	§ 475.120(2) B	§ 431.064 A; D; E
Montana	MONT. CODE ANN. § 72-5-321 (2007)	B	C	F
Nebraska	NEB. REV. STAT. § 30-2628 (Supp. 2006)	C	A	F
Nevada	NEV. REV. STAT. §§ 159.079, 159.0805 (2003)	§ 159.079(1) A	C	§ 159.0805 B; C
New Hampshire	N.H. REV. STAT. ANN. §§ 137-J:2, 464-A:25 (2006)	§ 137-J:2 A	§§ 137-J:2, 464-A:25 B	§ 464-A:25 B; C; D; E
New Jersey	N.J. STAT. ANN. §§ 3B:12-57, 30:4-24.2 (2007)	E	§ 3B: 12-57 A	§ 30:4-24.2 B; C; D; E
New Mexico	N.M. STAT. § 45-5-312 (2007)	C	A	F
New York	N.Y. MENTAL HYG. LAW § 81.22 (McKinney 2006)	A	A	F
North Carolina	N.C. GEN. STAT. §§ 35A-1241, 35A-1245 (2003)	§ 35A-1241 A	B	§ 35A-1245 B
North Dakota	N.D. CENT. CODE §§ 23-12-13(3), 23-12-13(4) (2002)	§ 23-12-13(3) A	A	§ 23-12-13(4) A; B; C; E
Ohio	OHIO REV. CODE ANN. §§ 2111.13, 5123.86 (LexisNexis 2007)	§ 2111.13 E	§ 2111.13 C	§ 5123.86 D
Oklahoma	OKLA STAT. tit. 30, § 3-118 (West 1991)	A	A	F
Oregon	OR. REV. STAT. §§ 125.320, 127.535 (2005)	§ 127.535 A	§ 127.535 A	§ 125.320 A
Pennsylvania	20 PA. CONS. STAT. ANN. § 5521 (West 2005)	B	A	A; B; C; D; E
Rhode Island	R.I. GEN. LAWS § 40.1-26-3 (2002)	E	A	F
South Carolina	S.C. CODE ANN. § 62-5-312 (2002)	C	C	F
South Dakota	S.D. CODIFIED LAWS § 29A-5-402	A	A	F
Tennessee	TENN. CODE ANN. § 3-219 (2002)	A	A	F
Texas	TEX. PROB. CODE ANN. § 767 (Vernon 2001)	A	A	F
Utah				

Vermont	VT. STAT. ANN. tit. 14, § 3069 (Supp. 2007); VT. STAT. ANN. tit. 14, § 3071 (2002); VT. STAT. ANN. tit. 18, § 8708 (2000)	§§ 3069, 3071 A	§§ 3069, 3071 A	§ 8708 B
Virginia				
Washington	WASH. REV. CODE. ANN. §§ 11.88.010, 11.92.043(5) (West 2006); WASH. REV. CODE. ANN. § 7.770.065 (West 2007)	§ 11.88.010 E	§ 7.70.065 A	§ 11.92.043 (5) F
West Virginia	W. VA. CODE § 44A-3-1 (2006)	A	A	F
Wisconsin	WIS. STAT. ANN. §§ 54.20, 54.25 (West Supp. 2006)	§ 54.20 D	§ 54.20 A	§ 54.25 B; C
Wyoming	WYO. STAT. ANN. §§ 3-2-201, 3-2-202 (2007)	§ 3-2-201 A	§ 3-2-201 A	§ 3-2002 B; D; E

Toward Solving the Health Care Crisis: The Paradoxical Case for Universal Access to High Technology

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INTRODUCTION

Nobody questions that the United States is in a health care crisis. Annual health care spending is over $1.9 trillion, 16% of the nation's GDP.[1] Public spending is about 60% of that total, only 10% below that of public funding in countries with universal health care, yet there is no basic universal health care coverage[2] and over 46 million people are uninsured.[3] The daily news and print media are rife with distressing stories of underinsured individuals who are forced to declare personal bankruptcy, as insurers reimburse for fewer services and elevate co-insurance.[4] In fact, 76% of individuals filing for personal bankruptcy due to medical expenses have insurance but are underinsured.[5]

Not surprisingly, proposed health care reforms focus on the *supply* of health care goods to patients.[6] The problem, as reformers see it, is a simple and obvious one: More people need access to basic health care services.[7] As straightforward

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1. John A. Poisal et al., *Health Spending Projections Through 2016: Modest Changes Obscure Part D's Impact*, HEALTH AFF., W242, W243 (Feb. 21, 2007), http://content.healthaffairs.org/cgi/reprint/26/2/w242.pdf (using 2005 statistics from the Centers for Medicare and Medicaid Services; the Office of the Actuary; the National Health Statistics Group; and the U.S. Department of Commerce, Bureau of Economic Analysis, and Bureau of Census).

2. Steffie Woolhandler & David U. Himmelstein, *Paying for National Health Insurance—And Not Getting It*, 21 HEALTH AFF. 88, 91, 94 (2002).

3. CARMEN DENAVAS-WALT ET AL., U.S. CENSUS BUREAU, INCOME, POVERTY, AND HEALTH INSURANCE COVERAGE IN THE UNITED STATES: 2005, at 20 (2006).

4. *See, e.g.*, John Leland, *When Health Insurance Is Not a Safeguard*, N.Y. TIMES, Oct. 23, 2005, at A1.

5. David U. Himmelstein et al., *MarketWatch: Illness and Injury As Contributors to Bankruptcy*, HEALTH AFF., W5-63 (Feb. 2, 2005), http://content.healthaffairs.org/cgi/reprint/hlthaff.w5.63v1.pdf.

6. The health care plans of the 2008 Democratic presidential hopefuls would create a level of universal, basic health care. *See, e.g.*, NYTimes.com, The Presidential Candidates on Health Care, http://politics.nytimes.com/election-guide/2008/issues/healthcare/index.html (last visited Nov. 30, 2007). Republican proposals suggest market incentives to lower health care costs or tax credits or deductions to enable greater access to private health care plans. *Id.* President Bush recently proposed discontinuing tax exclusions for insurance premiums for some individuals insured through their employers in order to allow equivalent deductions for workers purchasing insurance as individuals. *See* Sheryl Gay Stolberg & Robert Pear, *Bush Urges Tax To Help Cover the Uninsured*, N.Y. TIMES, Jan. 21, 2007, § 1, at 1. By shifting the costs of health care in this way, some consumers may have access to fewer services since they will need to internalize costs. This effectively limits the supply of health care services to these individuals, though it may appear that it alters demand.

7. *See supra* note 6 and accompanying text.

as this reasoning may seem, it is based on a misperception of critical points within the problem.

Altering the supply of basic health care services will not address the current health care crisis. Part of the problem is failure to understand the health care services that support the goals of basic health care. Programs that seek to provide basic health care services to target populations have historically focused on traditional health care services. Yet the crisis stems from rising costs created by consumer choices substantially unrelated to traditional health care services, namely, demand for high technology health care[8] and convenient access to it.[9] While the ontology of this demand is disputed, and demand for ineffective or unnecessary services must be eliminated, it is clear that understanding and appreciating demand for high technology health care must be at the heart of health care reform.[10] Curiously, no existing or proposed health policy seems to

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8. *See, e.g.*, INST. OF MED., MEDICAL INNOVATION IN THE CHANGING HEALTHCARE MARKETPLACE 16 (Philip Aspden ed., 2002) ("[T]echnological change has been the largest single driver of growth in health care spending over the past 50 years."); *see also* Timothy Stoltzfus Jost, *The American Difference in Health Care Costs: Is There a Problem? Is Medical Necessity a Solution?* 43 ST. LOUIS U. L.J. 1, 9 (1999) ("Both comparative research and also research performed within the United States has [sic] identified increased availability and use of health care technology as a major cause in the growth of health care costs. In particular, increased costs attributable to the use of imaging services and tests and other diagnostic technologies have dramatically outstripped general health care cost inflation in recent years."). The demand for high technology health care is so strong, that, as one study indicates, requiring large consumer contributions for high technology health care does not enervate demand. *See* Mark McClellan & Daniel Kessler, *A Global Analysis of Technological Change in Health Care: The Case of Heart Attacks*, 18 HEALTH AFF. 250, 253 (1999).

9. Cultural intolerance for inconvenience mandates the availability of high technology health care within small geographic regions; this causes high health care costs in many integrated health care delivery systems. *See, e.g.*, Jost, *supra* note 8, at 10-12. While the rising cost of pharmaceuticals is also a contributor, consumer preferences for advanced medical technologies and more high technology health care facilities is fueling most of the crisis. *See* Poisal et al., *supra* note 1, at w243. Prescription drugs contributed only 10% to the 9.4% overall increase in health care costs from 2004 to 2005. *Id.*

10. John E. Wennberg and Elliott S. Fisher have long argued that health care providers and facilities drive use of high technology medical care. Over a period of thirty years, they conducted studies focused on Medicare, publishing findings of doctor-imposed preferences, ineffective treatments, and medical waste. *See, e.g.*, John E. Wennberg, Variation in Use of Medicare Services Among Regions and Selected Academic Medical Centers, Duncan W. Clark Lecture, New York Academy of Medicine (Jan. 24, 2005), *available at* http://www.ihi.org/NR/rdonlyres/C871D6885E344C3085296089D9A70B54/0/NYAM_Lecture_FINAL.pdf; John E. Wennberg & Floyd J. Fowler, *A Test of Consumer Contribution to Small Area Variations in Health Care Delivery*, 68 J. ME. MED. ASS'N 275 (1977). Perhaps most disturbing is the finding that decreased utilization of health care services among Medicare patients is associated with better

address directly demand for high technology health care, and the legal structures supporting basic minimum and rationing schemes historically neglect such services.[11] The result is sadly ironic: Increasing the supply of traditional, basic health care services through government or private spending is like offering bottled water to members of a dehydrated population; while it may provide relief to some or even many, it does not address the causes of deprivation, that is, why the needs of a population are not being met, and supplies a resource in an ineffective manner.

At the root of the problem is the lag in legal response to changing medical technology. Our legal structures generally are unresponsive to consumer demand for high technology health care, due to its perceived cost and the misperception that it fails to support the goals of basic health care.[12] State and federal programs

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medical outcomes. *See, e.g.*, DARTMOUTH ATLAS PROJECT, THE CARE OF PATIENTS WITH SEVERE CHRONIC ILLNESS: AN ONLINE REPORT ON THE MEDICARE PROGRAM (2006), *available at* http://www.dartmouthatlas.org/atlases.shtm (follow link on the word "here" in the second paragraph) (last visited Nov. 30, 2007); Elliott S. Fisher et al., *The Implications of Regional Variations in Medicare Spending. Part I: The Content, Quality, and Accessibility of Care*, 138 ANN. INTERNAL MED. 273 (2003); John E. Wennberg et al., *Use of Hospitals, Physician Visits, and Hospice Care During Last Six Months of Life Among Cohorts Loyal to Highly Respected Hospitals in the United States*, 328 BRIT. MED. J. 607 (2004). While special considerations undoubtedly apply to the use of high technology health care at the end of life and to chronic care generally, Wennberg and Fisher raise serious concerns about the misuse (including overuse) of high technology health care and possible patient coercion. This Article seeks to distinguish between the misuse of high technology and patient demand for clinically effective services. Further, this Article does not address patient coercion at any level, but assumes appropriate physician involvement in patient decision-making, comporting with a common law standard for informed consent. In this context, regardless of whether consumers who demand these services are influenced by physician recommendations, if the services are necessary and clinically effective, the demand for them must be considered directly. This Article argues that, paradoxically, focusing on this demand amid some important constraints (clinically efficacy and need, financial limitations including the need to self-ration, limited versus long-term treatment) is a step toward understanding and solving the health care crisis.

11. *See supra* note 6 and accompanying text. Both rationing and basic minimum frameworks seek to reduce costs by providing a limited range of health care services to more people. Oregon has operated its Medicaid program, part of the Oregon Plan, as a rationing scheme since the late 1980s. The approach is premised upon a cost-utility or Quality Adjusted Life Year (QALY) scheme and seeks to ration health care by providing basic services to those who will benefit most from them in terms of life-span and quality of life.

12. As health care technology increases, our conception of necessary health care services expands. Earlier, simplistic frameworks in the 1970s and 1980s sought to ration basic health care either directly, as with the Oregon Plan, or indirectly through the rise of health maintenance organizations (HMOs). HMOs offer a limited range of services provided by designated physicians for a lower cost than traditional fee-for-service medicine. The late 1990s saw a decline in HMO-

fund limited, largely traditional care for select groups of individuals.[13] Public and private health plans may ration care or otherwise deny benefits under certain cost-saving managed care schemes;[14] consequently, high technology health care services are often not covered.[15] Further, most Americans receive their health

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oriented managed care schemes, in response to litigation over denial of what were perceived to be necessary health care benefits, often high technology health care services. Many health law scholars view the current state of health care as a shift back towards something like fee-for-service medicine, where patients pay more for the care they receive and exercise greater control over the treatment options available to them and practitioner selection. See, e.g., Jon R. Gabel et al., *Consumer-Driven Health Plans: Are They More than Talk Now?*, Health Aff., W395, W395-96 (Nov. 20, 2002), http://content.healthaffairs.org/cgi/reprint/hlthaff.w2.395v1.pdf.

13. Federal programs include Medicare, the military entitlement programs (TRICARE and the Civilian Health and Medical Program of the Department of Veteran Affairs (CHAMPVA)), and programs for government workers. Medicaid and the State Children's Health Insurance Program (SCHIP) receive federal funds but are operated largely on the state level. Medicaid funds health care benefits for indigent families with dependent children and some indigent, disabled individuals. *See* 42 U.S.C. § 1396 (2000). Covered individuals typically are at or below 150% of the federal poverty line. Medicare funds hospital, home, and hospice care for individuals sixty-five and older, certain railroad employees and disabled individuals, and those with end-stage renal disease. *See* 42 U.S.C. § 1395c (2000). SCHIP operates as a subsidized insurance program for low-income pregnant woman and children who are usually at or below 200% of the poverty line. *See* 42 U.S.C. §§ 1397aa-1397jj (2000).

14. Pegram v. Herdrich, 530 U.S. 211, 220-22 (2000) (recognizing that the need for HMOs to ration care is not a violation of fiduciary duty).

15. Relative to public insurance, private insurance often funds more high technology health care, though coverage is still limited. One striking difference in coverage arises in the area of genetic testing. For instance, under public programs, prenatal genetic testing is sparsely funded and only in situations of family history of genetic anomaly or high-risk pregnancies, and child and adult predictive testing is unfunded. For example, the TRICARE Handbook states:

> Genetic tests to find out if your unborn child has genetic defects are covered. But TRICARE Standard helps pay only if: You are pregnant and age 35 years old or over, or You had rubella during your first 3 months of pregnancy, or You or your husband have had a child with a genetic (congenital) defect, or You or your husband comes from a family that has a history of genetic (congenital) defects.

TRICARE Handbook, http://www.tricare.osd.mil/TricareHandbook/results.cfm?tn=18&cn=8 (last visited Nov. 30, 2007). In the private sphere, large managed care operations, like Kaiser Permanente, offer a range of genetic testing services for adults and children. *See, e.g.*, Kaiser Permanente, Genetics Northern California, http://genetics.kaiser.org/home/regionalprograms.htm (last visited Nov. 30, 2007). Nevertheless, when private insurers deny requests for prenatal genetic testing services, people are forced to refute these denials rather clumsily through actions like wrongful birth and life, which are recognized in only a few jurisdictions and have a low success rate. Legal claims based upon denial of access to testing after birth may be unsuccessful under judicial construction of the Employee Retirement Income Security Act (ERISA), *see infra* note 17, and the legality of cost-saving managed care measures. *See Pegram*, 530 U.S. at 211.

insurance through their employer, and coverage continues to decline under employee benefit plans,[16] without legal recourse for beneficiaries denied care.[17]

In order to understand demand for high technology health care services, health care must be viewed as a different type of good. It is necessary to make a distinction between functional and service goods. A service good may generally be understood as something that is distributed by a government across a population according to a perceived need. A functional good is something *chosen* by an individual from a set or range of goods. Health care goods are functional goods. Patients choose particular goods because they are preferred over others to further a certain health state.[18] This choice is made in light of individual biological variation, preferences (including risk assessment and possible therapeutic benefit), and resource entitlement. Recognizing health care as a functional good is vital to understanding individual differences that affect demand for health care services.

To aid in making this distinction between service and functional goods—to analyze the importance of *demand* instead of supply in situations of scarcity—a theoretical framework is available, though long overlooked: Amaryta Sen's theory of basic capability equality. Sen, a philosophically-minded economist, offers a framework that may be used to represent value in choosing between

16. Employee coverage may be limited due to the unavailability of health care benefit plans; high employee premiums, co-payments, and deductibles; or restrictions on the services offered under employer plans. From 2000 to 2005, there was a 9% decrease in employers offering health insurance. KAISER FAMILY FOUND., EMPLOYER HEALTH BENEFITS: 2005 SUMMARY OF FINDINGS 4, *available at* http://www.kff.org/insurance/7315/sections/upload/7316.pdf. Employees participating in health benefit plans are generally required to pay high premiums, deductibles, or co-payments in order to access services. *Id.* at 3-4. Premiums increased 42% from 1998 to 2003, resulting in a decline of 5% of eligible workers subscribing to employer-based plans. ROBERT WOOD JOHNSON FOUND., SHIFTING GROUND: CHANGES IN EMPLOYER-SPONSORED HEALTH INSURANCE 8-9, 22 (2006), *available at* http://www.rwjf.org/newsroom/CTUWFinalResearchReport2006.pdf. Individuals covered under employee benefit plans face additional restrictions. Hospital care often requires a separate deductible or co-payment. KAISER FAMILY FOUND., *supra*, at 3. Further, patients must typically receive prior certification for procedures performed in a hospital or out-patient facility, and these or other needed medical services may not be provided in light of cost-saving measures employed by health care entities. *Id.* at 5.

17. Under ERISA, most state tort claims for denial of benefits are preempted, *see* Aetna Health Inc. v. Davila, 542 U.S. 200 (2004). Employers who self-insure are able to avoid state regulation of, and state law claims against, their plans. *See* 29 U.S.C. § 1114(b)(2)(B) (2000); *see also* FMC Corp. v. Holliday, 498 U.S. 52 (1990).

18. This concept is long established by the doctrine of informed consent, which requires that patients be provided with information about the availability and the risks and benefits of health care options in order to determine their course of treatment. *See, e.g.*, Canterbury v. Spence, 464 F.2d 772 (D.C. Cir. 1972) (adopting the reasonable patient standard for informed consent).

different types of health care services and to understand the biological and resource constraints that affect decision-making.

Most importantly, basic capability equality addresses the basic health care benefits of high technology health care better than dominant utilitarian or contractarian frameworks. Under Sen's theory, capabilities are maximized across a given population according to a specific calculus. Generally speaking, individuals choose a capability set, constrained by both personal characteristics and commodity entitlement. Applying basic capability equality to the distribution of basic health care services, patients choose health care services that best support their basic capabilities, where their choice is limited by their biological constitution and funding for such services. This approach allows patient choice among high technology and traditional health care services, while operating within budget constraints, such as caps on spending. While this Article does not develop discrete health care financing structures that support basic capability equality, the theoretical framework developed offers the possibility of more effective resource distribution, which may lower health care expenditures.

Basic capability equality is frequently referenced in legal scholarship,[19] but no legal scholar has grappled with the formal expression of Sen's theory. Only Sen's formal model fully captures what is at stake in the analysis of capabilities, that is, its ability to account for a richer conception of well-being in light of biological and other constraints affecting medical decision-making. Basic capability equality is typically applied as a device rather than a framework to conceptualize well-being,[20] resulting in generalizations that seem to misinterpret it.[21] Further, undoubtedly due to its complexity, few scholars in other disciplines

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19. A survey of law reviews on Nov. 18, 2007, using LEXIS-NEXIS (search terms: "Amartya Sen" and "capabilit!"), revealed 527 articles referencing Sen's work on capabilities.

20. *See, e.g.*, Carlos Ball, *Autonomy, Justice, and Disability*, 47 UCLA L. REV. 599, 637 (2000); Steven P. Croley & Jon D. Hanson, *The Nonpecuniary Costs of Accidents: Pain-and-Suffering Damages in Tort Law*, 108 HARV. L. REV. 1785, 1828-34 (1995); Robert Post, *The Rule of Law: What Is It: Democracy and Equality*, 603 ANNALS AM. ACAD. POL. & SOC. SCI. 24 (2006). Martha Nussbaum offers a different account of basic capability equality, often confused with that of Amartya Sen, premised upon Aristotelian notions of human flourishing rather than a consequentialist framework. *See, e.g.*, MARTHA C. NUSSBAUM, FRONTIERS OF JUSTICE: DISABILITY, NATIONALITY, AND SPECIES MEMBERSHIP (2006). Nussbaum identifies ten capabilities, including "bodily health"; a threshold or basic minimum of each is required for human dignity. *Id.* at 76-78. The capability list and the threshold is the same for all individuals. *Id.* at 179. As a result, Nussbaum's approach does not provide the same flexibility as Sen's in accounting for individual biological and other variation.

21. *See, e.g.*, Ball, *supra* note 20, at 638 (failing to recognize that it is not the range of choice itself that is valuable but the value of the elements contained within that range; "The individual with few vectors from which to choose may have her needs satisfied but will have a reduced freedom."); Croley & Hanson, *supra* note 20, at 1833-34 (overlooking the fact that biological

apply the formal model of basic capability equality to practical problems.[22] Sen himself provides limited bridges between his moral theory and his applied work in poverty and famine.[23] Nevertheless, it is through the lens of basic capability equality that it is possible to see an especially strong case for universal access to high technology health care.

This Article argues that if basic health care is to be provided to a target or the national population, high technology health care that supports the goals of basic health care should be universally available. Under basic capability equality of health care, individuals will have access to a range of basic health care services—traditional and high technology—and choose from among these goods.[24] This gives rise to an alternative type of distributive structure, which might be described as "self-rationing." It is important to emphasize that self-rationing is not an argument for greater health care expenditures; rather, it demands spending money in a different, and possibly more efficient, manner.[25] Self-rationing requires that legal structures support the availability of a range of clinically effective goods from which a patient will choose but not that every service be provided to an individual.[26] A patient will choose services with

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constraints, including disabilities, limit capability sets); Post, *supra* note 20, at 32 (failing to recognize basic capability equality as a non-welfarist, maximizing approach; "Sen . . . [is] ambiguous as to whether the set of capabilities . . . are to be measured by the criteria of 'justice as fairness' or . . . 'autonomy.'").

22. Economists are an exception. *See, e.g.*, E. Chiappero Martinetti, *A Multi-Dimensional Assessment of Well-Being Based on Sen's Functioning Approach*, 108 RIVISTA INTERNAZIONALE DI SCIENZE SOCIALI 207 (2000) (Italy); Mozaffar Qizilbash & David A. Clark, *The Capability Approach and Fuzzy Property Measures: An Application to the South African Context*, 74 SOC. INDICATORS RES. 103 (2005).

23. *See, e.g.*, AMARTYA SEN, COMMODITIES AND CAPABILITIES 46-69 (1999) [hereinafter SEN, COMMODITIES AND CAPABILITIES]; *see also* AMARTYA SEN, RESOURCES, VALUES AND DEVELOPMENT (1984) [hereinafter SEN, RESOURCES, VALUES AND DEVELOPMENT].

24. Technology should be provided in a cost-effective manner, likely requiring less equipment and fewer medical specialists in particular geographic regions.

25. Self-rationing has the potential to lower health care costs provided a few assumptions hold: tolerance for high technology health care services provided at fewer locations, *see supra* notes 9 and 24 and accompanying text; greater clinical efficacy, *see infra* notes 26, 42-44 and accompanying text; and a reduction in costs as high technology health care becomes more routine.

26. "Clinical efficacy" is demonstrated by services that generally bring about a desired medical result. How clinical efficacy will be determined is an important topic to be taken up elsewhere. A number of 2008 presidential candidates, including Hillary Clinton, Dennis Kucinich, and Barack Obama, have called for governmental boards to assess the effectiveness of treatments, presumably including medical innovations, as a cost-saving measure. *See Candidate Commentaries*, MODERN HEALTHCARE, Nov. 26, 2007, at 12, 12, 19, 21; *see also* H.R. 676, 110th Cong. § 305 (2007). Equally important are comparative efficacy studies to aid consumer choice.

professional guidance,[27] and within a given level of health care funding such as a yearly or lifetime cap, in order to support the goals of basic health care.[28] Choice of a particular service may foreclose other options based upon the resources available. This differs dramatically from traditional rationing schemes, where a narrow range of basic health care services are provided to certain individuals based upon criteria determined largely by governments or medical institutions. Under traditional rationing, not every patient is eligible for health care services, and patient choice is not directly valued.

This Article interprets Sen's formal model of basic capability equality to support an argument for universal access to high technology health care. It is argued that the dominant legal paradigms of basic minimums and rationing, and the moral theories from which they are derived, lack the ability to address patient choice for high technology health care goods and, as a result, cannot support self-rationing. Utilitarianism and Rawlsian-derived models fail to account adequately for the value of choice as well as the biological and external constraints an individual faces when making medical decisions. In addition, they do not accommodate all of the basic health care benefits enabled by high technology health care.

The Article is divided into three Parts and an Appendix. Part I briefly addresses limitations of current theoretical frameworks applied to the distribution of health care resources and proposes a new legal paradigm derived from basic capability equality for accommodating patient demand for medical services. It interprets Sen's formal model of basic capability equality, outlining the basic theory and discussing the role and nature of choice under the theory. These concepts are applied to the distribution of basic health care services and to patient decision-making. Part II applies basic capability equality to high technology health care specifically and develops a new approach to the distribution of basic health care: basic capability equality of health care. Predictive testing is presented as a case study. Such health care is discussed in terms of enabling a range of basic capabilities: broad capabilities, including a decent health status and endowment, and narrower capabilities, encompassing prophylactic measures, psychological preparedness, and family planning. The ability of high technology health care to expand one's capability set, or the range of capabilities available to an individual, is also discussed. Part III addresses potential problems with basic capability equality of health care, such as difficulty in valuing other-regarding choices, the loss of freedom when one medical choice forecloses another, and the implications of moving toward a new legal paradigm for health care distribution

27. A patient's choice must be informed by a physician's advice about the relative strengths and weaknesses of effective options.

28. Given financial constraints, there are incentives for patients to choose lower-priced, clinically effective services.

given the social role of basic minimum and rationing schemes. Because this is the first time Sen's formal model has been interpreted in the legal literature, a detailed Appendix is provided, offering insights into how capability sets might be valued in order to make intrapersonal or interpersonal comparisons.

I. CAPABILITY EQUALITY MATTERS: DEMAND FOR HIGH TECHNOLOGY HEALTH CARE

Deprivation cannot always be understood in the simple terms of lack of supply. Studies have shown, for example, that in Bombay, one of the most technologically sophisticated cities in India, female children and adults have a lower treatment ratio in hospitals than male children and adults.[29] Similarly, in Calcutta, more females than males perish from medical conditions.[30] Strikingly, this differential applies across every income group.[31] What is occurring in these situations? Health care services are available for consumption. The women are not sicker than the men. Rather, the choices of parents, husbands, and physicians support inferior treatment of women.[32] These choices embrace gender bias and cause the deprivation of care; the deprivation is not the result of lack of available medical services in a more pure sense.[33] In these instances, women lack equality in treatment and the basic capabilities it enables, such as the ability to enjoy a decent health state.

Similarly, there is more to the story of the causes of deprivation in the U.S. health care system than lack of supply of basic health care services. One cause is the inability of current social and legal structures to account for patient demand for high technology health care services. As a result, high technology is provided inefficiently, and this elevates costs.[34] In order to address rising health care costs, insurers require that consumers contribute more to their care.[35] High costs ultimately limit access to basic health care services, leading to more underinsured or uninsured individuals. Once the deprivation is understood in this way, it is clear that increasing the availability of traditional, basic health care services will not address it. Nor does it address the deprivation experienced by individuals who seek high technology health care services but are unable to afford them. Lack of access to high technology health care is significant because it may

29. SEN, COMMODITIES AND CAPABILITIES, *supra* note 23, at 61-65. Female children fare the worst. *Id.* at 65.

30. *Id.* at 65-69.

31. *Id.* at 69.

32. *Id.*

33. *Id.*

34. *See supra* notes 8-9 and accompanying text.

35. *See supra* note 16 and accompanying text.

support the goals of *basic* health care.

A. High Technology Health Care as Basic Health Care

Both traditional and high technology health care services may support the goals of basic health care. Thus, in order to further health care states enabled by basic health care, both types of health care services should be available. In situations of scarcity, an individual may need to engage in self-rationing, or to make trade-offs between traditional and high technology health care services, but this does not undermine the claim that the spectrum of technology that supports basic health care should be universally available.

While the line between traditional and high technology health care services need not be rigidly defined, working definitions are in order. *Traditional health care* services may be roughly understood as preventative, diagnostic, and therapeutic services that do not involve sophisticated medical equipment for imaging, analysis, or treatment. Bacterial cultures and urine samples followed by microscopic analysis, antibiotic treatments, and bone-casting are examples. *High technology health care* may be defined as health care services that involve sophisticated medical equipment for imaging, analysis, or treatment; these services typically are more costly.[36] Examples include advanced diagnostic imaging through use of computed or positron emission tomography (CT or PET) scans or magnetic resonance imaging (MRI), genetic testing, artificial tissue and organ repair and replacement, individually-tailored medicines, and, perhaps in the near future, nanotechnology-based drug delivery systems.[37] Obviously, as technology advances, some high technology health care services will become more traditional. What is important for present purposes is that some services considered high technology health care services are overlooked in contemplating health care reform, even though they support the goals of basic health care.

Basic health care may be defined loosely as health care services that support the goals of prevention, diagnosis, and limited treatment or amelioration of diseases or conditions. Traditional health care services are commonly associated with these goals. Basic health care may be understood in the context of the

36. Some authors use cost itself to distinguish between high and low technology health care. *See, e.g.*, McClellan & Kessler, *supra* note 8, at 253-54 (defining high technology treatments as "those with high fixed costs to adopt or high variable costs per use" and low technology treatments as "those with low fixed and incremental costs of use").

37. *See, e.g.*, Theresa M. Allen & Pieter R. Cullis, *Drug Delivery Systems: Entering the Mainstream*, 303 SCIENCE 1818 (2004); Roger Langer, *Drug Delivery and Targeting*, 30 NATURE 5 (1998); *Nanotech Delivers Cancer Treatment*, CNN, June 23, 2005, http://www.cnn.com/2005/HEALTH/06/21/cancer.nanotech/ (referring to Jolanta F. Kukowska-Latallo et al., *Nanoparticle Targeting of Anticancer Drug Improves Therapeutic Response in Animal Model of Human Epithelial Cancer*, 65 CANCER RES. 5317 (2005)).

conventional physician-patient relationship; it reflects common intuitions about the reasons individuals seek medical attention within a primary health care setting and the expectations they possess about those experiences.[38] A patient who is ill or dysfunctional, or who has reason to believe she could be in the future, seeks medical attention in a primary care setting. The medical practitioner handles the matter in the requisite number of appointments or refers the patient to a specialist, such as urologist, cardiologist, or geneticist. Primary care encompasses the time the patient presents with symptoms, dysfunction, or anticipates illness as well as diagnosis or limited treatment of the condition. Limitations in treatment are crucial to defining basic health care; it does not extend to long-term critical care, that is, extensive treatments and palliative care. Basic health care could include ongoing but not critical care of disabled individuals who remain functional in the community, however, as this is essentially ongoing primary care.

Basic health care is necessarily interpreted relative to both the state of current technology and the affluence of a given society. For example, in some developing nations, access to clean water and anti-parasitic drugs may constitute basic health care. In developed nations, high technology health care may support the goals of basic health care. Treatment may involve high technology health care when advanced pharmaceuticals, medical devices, or surgical procedures are used. High technology diagnostics may include CT, PET, and MRI scans as well as genetic tests. Prevention may also be enabled by these tests, if they are employed presymptomatically and are followed by prophylaxis; in this case, the tests constitute predictive technology.

Prediction may seem like a new addition to the traditional goals of basic health care delivery, but only in the sense that it is separated from the broader category of prevention. Predictive tests often enable prevention of disease. For example, cholesterol tests, a traditional form of cardiac health care, indicate risk of heart disease and allow patients the opportunity to improve their future health through diet and exercise. In cases where prophylactic options are unavailable, prediction enables patients to prepare psychologically for the onset of diseases or other conditions or, in the alternative, to confirm that they are not at risk for such conditions. In these cases, prediction provides indirect, basic health care benefits such as comfort, reassurance, and psychological preparedness related to diagnosis. In addition, prediction allows individuals to follow, and possibly invest in, research for their conditions and allows prompt use of prophylactics or

38. While this Article presents basic health care in terms of a descriptive, relational model, that is, it is premised upon the patient-primary practitioner relationship, others understand the goals of prevention, diagnosis, and limited treatment as supporting a baseline of human functioning that is of normative import. *See, e.g.*, NORMAN DANIELS, JUST HEALTH CARE (1985); *see also* ALLEN BUCHANAN ET AL., FROM CHANCE TO CHOICE: GENETICS AND JUSTICE (2000).

treatments as they become available. In the prenatal context, prediction allows family planning, either through preventing or preparing for particular births. Given the possible influence of predictive testing on reproductive decision-making and life plans, limited access to these technologies has the potential to exacerbate social stratification.

Aside from the benefits of high technology health care already discussed, consumers may demand such health care because it is lower in cost or more effective than traditional health care services. This is true for some genetic tests, for example. Genetic testing is inexpensive compared to traditional diagnostic methods for multiple endocrine neoplasia type II (MEN-II) thyroid disease,[39] familial adenomatous polyposis (FAP) screening in families for colorectal cancer predisposition syndrome,[40] and, in some cases, homochromatosis screening on a population level for iron build-up.[41] Further, holding clinical efficacy and initial cost constant for both genetic and nongenetic tests, genetic testing usually affords long-term cost benefits because most genetic tests are only performed once. Higher clinical efficacy is achieved with genetic tests used to detect "sensitive" leukemia and Duchenne muscular dystrophy.[42] Genetic testing for sensitive leukemia is necessary to calculate the correct dose of chemotherapy and to avoid the unnecessary toxicity of a high dose or an ineffective, low dose.[43] Advanced genetic testing for Duchenne muscular dystrophy detects most possible mutations, whereas measurement of serum creatine kinase levels, and even older genetic tests, fail to catch the disease approximately 29% of the time and usually involve painful muscle biopsies.[44]

This Article argues that a legal paradigm for the distribution of basic health care resources must consider consumer demand for both traditional and high technology health care services. High technology health care may be more effective for particular individuals or confer benefits that are not provided by most traditional health care services, such as those associated with prediction. In

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39. Leigh Delbridge & Bruce Robinson, *Genetic and Biochemical Screening for Endocrine Disease: III. Costs and Logistics*, 22 WORLD J. SURGERY 1212 (1998).

40. B. Bapat et al., *Cost Comparison of Predictive Genetic Testing Versus Conventional Clinical Screening for Familial Adenomatous Polyposis*, 44 J. BRIT. SOC'Y GASTROENTEROLOGY 698 (1999).

41. Paul C. Adams & Leslie S. Valberg, *Screening Blood Donors for Hereditary Hemochromatosis: Decision Analysis Model Comparing Genotyping to Phenotyping*, 94 AM. J. GASTROENTEROLOGY 1593 (1999); Howard L. McLeod & William E. Evans, *Pharmacogenetics: Unlocking the Human Genome for Better Drug Therapy*, 41 ANN. REV. PHARMACOLOGY & TOXICOLOGY 101, 106-07 (2001) (discussing leukemia).

42. Kevin M. Flanigan et al., *Rapid Direct Sequence Analysis of the Dystrophin Gene*, 72 AM. J. HUM. GENETICS 931, 934-38 (2003) (discussing Duchenne muscular dystrophy).

43. McLeod & Evans, *supra* note 42, at 107.

44. Flanigan et al., *supra* note 42, at 931, 933, 935-36, 938.

some cases, innovative medical technologies may also be more cost effective. Finite resources mandate that individuals cannot choose every service within a given range of services, however, it is necessary to find a way to value and understand choices within each range. This entails shifting focus away from the supply of traditional health care services available to an individual towards the demand for services—traditional or high technology—that support prevention, diagnosis, and limited treatment. Dominant theoretical frameworks employed to contemplate health care distribution are limited in their ability to consider demand in this way.

B. Limits of Cost-Utility and Contractarian Approaches

While academic conceptions about health care goods have grown in sophistication, dominant theoretical approaches to the distribution of health care services experience difficulty accounting for consumer demand for high technology health care that supports the goals of basic health care. Basic minimum and rationing paradigms are derived from contractarian and cost-utility theories, respectively. These frameworks fail to value adequately consumer demand or choice in medical decision-making and to account for certain health benefits, biological differences, and economic and social influences that inform choice.

Briefly stated, cost-utility conceptions, like those embraced by the Oregon Plan of medical rationing, embed utility within a framework of health-related welfare measured by access to health care services over a lifetime.[45] Services are provided based upon Quality Adjusted Life Year (QALY) measurements, which determine health care entitlement by making assessments of the quality (utility) of length of life associated with certain identified health states.[46] Under this type of framework, a costly high technology health care service is provided to a

45. *See* Oregon Health Plan, http://www.oregon.gov/DHS/healthplan/index.shtml (last visited Nov. 30, 2007).

46. QALYs are one measure of utility. A QALY is one life year weighted by the perceived quality of life after a particular health service. Patients, doctors, other medical practitioners, third party payors, or a certain geographic population are surveyed to make quality of life rankings, on a scale of zero to one, where zero is death and one reflects a state of full health. The results for each individual are scaled according to the number of QALYs gained, and the scales are combined or aggregated to produce a utility index that is used to make interpersonal comparisons between health states. JOHN MCKIE ET AL., THE ALLOCATION OF HEALTH CARE RESOURCES: AN ETHICAL EVALUATION OF THE 'QALY' APPROACH 21-22 (1998). The estimated utility is multiplied by the predicted number of remaining years. For example, an individual who is 45 years old and suffering from hypertension might be expected to live 25 more years with an estimated utility of .95. Discounting for the change in health status, 25 x .95 = 23.75 QALYs. *Id.* at 22 (presenting a similar example). Resources are distributed so as to maximize the number of QALYs.

population only if its lifetime benefits are perceived as significant, relative to health states achieved by means of different medical technologies.[47] Some argue that this form of rationing places in double-jeopardy those who are most in need; the sickest are worse-off by nature of their conditions and then, as a result of their shorter life-spans, may receive limited health care services.[48]

Partially in response to these shortcomings, scholars began to argue that there is something fundamental about health care as a good and its role relative to well-being. Scholars extending the contractarian theory of John Rawls embrace the idea of health care as a primary social good, that is, a good needed to fulfill all rational life plans,[49] or as a good necessary to achieve fair equality of opportunity.[50] Treating health care as a primary good poses a number of difficulties, including resource drain and the inability to make trade-offs between health care and other primary goods.[51] Motivated by cost-saving considerations, the prominent work of Norman Daniels conditionally extends Rawls's fair equality of opportunity principle in order to proffer a theory that health care should be provided to preserve a baseline of normal functioning.[52] Under this theory, basic health care services are provided to prevent deviation from, restore, and maintain normal functioning.[53] As the theory looks to direct and immediate benefits in relation to disease, problems arise in accounting for indirect, uncertain, and future health care benefits.

As explained below, both utilitarian and contractarian frameworks undervalue basic health care services with these benefits. Most importantly, however, neither contractarian nor cost-utility approaches account directly for

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47. *Id.* at 21-22.

48. *Id.* at 99-101.

49. *See* Ronald M. Green, *Health Care and Justice in Contract Theory Perspective*, *in* ETHICS AND HEALTH POLICY 112, 117-18, 120 (Robert M. Veatch & Roy Branson eds., 1976) ("[H]ealth care ought to be considered a primary social good in [Rawls's] terms."); *see also* Ani B. Satz, Testing Access: Toward a Theory of Entitlement to Genetic Testing and Screening as a Form of Health Care 147-52 (June 30, 2001) (unpublished Ph.D. dissertation, Monash University, Melbourne, Australia) (on file with author) (arguing that some forms of health care may be understood to support the social primary good of the social bases of self-respect).

50. *See* DANIELS, *supra* note 38, at 33-34 (conditionally extending the fair equality of opportunity principle in order to ground entitlement to health care services that support the normal opportunity range, that is, the ability to pursue reasonable life plans and goals relative to an individual's skills and talents); THOMAS W. POGGE, REALIZING RAWLS 181-96 (1989) (presenting a "semiconsequentialist" view that individuals behind the veil of ignorance would choose a variation of Rawls's fair equality of opportunity for "health protection" that would be of lexical priority to (not compromised in favor of) the difference principle).

51. *See* Satz, *supra* note 49, at 147-52.

52. DANIELS, *supra* note 38, at 33-34.

53. *Id.*

patient choice in selecting health care services. In addition, they do not address the biological, economic, and social constraints under which patients make medical decisions.

1. Valuing and Understanding Choice in Medical Decision-Making

Both utilitarian and contractarian approaches experience difficulty in accounting for the nature of patient choice.[54] The difficulty lies in the ability to distinguish between choice and non-choice factors.[55] Choice factors are those where an individual chooses something because it is preferred; non-choice factors include variations in biology and social constraints that inhibit or prevent an individual from choosing something desired, causing them to choose something else. Generally speaking, neither dominant theoretical approach appreciates this distinction.

Consider the withdrawal of a feeding tube and hydration from a terminally ill, conscious patient who is competent to make medical decisions. By removing the feeding tube and hydration, the individual is making the decision to starve, dehydrate, and die. This choice seems clearly different from the starvation and dehydration of an individual who lacks food and water.[56] In the later case, it is absence of material resources, or a non-choice factor, that results in starvation.

Under a cost-utility scheme, when there is great expense at the end of life with limited life extension, withdrawal of food and hydration may support the greatest utility. But the patient may be seeking death to end pain, incapacitation, depression, or family strife; these biological and social non-choice factors exist independently of the cost-utility of continuing care. While it is possible that these non-choice factors might be considered under a different understanding of well-being if they relate to utility, such a cost-utility framework still may not capture what is at stake.[57] For example, mandating patient food and hydration does not

54. Here, "utilitarian" is used to mean cost-utility and "contractarian" refers to extensions of Rawls's theory of distributive justice. "Utilitarian" is also used in this Article to refer to classical utilitarianism, and this is so indicated where relevant. This Article speaks in general terms about utilitarian and contractarian approaches and does not seek to draw fine distinctions between them.

55. SEN, COMMODITIES AND CAPABILITIES, *supra* note 23, at 18.

56. AMARTYA SEN, INEQUALITY REEXAMINED 52, 111-12 (1992) [hereinafter SEN, INEQUALITY REEXAMINED] (speaking about the difference between fasting and starving due to lack of nourishment).

57. Sen provides another example regarding the inability of utilitarian (and contractarian) approaches to account for non-choice factors. The ability to metabolize food at a normal rather than a high rate is advantageous for preventing starvation. In order to prevent starvation within certain populations or to ensure sufficient humanitarian aid, metabolic rate must be considered directly along with the amount of food distributed. Utilitarian and contractarian theories premised on the distribution of primary goods consider metabolic rate only insofar as it affects desired mental states

eliminate the deprivation a depressed or incapacitated patient experiences. Similarly, contractarian approaches consider the circumstances behind the decision to withdraw treatment only indirectly; for example, whether the feeding promotes a social primary good or serves fair equality of opportunity.

Biological variation is another constraint on choice with significant implications for the distribution of high technology health care services. Individuals may function effectively in different ways.[58] Some may walk with prostheses while others wheel for mobility, for example.[59] Some high technology health care services, like pharmacogenetics and certain forms of genetic testing, rely upon individual variations of biological function for clinical efficacy; in other words, their medical appropriateness depends upon distinctions between individuals. For these reasons, it is necessary to use a framework for distributing health care services that accounts for biological variation and how individuals transform commodities, such as health care services, into certain health states.

A classical utilitarian approach and derivative cost-utility approaches, however, do not account directly for the different biological abilities of individuals. Rather, access to certain resources is presumed to have certain effects; "a bicycle is treated as having the characteristic of 'transportation,' and this is the case whether or not the particular person happening to possess the bike is able-bodied or crippled."[60] Similarly, under a cost-utility scheme, rankings of health care services are determined by aggregative scales, which assign a set value to a given service.[61]

Further, one must be able to account for external barriers to well-being or lack of commodity entitlement in order to understand consumer demand. These barriers might include social pressures, employment regulations, taxes, or national economic development.[62] In the health care context, limitations pertaining to funding of health care and technological advancement, as well as cultural views about health care, are also relevant. A cost-utility approach considers these constraints only indirectly, to the extent that they impact the utility of a particular health care service.

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or preferences, the availability of primary goods, or fair equality of opportunity. Thus, metabolic rate is considered indirectly, in terms of maximizing utility or determining who is disadvantaged by the distribution of primary goods or is not afforded fair equality of opportunity. SEN, COMMODITIES AND CAPABILITIES, *supra* note 23, at 18.

58. I have argued elsewhere the importance of considering alternative modes of functioning in disability accommodations. *See* Ani B. Satz, *A Jurisprudence of Dysfunction: On the Role of "Normal Species Functioning" in Disability Analysis*, 6 YALE J. HEALTH POL'Y L. & ETHICS 221 (2006).

59. *Id.* at 238.

60. SEN, COMMODITIES AND CAPABILITIES, *supra* note 23, at 6.

61. *See supra* note 46 and accompanying text.

62. Some of the barriers to commodity entitlement may be voluntary, like career choice.

Contractarian frameworks also experience difficulty in directly accounting for biological and commodity restrictions. In part, this is because the relationship between the distributional goods—primary social goods in the case of Rawlsian devices—and health is not direct. Primary goods are social goods, or goods governed by social institutions; health is a natural primary good, or one based on natural endowment. Health may be influenced by social institutions, but such institutions alone cannot control the value of health care because biological variation among individuals informs health status. Restrictions on commodity entitlement are addressed only indirectly as well, by redistributing resources to benefit the least advantaged. Daniels' conditional extension of Rawls's fair equality of opportunity principle encounters similar problems.[63] Biological and resource barriers are relevant only insofar as they impede a baseline of normal functioning; they are not considered directly. Further, the relationship between health and fair equality of opportunity is not direct. Individuals may possess health-related abilities regardless of opportunities.[64]

In order to understand the relevance of consumer demand for some basic health care services over others, it is important to operate within a theoretical framework that accounts for an individual's biological, economic, and social restrictions. High technology health care may better advance the goals of basic health care for some individuals, based upon their biology or other constraints. In order to take patient choice seriously, our legal structures must support high technology health care services as part of the range of basic health care available to an individual.

2. Accommodating Indirect, Uncertain, and Future Health Care Benefits

Utilitarian and contractarian approaches consider direct benefits to well-being. Direct health care benefits afforded by diagnosis, prevention, and limited treatment are typically accommodated by these frameworks. Traditional and high technology may also provide indirect benefits, however, such as psychological preparedness, comfort, security, reassurance, and family planning, which support the goals of basic health care. These benefits are most often associated with high technology health care, and, in particular, innovative predictive health care services. Accommodating indirect benefits under a utilitarian or contractarian approach becomes especially difficult when the benefits are uncertain, even if their potential efficacy is great. Additional complications arise when uncertain benefits would not be immediate but in the future.

The importance of indirect, uncertain, and future health care benefits is

63. DANIELS, *supra* note 38, at 39-40.

64. One cannot have certain opportunities, however, without the requisite capabilities for health.

illustrated by the shortcomings of the Tengs study, which measured the QALYs associated with testing for the breast and ovarian cancer genes BRCA1 and BRCA2.[65] The Tengs study serves as an example of how a utilitarian or cost-utility scheme for distributing high technology health care might function in practice. While the study indicates people desire predictive testing, and it has the potential to confer basic, indirect health care benefits like reassurance, these benefits are undervalued by the measures the study employs.[66] Using data from published studies, a public database, and eighteen cancer experts (a response rate of 33%), the study found about a 0.5–2.0 QALY gain for women with a family history of early breast and/or ovarian cancer who were able to use the information to guide decision-making about prophylactic surgery.[67] For women at average risk–that is, without such a family history–the estimated QALY gain was only .002–.008 QALYs, or one to three days.[68] The QALY ranges reflect the spectrum between a perfect test of 100% sensitivity and specificity to ones with 80% sensitivity and 99% specificity, the lower boundaries being an estimate of the actual sensitivity and specificity.[69] At the extremes of family history risk (that is, very high and very low risk), a test with less than 100% sensitivity and specificity has no QALY value because the test fails to supplement sufficiently the knowledge of the tested individual.[70] This assumes that a slight chance of having or not having a life-threatening condition would fail to cause a large amount of distress.

The study ignores the indirect health care benefits associated with predictive testing, including comfort, security, and psychological preparedness pertaining to health status, and, as the study itself indicates, reassurance.[71] Arguably, this translates into undervaluing the quality of life associated with testing. Testing may also invoke anxiety or fear for those who test positive and survivor guilt in those who test negative, but these negative, indirect influences on quality of life need to be weighed against the positive ones.[72] Although it is possible that indirect benefits associated with BRCA1 and BRCA2 testing could be added to future QALY assessments, the Tengs study makes clear that these benefits present problems for standard interpretations of QALYs.

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65. Tammy O. Tengs et al., *Testing for the BRCA1 and BRCA2 Breast-Ovarian Cancer Susceptibility Genes: A Decision Analysis*, 18 MED. DECISION MAKING 365 (1998).

66. *Id.* at 366, 374.

67. *Id.* at 368, 373-74.

68. *Id.* at 371.

69. *Id.* at 367.

70. *Id.* at 371.

71. *Id.* at 374.

72. Marlene Huggins et al., *Predictive Testing for Huntington Disease in Canada: Adverse Effects and Unexpected Results in Those Receiving a Decreased Risk*, 42 AM. J. MED. GENETICS 508 (1992) (discussing survivor guilt among those with a reduced risk for Huntington's disease).

More importantly, the case of risk extremes suggests that the QALY method is likely not flexible enough to accommodate indirect benefits. Individuals who are at very high or low risk might benefit tremendously from genetic testing because of indirect, psychological benefits, but they will almost always receive a QALY score of zero because they are perceived not to benefit medically from the information. Thus, the indirect or uncertain benefits of low or high risk individuals will be inappropriately discounted.

The Tengs study also does not address the possible future benefit of testing, which raises the question of how QALYs would accommodate a time lag in possible benefit; that is, testing now in hopes of benefits such as prophylactic treatment later. QALYs measure benefit over a lifetime, but in terms of all possible services, rather than one particular service with protracted benefits. In this sense, QALY schemes only create entitlement to services with expected benefit. Under such frameworks, predictive, presymptomatic testing probably would not be provided when there are no prophylactics or other treatments for the tested conditions available other than experimental treatments.[73]

Contractarian approaches that appeal to baselines of functioning or basic minimums face similar challenges. These theories largely contemplate direct, current benefit. Health care services are valued to the extent they promote a current level of biological functioning or ameliorate a condition or risk of one in the present. Future benefit is considered only in the sense that services are provided for immediate advantage at certain points in time in order to benefit an individual over a lifetime, as, for example, in the case of vaccinations. These theories do not speak to the largely future benefits of health care services provided in the present. Yet some forms of innovative predictive technologies may allow individuals with certain predispositions to follow or invest in research for their predicted conditions and to use prophylactic or other treatments as soon as they become available in the future. These options have value, even if the benefits they confer are not realized at a given point in time.[74]

Capability equality more adequately addresses the benefits of high technology health care and consumer demand for such care. It accommodates technologies with indirect, uncertain, and future benefits. In addition, basic

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73. Insurance coverage of experimental treatments is limited. *See, e.g.*, Earl P. Steinberg, Sean Tunis & David Shapiro, *Insurance Coverage of Experimental Technologies*, 14 HEALTH AFF. 143 (1995); Sean R. Tunis & Steven D. Pearson, *Coverage Options for Promising Technologies: Medicare's 'Coverage with Evidence Development'*, 25 HEALTH AFF. 1218 (2006).

74. Bernard Williams, *The Standard of Living, Interests and Capabilities*, *in* THE STANDARD OF LIVING 94, 99 (Geoffrey Hawthorn ed., 1987) (discussing the value of considering the actual abilities one has, given certain conditions, such as breathing clean air if one lives in the right part of the U.S. or is able to travel there, versus the actual abilities one has at the moment, like breathing clean air while one is living in Los Angeles).

capability equality has the ability to account for biological variance and commodity restrictions affecting medical decision-making. Further, the connection between capabilities and health is more direct than that between health and social primary goods, baselines of functioning, or utility. Basic capabilities, in fact, may be understood to support directly basic health care.

C. *Interpreting Basic Capability Equality*

Sen describes his theory of basic capability equality in a collection of works.[75] The theory is expressed formally. For these reasons, interpretation of Sen's theory is itself a rigorous enterprise.[76] Due to the complexity and value of the theory, it is necessary to discuss its interpretation in greater detail than is normally warranted in an Article of this length. What follows is an interpretation of the key components of basic capability equality and their application to high technology health care. As Sen's theory relies upon choice among particular sets of capabilities, valuation is an important aspect of the theory. Given the confines of this Article, however, the discussion of valuation is reserved for the Appendix.

1. Basic Theory

In very general terms, basic capability equality maximizes capabilities across a given population. Capabilities are defined generally in terms of functionings, which are in turn conceptualized as "doings and beings." Functionings are "parts of the state of a person, particularly the various things he or she manages to do or be in leading a life."[77] For example, the capability to overcome ailments may include functionings like the ability to sleep, to consume nourishing and fresh

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75. These works include: SEN, COMMODITIES AND CAPABILITIES, *supra* note 23; SEN, INEQUALITY REEXAMINED, *supra* note 56; Amartya Sen, *Capability and Well-Being*, *in* THE QUALITY OF LIFE 30 (Martha Nussbaum & Amartya Sen eds., 1993) [hereinafter Sen, *Capability and Well-Being*]; Amartya Sen, *Equality of What?*, *in* CHOICE, WELFARE, AND MEASUREMENT 353 (Amartya Sen ed., 1982) [hereinafter Sen, *Equality of What?*]; Amartya Sen, *On the Foundations of Welfare Economics: Utility, Capability and Practical Reason*, *in* ETHICS, RATIONALITY AND ECONOMIC BEHAVIOUR 50 (Francesco Farina et al. eds., 1996); Amartya Sen, *The Standard of Living: Lecture I, Concepts and Critiques*, *in* THE STANDARD OF LIVING, *supra* note 74, at 1 [hereinafter Sen, *The Standard of Living: Lecture I*]; Amartya Sen, *The Standard of Living: Lecture II, Lives and Capabilities*, *in* THE STANDARD OF LIVING, *supra* note 74, at 20 [hereinafter Sen, *The Standard of Living: Lecture II*]; and Amartya Sen, *Well-being, Agency, and Freedom: The Dewey Lectures 1984*, 82 J. PHIL. 169 (1985) [hereinafter Sen, *Well-being, Agency, and Freedom*].

76. Any relatively concise interpretation of basic capability equality is surely inadequate. Nevertheless, that is the most one can hope to present in an article—enabling some connections between Sen's complex and robust theory and determining access to health care.

77. Sen, *Capability and Well-Being*, *supra* note 75, at 31.

food, and to develop white blood cells to fight infection.[78]

Basic capability equality incorporates a consequentialist but non-welfarist (and non-utilitarian) conception of the good. It is consequentialist because it measures the moral value of actions in terms of the outcomes they bring about; basic capabilities are to be maximized across populations. Theoretically, such populations may be as small as families or as large as cultural communities. It is non-utilitarian because the "units" of distribution are capabilities, not utils or measurements of utility.[79] Further, unlike utilitarianism, basic capability equality involves maximization without aggregation or summation.[80] By maximizing capability sets rather than utility, basic capability equality avoids the classic arguments against utilitarianism about individuals adapting to, or accepting, objectively undesirable states.[81] In addition, basic capability equality may be distinguished more broadly from welfarist approaches because it is concerned with what a person can do or be, rather than with a person's well-being independently of what she is capable of doing or being.[82] This factor is important

78. Capabilities may also be more narrowly construed, like the capability to sleep, which also could be composed of functionings relating to the ability to fall and stay asleep and to experience the relevant restorative sleep cycles.

79. A mental state, such as pleasure, could be maximized as a functioning, although this would raise the classic problems of utilitarianism, such as offensive and expensive tastes. *See* J.J.C. SMART & BERNARD WILLIAMS, UTILITARIANISM FOR AND AGAINST (1973).

80. In other words, the mechanics of maximization for utilitarianism involves translating conditions into utils and then adding those units. Sen, *Equality of What?*, *supra* note 75, at 359, 369; *see also infra* Appendix.

81. *See* SMART & WILLIAMS, *supra* note 79. Basic capability equality shares some similarities with utilitarianism, however. Like utilitarianism, basic capability equality focuses on what goods do for individuals. Capabilities are agent-oriented; they are chosen from a capability set by an individual, and they pertain to what that individual is able to do or be. Sen, *Capability and Well-Being*, *supra* note 75, at 31. Capability indexes also may be used in ways similar to utility indexes to account for incremental contributions to well-being, although the units differ from utility. Sen, *Equality of What?*, *supra* note 75, at 369. Utilitarian considerations are only concerned with what goods contribute in terms of their utility, as measured by a valued mental reaction such as happiness, pleasure, or desire fulfillment. *See* SEN, COMMODITIES AND CAPABILITIES, *supra* note 23, at 19-20. Basic capabilities are multi-dimensional and allow for more direct evaluation of human conditions. SEN, INEQUALITY REEXAMINED, *supra* note 56, at 44.

82. In general, well-being is the way in which Sen speaks of assessing an individual's achievement in the sense of "how 'well' is his or her [state of] 'being'?" SEN, COMMODITIES AND CAPABILITIES, *supra* note 23, at 3. Sen's definition of well-being also may be distinguished from economic conceptions of well-being, which rely upon opulence or control of commodities. Sen divides valuation of well-being into two interrelated parts: (1) specification of valued functionings (value-objects) and (2) valuation of functioning achievements. SEN, COMMODITIES AND CAPABILITIES, *supra* note 23, at 20. Formally, valuation entails specification, though specification substantively makes valuation possible. *See* Sen, *Capability and Well-Being*, *supra* note 75, at 32.

for understanding Sen's theory. He argues that basic capability equality supports well-being, but his conception of well-being should not be confused with welfarist conceptions of well-being.

Basic capability equality differs from contractarian frameworks like Rawls's primary goods approach[83] and Ronald Dworkin's resource allocation theory,[84] both in the units it seeks to distribute and in its approach to distribution. Such contractarian approaches focus upon the primary social goods or resources an individual possesses, while basic capability equality is concerned with a person's capabilities, or opportunities or freedoms, given the characteristics and commodities she possesses.[85] In addition, Rawls's and Dworkin's theories may generally be understood to distribute resources according to just procedure, while Sen's theory looks to outcomes.

Another distinctive feature of basic capability equality is how it addresses inequality. The theory recognizes inequality as involving more than disparity in income, goods possessed, and utility. In so doing, it rejects classic economic models appealing to utility (commodities and income), Rawlsian primary good and other resource models, and utilitarianism. Instead, capabilities, which are believed to capture better the essence of well-being, are to be equalized at the highest possible level.[86]

The ability of the basic capabilities model to consider more directly the essential functionings of life, or the "fuller recognition of the variety of ways in which lives may be enriched or impoverished," is a driving factor behind Sen's approach.[87] As a result, basic capability equality requires that the values of basic capabilities are assessed directly, contributing to a multi-dimensional approach to well-being that more completely considers individual contributions to well-being

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83. JOHN RAWLS, A THEORY OF JUSTICE (1971).

84. Ronald Dworkin, *What is Equality? Part 2: Equality of Resources*, 10 PHIL. & PUB. AFF. 283 (1981).

85. Basic capability equality does, however, share some important features with the contractarian models Sen rejects. Sen's work in capabilities is, in fact, inspired by Rawls's conception of primary goods. Sen, *Equality of What?*, *supra* note 75, at 368. Both primary goods and basic capabilities are objectively valued entities that are distributed equally in some sense. Basic capabilities are to be maximized, and parties at the original position desire primary goods to the greatest extent possible. Unlike primary goods, capabilities are not static because individual choice affects which capabilities are valued. Capabilities also differ from primary goods because they do not comprise a finite list of goods. *See id.* These two differences may avoid the "fetishist handicap" often associated with Rawls's list of invariable goods.

86. Sen argues that this type of maximization, basic capability equality, "corresponds to total utility equality" in that it looks to a total measure of equality based upon observed facts. Sen, *Equality of What?*, *supra* note 75, at 359, 369. This is different from maximization through aggregation or summation. *Id.* at 359; *see also supra* notes 80-82 and accompanying text.

87. SEN, INEQUALITY REEXAMINED, *supra* note 56, at 44.

and better understands the causes of deprivation.[88] In this way, Sen's approach differs from Rawls's primary goods approach, which only looks to the value of specific social goods, and may be contrasted with utility measurements, which are viewed as means to achieve given welfare ends rather than as contributors to well-being.[89]

Sen uses formal language to represent the functioning vectors, and thus capabilities, which it is possible for an individual, i, to choose.[90] The formal representation is useful because it is a concise expression of Sen's theory and illuminates its flexibilities and constraints. For person i, capability sets are formally represented as follows:

$$Q_i(X_i)=[b_i \mid b_i = f_i(c(x_i)), \text{ for some } f_i(\cdot) \in F_i \text{ and for some } x_i \in X_i].$$[91]

That is, a capability b_i is a vector of functionings. There is a personal utilization function f_i, such that b_i is obtained through the application of a utilization function f_i to $c(x_i)$ for some x_i, where x_i is a commodity bundle and $c(x_i)$ are characteristics of the commodity bundle for person i. $Q_i(X_i)$ is the set of relevant capabilities.

Sen views b_i as an individual's "being" or functionings indicative of one's well-being.[92] Of relevance to applying capabilities in a health care context is the fact that b_i may depend upon the commodities possessed by others, such as access to public health care programs to prevent the spread of contagious disease, as well as the functionings of others, like contagious illness itself.[93] For parents, b_i may be influenced by the medical care or other needs of their children. These are other-regarding choices to which we will return in Part III.

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88. *Id.* at 43-44.

89. *Id.*

90. SEN, COMMODITIES AND CAPABILITIES, *supra* note 23, at 7.

91. *Id.* at 9. The following preliminary definitions are provided by Sen. *Id.* at 7. This model resolves the ambiguity about Sen's expression of functionings and capabilities in favor of the idea that capabilities are vectors of functionings, that is, capabilities are more generally vectors of doings or beings. *See infra* Subsection I.C.2.

x_i = the vector of commodities possessed by person i.

$c(\cdot)$ = the function (linear or nonlinear) converting a commodity vector into a vector representing characteristics of those commodities.

$f_i(\cdot)$ = a personal 'utilization function' of i reflecting one pattern of use of commodities that i can actually make (in generating a functioning vector out of a characteristic vector of commodities possessed).

F_i = the set of 'utilization functions' f_i, any one of which person i can in fact choose.

b_i = achieved functionings (that is, a vector) resulting from choice of utilization function $f_i(\cdot)$, with commodity vector x_i, $b_i = f_i(c(x_i))$.

92. *Id.* at 8. Arguably this would also apply to standard of living. *See infra* note 155.

93. SEN, COMMODITIES AND CAPABILITIES, *supra* note 23, at 7.

Sen asserts that, in general, capabilities are limited or enabled by both the possible functionings an individual may achieve based upon personal characteristics and her entitlement to, or command over, commodities.[94] $Q_i(X_i)$ represents a capability set: the ability to choose functionings based upon the conversion of personal characteristics into functionings, F_i, and commodity entitlements, X_i. Both personal characteristics and command of commodities may restrict capabilities. Restrictions on capabilities may be the product of voluntary or involuntary choice.[95] Considering personal characteristics, for example, nutrition may be voluntarily controlled, but certain biological conditions such as genetic disease may not be so restrained. Income and other commodity entitlements may be affected by voluntary choices about education or careers,[96] while government employment regulations, taxes, or national economic development may involuntarily limit commodity entitlement.[97]

There are various possible permutations of Sen's theory, demonstrating flexibility in how the base theory functions and how it might be applied to new contexts. In order to understand how Sen's theory could be applied to basic health care, it is helpful to conceptualize it in terms of two relationships: functionings and capabilities, and freedom and capabilities. Ambiguity within each of these relationships contributes to the complexity of basic capability equality, even before one arrives at the point of valuing capabilities.

2. Functionings, Capabilities, and Health Care

Capabilities pertain to the possible social and natural states of a person.[98] They are abilities that may be realized. Health is closely related to the abilities or states of a person and may be viewed as a collection of capabilities.[99] While Sen does not define "basic" in basic capability equality, he identifies basic capabilities as those roughly needed to live.[100] On these terms, basic capabilities may be understood to support basic health care. As such, it is vital to explain the dimensions of capabilities within Sen's theory.

Capabilities are defined generally in terms of functionings, or the "doings

94. *Id.* at 9.

95. *Id.* at 18.

96. This assumes a range of career options.

97. This assumes an affected individual has a limited capacity to change the government.

98. Capabilities refer directly to the states of a person, rather than to the relation of her external circumstances to her ability to function.

99. *See supra* Section I.A. and Subsection I.C.1.

100. Sen, *Capability and Well-Being, supra* note 75, at 41 ("'[B]asic capabilities' . . . was intended to separate out the ability to satisfy certain crucially important functionings up to certain minimally adequate levels.").

and beings" in leading a life.[101] There are two ways to understand capabilities under Sen's model:[102]

> (a) Alternative combinations of functionings that a person can achieve, and from which she can choose one collection; that is, a capability is a vector of functionings,[103] or
>
> (b) A set of vectors of functionings, reflecting a person's freedom to lead one type of life over another.[104]

In the first case, capabilities themselves are vectors consisting of functionings, or capability-vectors. On this reading, the components of a capability-vector are functionings, which may be either doings or beings. Thus, the term "functioning" does not describe a vector of doings and beings, but is instead a more general term for doings and beings. In the alternative, functionings are vectors of doings and beings, and capabilities are sets of functionings, that is, sets of functionings-vectors.[105]

To understand this distinction, consider the following examples of functionings: the ability to consume a balanced diet, to exercise, to breathe without obstruction, and to be immune from, or to have the ability to overcome, ailments. Using understanding (a) of capabilities above, these functionings could be components of a vector and constitute the capability of "having basic health" or "having a decent health status." Using understanding (b), the functionings would be components of a vector, and would be combined with other vectors of functionings to constitute a capability. For example, having basic health could be one vector within the capability set for being able to learn. Other vectors might include being able to read, to comprehend, to freely express ideas, and to interact socially.

Although capabilities and functionings should be distinguished from the common language usage of the terms, they may be applied whenever the formal

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101. *Id.* at 31.

102. This ambiguity may be explained by Sen's motivation to capture the essence of well-being by using capabilities. Sen emphasizes that what should matter for distributive justice is that people are placed in a position to function at roughly the same level, though not necessarily in the same way. That is, the range of things an individual can do or be should be equalized, rather than welfare or resources. The amorphous nature of this idea makes finding models that capture all, or at least most, of its aspects difficult.

103. Sen, *Capability and Well-Being*, *supra* note 75, at 31. This view of capabilities is also endorsed in SEN, COMMODITIES AND CAPABILITIES, *supra* note 23.

104. SEN, INEQUALITY REEXAMINED, *supra* note 56, at 40.

105. Sen, *Capability and Well-Being*, *supra* note 75, at 31.

notions that support them can be interpreted to match concrete factual assumptions. In this way, the ambiguity that is a problem for systemic discussion makes it possible to conceptualize capabilities in ways appropriate for different contexts. It seems that the more specific the capabilities being considered, the smaller the number of relevant functionings. The opposite is true for general capabilities, which likely involve more functionings. For instance, broad capabilities like health, nourishment, and average lifespan may include more functionings than the less general capabilities of seeing, walking, and hearing.[106] For the purpose of thinking about high technology health care, it is useful to invoke a broad capability category, like decent health endowment or health status, as well as narrow capabilities, such as the ability to take advantage of prophylaxis or family planning, as enabled by predictive testing.

Capabilities and their corresponding functionings vary not only in generality but also in importance, ranging from significant to trivial.[107] The capabilities to eat, to drink, and to be clothed and sheltered may be the most basic and important. The capability to possess health is perhaps at a level above these most basic capabilities but is still very basic. Level of specificity does not inform significance. For example, the ability to have a decent health status is a vital but very general capability, while the ability to have straight teeth is a specific but nonessential health status. Applying Sen's theory only requires a choice of capabilities relevant to understanding the deprivations of a given population.[108] The focus of this Article is the range of basic capabilities that are supported by high technology health care.

3. Capability, Freedom, and Medical Decision-Making

Capability sets reflect a person's freedom because, by construction, capabilities are chosen by the relevant agent.[109] Sen believes that, in general, capability sets account for positive freedom: "[t]he freedom to lead different

106. *Id.*

107. Most of Sen's writings focus upon basic capabilities, though the flexible formal language of his theory could be applied to non-basic (and possibly even trivial) capabilities.

108. Sen, *Capability and Well-Being*, *supra* note 75, at 32.

109. *Id.* at 33. Sen claims that basic capability equality supports the ability of an individual to have and evaluate options (capability sets). *See, generally*, works cited *supra* note 75. Commentators argue that this is one possible interpretation of basic capability equality; the other is that chosen functionings are what matter. *See* Anthony Atkinson, *The Contributions of Amartya Sen to Welfare Economics*, 101 SCANDINAVIAN J. ECON. 173 (1999). The former interpretation of basic capability equality values freedom of choice and supports, for present purposes, something akin to freedom in medical decision-making. On the latter reading, it is not freedom to choose that is significant, but rather the outcome, or whether capabilities are maximized by actual choice. This interpretation supports something like maximal health status.

types of life is reflected in a person's capability set."[110] In fact, he finds fault with Rawls's and Dworkin's contractarian theories on the ground that both fail to consider adequately positive freedom.[111] Sen believes that this freedom may be of intrinsic significance itself, in addition to its instrumental importance to well-being.[112] He goes further to tie freedom to the moral importance of capability; "if freedom is valued then capability itself can serve as an object of value and moral importance."[113] The choice of one capability vector over another is characterized by commentators as a positive freedom in the spirit of Isaiah Berlin's classic account.[114] Capabilities are viewed as fully capturing positive freedom.[115]

On this positive freedom account of basic capability equality, it is the choice involved in generating outcomes that is of value to the theory. It is this interpretation that distinguishes basic capability equality, in part, from welfarist approaches, including cost-utility approaches, because freedom is valued independently of outcome. Thus, there is value in an individual being able to choose high technology health care that is unproven or risky, but potentially greatly rewarding, even if it ultimately does not lead to the desired health state.[116] This freedom in decision-making is also not captured by contractarian-derived models, which allocate services to supply a baseline of care to support a certain level of functioning, without attention to patient choice among services. Contractarian models do not value freedom independently of process.

Considering freedom of choice with regard to capability sets has important implications for the valuation of such sets and medical decision-making. First, it implies that there is value in a range of choice.[117] The example of choosing to

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110. Sen, *Capability and Well-Being*, *supra* note 75, at 33.

111. SEN, RESOURCES, VALUES, AND DEVELOPMENT, *supra* note 23, at 323.

112. Amartya Sen, *Well-Being, Capability, and Public Policy*, 53 GIORNALI DEGLI ECONOMISTI E. ANNALI DI ECONOMIA 333, 343 (1999) (Italy) [hereinafter Sen, *Well-Being, Capability, and Public Policy*].

113. SEN, RESOURCES, VALUES, AND DEVELOPMENT, *supra* note 23, at 316.

114. Berlin discusses two types of freedom: negative and positive. Negative freedom is freedom from interference by others. Positive freedom is freedom to act in accordance with one's own will. *See* Isaiah Berlin, *Two Concepts of Liberty*, *in* FOUR ESSAYS ON LIBERTY 118, 121-34 (1969).

115. *See, e.g.*, Mozaffar Qizilbash, *Capabilities, Well-Being and Human Development: A Survey*, 33 J. DEV. STUD. 143, 144 (1996).

116. Sen uses this idea of freedom in his development work to argue for "capability expansion" as emancipation from deprivation, instead of preference satisfaction or greater utility. SEN, RESOURCES, VALUES, AND DEVELOPMENT, *supra* note 23, at 509-10; Qizilbash, *supra* note 115, at 143-48, 159.

117. Atkinson, *supra* note 109, at 179. The range of choice cannot be assessed independently of an individual's valuation of the elements in that range, however. *See infra* Section II.C. Bernard Williams questions whether capabilities may so easily be equated with freedom in terms of agency as freedom of choice. Williams, *supra* note 74, at 97-98. He suggests that factors considered by Sen

starve given biological or social restrictions on choice (for example, one's own pain or the burden on one's family) versus the same choice without these restrictions (for example, to make a political statement through a hunger strike) is informative here.[118] Only the latter involves freedom of choice. Second, it demands the availability of more information than a situation where the maximal outcome is sufficient. Namely, it requires sufficient information to consider possible alternatives. As will be discussed in Part II, high technology health care, like predictive testing, may help provide this information.

In sum, basic capability equality values patient choice for high technology and other health care independently of outcome or predicted health status. As a result, basic capability equality accounts for patient freedom in medical decision-making more fully than cost-utility or contractarian-derived frameworks. It captures the value to patients of both the direct and indirect benefits of high technology health care, including uncertain therapies with the potential to increase basic capabilities, now or in the future.

II. BASIC CAPABILITY EQUALITY OF HIGH TECHNOLOGY HEALTH CARE: PREDICTIVE TESTING AS A CASE STUDY

In passing, Sen recognizes basic health care as enabling basic capabilities

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to be capabilities and enabled by high technology health care, such as life expectancy, do not involve a meaningful sense of freedom in terms of choice. The choice, he says, relating to life expectancy, is whether to live or die, and it is odd to think that living longer preserves a choice about whether one wishes to commit suicide (physician assisted or otherwise). *Id.* (Williams holds, though, that capabilities need not be directly related to choice; it is enough for the capability to generate a valued good or for choice to be relevant in an indirect way. *Id.* at 98.) If valid, Williams' criticism would affect the claim that Sen's basic capabilities approach more directly accommodates high technology health care than the Rawlsian one, insofar as it relates to freedom to make certain choices that affect health, family planning, or individual life plans. Williams' quibble with Sen's use of life expectancy seems misplaced, however. It is more an interpretation of the reason that life expectancy is a capability, rather than evidence that capabilities are not related directly to freedom as choice. An increase in life expectancy, for example, need not be associated with whether to live but, rather, with the freedom to make choices about how to live. Surely this is at least part of what Sen means when he speaks about the lower life expectancy of women in India and China in his development work. *See, e.g.*, SEN, COMMODITIES AND CAPABILITIES, *supra* note 23, App. B at 52-69 (India); SEN, RESOURCES, VALUES AND DEVELOPMENT, *supra* note 23, at 526-27 (China). The same types of considerations motivate predictive testing employed to determine life expectancy. Individuals may undergo testing in order to determine whether they (or their fetuses) are at risk for disorders that affect life expectancy. The concern is that one has a life of sufficient length to make subsequent choices about life plans, experience certain qualities or aspects of life, et cetera, and not whether one has a longer time to choose whether to continue to live.

118. SEN, INEQUALITY REEXAMINED, *supra* note 56, at 33, 111-12.

vital to well-being and economic development,[119] and others have assessed the impact of basic health care upon developing countries.[120] I am unaware, however, of any work that considers the role of health care in enabling basic or other capabilities in more developed societies. This discussion makes plausible the idea that Sen's theory is applicable to health care, especially high technology health care, as it has been applied previously to poverty, famine, and other serious deprivations.

Applying basic capability equality to high technology health care requires that the "currency" or "units" of basic capabilities are applicable to innovative medical technologies. This Part will address basic capability equality as it applies to predictive testing, both genetic and otherwise. Section A will discuss broad health capabilities, or predictive testing as enabling a decent health status or endowment. Section B will address more specific capabilities allowed by predictive testing, such as psychological preparedness and the ability to take advantage of prophylactic treatments. It is also possible to make a case for high technology health care like predictive testing on a more foundational level, since it generates medical information that has the potential to broaden an individual's range of capability sets and thereby enhance her positive freedom to choose between sets. This is the topic of Section C.

Predictive testing is chosen as a test case for the application of Sen's theory to high technology health care for two reasons. First, it faces perhaps the greatest challenge in being recognized as a form of basic health care because of the indirect health care benefits it confers. Second, it likely has the most potential of high technology health care to impact social stratification, given its potential effect on the formation of life plans and future generations. This Part will demonstrate that predictive testing supports basic capabilities that inform basic health. The arguments in this Part apply broadly to demand for other forms of high technology health care that meet the goals of prevention, diagnosis, and limited treatment.

A. Broad Capabilities: A Decent Health Status or Endowment

Predictive testing that confers basic health care benefits may be viewed as enabling the broad capability of basic health. In other words, the capability set of basic health may include capability-vectors of functionings pertaining to capabilities for diagnosis, limited treatment, and prevention (including prediction). Functionings may vary depending upon whether basic health is

119. Amartya Sen, *Beyond Liberalization: Social Opportunity and Human Capacity* 29 (London School of Economics Development Economics Research Programme, DEP. No. 58, Nov. 1994) (on file with author).

120. PARTHA DASGUPTA, AN INQUIRY INTO WELL-BEING AND DESTITUTION (1993).

understood as a decent health status or a decent health endowment.[121] A decent health status may generally be conceptualized as a current state of affairs; a decent health endowment implies a more foundational health status, for example, that which results from favorable genes or other long-term biological advantages.[122] While the line between the two is not solid, the distinction is useful for identifying the contours of the capability of basic health as enabled by predictive technology.

Basic health care may relate to health status or endowment in different ways. Health status may be the result of prevention (including prediction), diagnosis, and limited treatment. Predictive testing may affect health status by generating information that contributes to comfort, security, or psychological preparedness. In other words, each of these benefits may be functionings supporting the capability of a decent health status. A decent health endowment is currently largely the product of predictive testing, such as prenatal or carrier genetic testing, followed by family planning (assisted reproduction or selective abortion) to avoid certain genetic diseases or other conditions.[123] In this instance, the capability of a decent health endowment may support any of a number of functionings related to having a healthy child. The line between health status and health endowment is not rigid, however, as predictive information may contribute to capabilities, such as the ability to take advantage of prophylactic options with long-term effects, which contribute to both status and endowment.

It is important to note that the capability to have a decent health status or endowment is relative to both social and biological constraints. Social constraints include wealth, material entitlements, and cultural norms. In more affluent societies, where assisted reproduction is available, obtaining a decent health endowment may entail genetic testing and embryo selection to prevent all known diseases or deleterious conditions. In these societies, the demand for high technology health care may mirror commodity entitlement.[124] In less economically advantaged societies, a decent health endowment may be one that results from traditional procreation and does not produce life-threatening disease. Predictive testing and other high technology health care may not play a role in

121. Either may be a capability, or, in the alternative, a functioning in a broader set of capabilities including other functionings needed to live a good life, such as basic education and rational life plan formation.

122. These advantages need not be ones that can be passed to future generations.

123. A decent health endowment could also result from genetic alteration, though this is not currently technologically possible.

124. On the other hand, a decent minimum could be defined regardless of wealth, as in societies where top genetic endowments are not required in order to be fully functional. *See, e.g.*, Ani B. Satz & Anita Silvers, *Disability and Biotechnology, in* ENCYCLOPEDIA OF ETHICAL, LEGAL, AND POLICY ISSUES IN BIOTECHNOLOGY 173, 183 (Thomas H. Murray & Maxwell J. Mehlman eds., 2000).

these societies.[125]

Social norms may also impact capabilities. Even if predictive testing is available, the information derived from it may not be of value in certain societies. This may be the case in countries with prenatal testing capabilities where abortion is viewed as immoral, for example. In other societies, patient belief that predictive genetic information is unique, and its disclosure is therefore likely to pose a greater threat of discrimination than other medical information, may limit use of testing.[126] Privacy laws that specifically target genetic or other predictive information may lessen the incentives for private insurers to reimburse for testing, due to fear of increased litigation over privacy breach.[127]

There are also biological restrictions. Some individuals may not benefit psychologically from predictive information, or they may prefer to live free from such knowledge.[128] Physical benefit may be limited if there are no treatments or prophylactics for one's particular disease or condition, though there may be other benefits to knowing such information, like comfort, reassurance, and security that are relevant to basic capabilities. Further, for individuals with uncorrectable defects, promoting one's health endowment may entail actions that do not further hinder functionality. It may not matter to someone born blind, for example, that she has a genetic mutation that causes night blindness. In contrast, night blindness might be of more concern to someone without congenital blindness.

The basic health care benefits derived from predictive information could be understood as enabling the broad capability of having basic health. This, in turn, may be viewed as either possessing a decent health status or a decent health endowment. A decent health status is supported by predictive testing that allows psychological benefits and prophylactic treatments. A decent health endowment may result from predictive testing that contributes to family planning or long-term prophylaxis. Under either conceptualization, the functionings that support basic health are defined relative to biological and social restrictions.

B. Specific Capabilities: Prophylactics and Mental Health

The ability to engage in predictive testing or know predictive information may itself be considered a basic capability resulting in basic health benefits. The capability to know predictive information is a more specific capability than a

125. The wealth of a society not only affects the availability of predictive testing but that of subsequent health care services needed to further certain capabilities, such as treatments, surgeries, and prenatal care.

126. Nongenetic information, such as information about contagious disease and exposure to environmental toxins, may also be predictive. Like genetic information, this medical information may reveal information about others. *See* Satz, *supra* note 49, at 104-06.

127. *Id.*

128. *See supra* note 72 and accompanying text.

"decent health status" or a "decent health endowment." The advantage to beginning with a smaller capability set under Sen's formal model is that it simplifies subsequent evaluations. This Section seeks to provide a general illustration of the application of the theory to the specific capability of knowing predictive health information.

A hypothetical is useful to apply Sen's model to the functionings, or basic health care benefits, associated with predictive testing. Assume for present purposes that prediction includes only presymptomatic testing, leaving aside carrier and prenatal testing. The capability to predict one's health status includes the following functionings: psychological preparedness, assurance, comfort, security, and prophylactic options. Also assume that genetic diagnostics are the best method of prediction.

Now imagine an indigent male, Harry, living in a society where access to predictive genetic testing is limited by the ability to pay for testing and by physical proximity to genetic testing centers, which are located in the wealthy suburbs of the city in which he lives. Harry is ineligible for Medicaid because of his gender and age,[129] and he does not live in a locality with a genetic testing center, nor is one easily accessible to him by public or private transportation. Harry wishes to know his predictive (genetic) health information, and it would be useful to him, since a genetic form of colon cancer runs in his family for which there is effective monitoring and treatment.

Recall the capability set equation for person, *i*:

$$Q_i(X_i)=[b_i \mid b_i=f_i(c(x_i)), \text{ for some } f_i(\cdot) \in F_i \text{ and for some } x_i \in X_i].^{130}$$

In the present example, for the capability to know predictive information, b_i, there is a vector of functionings containing psychological preparedness for the onset of disease, assurance, comfort, security, and the ability to take advantage of monitoring and prophylactic treatments. There is a personal utilization function f_i, such that b_i is obtained through the application of a utilization function f_i to $c(x_i)$ for some x_i, where x_i is a commodity bundle and $c(x_i)$ are characteristics of Henry's commodity bundle. In this case, Harry has several restrictions on his commodity entitlement, given his lack of health insurance and his geographic location. Harry has few restrictions in terms of relevant personal characteristics because he wants to know, and would benefit from, the information. $Q_i(X_i)$ is the set of the relevant capabilities, which contains diagnosis, prevention, and limited treatment.

The function v_i is defined by the achievable functionings, b_is, of the

129. *See supra* note 13 and accompanying text.

130. *See supra* notes 91-97 and accompanying text.

capability set $Q_i(X_i)$.[131] The values of well-being that it is possible for one to achieve are represented by Sen as:

$$V_i = [v_i \mid v_i = v_i(b_i), \text{ for some } b_i \text{ in } Q_i].^{132}$$

The set V_i shows the range of well-being that an agent may achieve with the capabilities available to her. In terms of the ability to know predictive information, the value expressed by V_i is low for Harry because he is burdened by restrictions on entitlement to commodities. He may favor a capability set with a greater chance of knowing predictive genetic information, but it is unavailable to him; his intrapersonal comparisons are limited to those capabilities actually achievable. As a result, he must choose a capability set of basic health care without the capability to know predictive genetic information. (Other sources of predictive information still might be available to him, however, such as non-genetic diagnostics that are performed by the clinics in his locality.)

Remember, though, that Harry lives in an affluent society. Other individuals within his metropolitan area may choose the capability to know predictive information, and in particular genetic information, as part of their capability sets. This alone may be enough to establish a partial dominance ranking favoring access to predictive genetic information as part of a measure of an overall living standard.[133] Interpersonal comparisons may reveal a partial ordering with weighted values that reflect increases in well-being for individuals who are capable of obtaining predictive genetic information regarding their health. This data might be obtained through statistics reflecting the length of life of individuals with and without such information, professional assessments of their psychological health, and their overall quality of life, assuming certain objective measures. In this case, there would be strong support for equalizing access to predictive genetic technologies through government funding, and, as an indigent male, Harry may eventually receive access to predictive genetic testing.

So far this discussion has focused on using the basic capability equality framework to contemplate the health care benefits of predictive genetic testing

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131. Sen formally represents the valuation v_i of individual i as: $v_i = v_i\ (f_i(c(x_i)))$. SEN, COMMODITIES AND CAPABILITIES, *supra* note 23, at 8-9. This reading of capabilities follows the view that they are alternative combinations of functionings a person can achieve, and from which she can choose one collection, where capabilities are vectors of functionings. *See supra* Subsection I.C.2. The valuation, v_i, then, is a valuation of capability-vectors. As with all valuation functions, this function pertains to a particular agent. Concisely stated, the valuation function associates a measure of well-being with each capability available to a specific agent.

132. SEN, COMMODITIES AND CAPABILITIES, *supra* note 23, at 9.

133. A partial ordering may result when it is possible to rank some capabilities over others without being able to rank every vector of functionings contained therein. *See infra* Appendix.

for purposes of furthering the goals of basic health care. Special attention was paid to the capability of knowing predictive genetic information. Predictive medical information may also serve a more foundational role in basic capability equality. That is, the information generated from such testing may expand capability sets, and concomitantly, patient choice.

C. *Capability Set Expansion*

Recall that freedom of choice is an integral part of evaluating capability sets.[134] The implications of this are that there is value in a range of choices, and information is needed to define the relevant range.[135] Sen is careful to point out, though, that it is not the range of choice itself that is valuable, but rather, the value of the *elements contained within that range.*[136] This is a fine distinction, but the value of the range of choice is tied to an individual's assessment of the freedom to choose a capability set from within that range, rather than the size of the range *per se.*[137] Choice from an expanded range may be valuable because the ability to evaluate and choose a capability set is a positive freedom.

Predictive information directly informs the range of choice available to an individual. In this sense, predictive testing, like genetic testing, facilitates the functionality of basic capability equality. If the range of choice is enlarged and valued by an individual, her positive freedom is enhanced. This might occur if predictive information allows treatment or prophylaxis, the ability to form reasonable life plans, or family planning, for example.

The range of choice would not necessarily be enlarged with access to predictive information, however. Medical information may narrow capabilities. This may be the case when an individual does not benefit psychologically from knowing the information, such as when there is no course of action to ameliorate the effects of a disease or other condition. Of course, even in these instances, psychological preparedness may be of value, but this depends upon the person's capability to use the information to her benefit, or the subjective aspect of the relevant disabling conditions. Some people prefer not to know predictive information about their health, and knowing it may cause them psychological harm. The salient example is the person who has only a very slight risk of a deadly disease but for whom this information dramatically limits her capabilities, by dominating and grossly restricting her life activities.

Regardless, predictive information provides a more accurate picture of an

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134. *See supra* Subsection I.B.1.

135. Sen, *Capability and Well-Being*, *supra* note 75, at 34-35.

136. *Id.* This point is missed in the legal literature. *See, e.g.*, Ball, *supra* note 20 and accompanying text.

137. Sen, *Capability and Well-Being*, *supra* note 75, at 34-35.

individual's capability sets with respect to her current and future health states. It allows a more complete understanding of an individual's personal characteristics and the limitations and advantages they pose for capabilities she may achieve. Thus, the potential of prediction to expand capabilities bolsters the argument for universal access to high technology health care. Access to health care, like predictive testing, not only supports the goals of basic health care, it has the potential to expand the range of medical choices available to an individual.

III. OBSTACLES

While basic capability equality offers strong advantages over dominant theoretical frameworks for distributing basic health care, a number of obstacles arise. The first is inherent to the formal model itself. Namely, the ability to consider constraints on choice is a limitation as well as an asset. The second problem occurs at a practical level: Using basic capability equality to develop a legal paradigm for the distribution of health care will require the abandonment of socially and legally entrenched basic minimum and traditional rationing schemes.

A. Limits of Theory: Constraints on Choice

At a theoretical level, the most significant limitations to applying basic capability equality to health care demand are constraints on choice. Thus far, the ability of Sen's formal model to accommodate these restraints is understood as a *benefit* of his theory: It allows one to better understand the circumstances surrounding an individual's medical decision-making. Nevertheless, these advantages create challenges for the formal model in accounting for negative freedom in choice as well as loss of freedom as a result of choice. The first challenge arises from requiring individuals to choose from among capability sets that may be significantly restricted by personal or social limitations. The second difficulty is created by the loss of freedom caused by making choices that foreclose or significantly restrict future choices, such as irreversible medical decisions. This loss of freedom may occur regardless of whether an individual maximizes her capabilities. The third difficulty is in accounting for other-regarding choices. Each is addressed in turn.

To begin, one must choose from a capability set restricted by personal characteristics, including personal knowledge.[138] One important implication of this model for medical services is that choice operates relative to an individual's biology.[139] For example, an individual who is ill must choose a capability set from among possibilities restricted by illness.[140] A permutation of this criticism is

138. *See supra* notes 54-61 and accompanying text.

139. *See supra* notes 58-61 and accompanying text.

140. Des Gasper, *Policy Arena: Sen's Capability Approach and Nussbaum's Capabilities Ethic*,

that Sen fails to account adequately for negative freedom. While basic capability equality considers commodity entitlements and personal characteristics with respect to positive freedom and capability, it fails to consider freedom *from* deviation from a certain kind of functioning when capability levels are maintained. For example, someone who is paralyzed but is capable of motion with the assistance of a wheelchair might be considered deprived of motion in the same manner as walking individuals, affecting her negative freedom or her freedom from being impaired in this way.

It is true that there is something lost when an individual suffers an accident and is paralyzed or must choose from capability sets affected by illness. What is lost, however, is largely individual. It is not necessarily the capability for mobility or better health, nor is it necessarily a loss of freedom. There may be alternative modes of functioning that support well-being.[141] In fact, alternative methods of functioning may be enabled by high technology health care such as advanced medical equipment,[142] pharmacogenetics,[143] and biological enhancements that serve as treatments for illness or other conditions.[144]

If functionings may be restricted by choice, an individual may also limit her own freedom, even if she maximizes her capabilities.[145] If individual i chooses the maximal element b_i for Q_i, and all other choices are rendered unavailable by this choice (or, in the alternative, the choices become unavailable due to a change in entitlement), capabilities will be maximized, but freedom in terms of choice will decline.[146] This problem is evident in irreversible medical choices. If an

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9 J. INT'L DEV. 281, 291 (1997).

141. *See supra* note 58 and accompanying text.

142. *See, e.g.*, Venkat Krovi et al., *Design of a Walking Wheelchair for the Motor Disabled*, 4 PROC. INT'L CONF. REHABILITATION ROBOTICS 125 (1994), *available at* http://citeseer.ist.psu.edu/krovi94design.html (follow "PDF" hyperlink under "View or download") (discussing the "walking wheelchair").

143. Researchers in pharmacogenomics seek to develop drugs to account for genetic variation among individuals. *See* William E. Evans & Mary V. Relling, *Moving Towards Individualized Medicine with Pharmacogenomics*, 429 NATURE 464 (2004); Robert F. Service, *Pharmacogenomics: Going from Genome to Pill*, 308 SCIENCE 1858 (2005); *see also* John F. Deeken et al., *Toward Individualized Treatment: Prediction of Anticancer Drug Disposition and Toxicity with Pharmacogenetics*, 18 ANTI-CANCER DRUGS 111 (2007).

144. Certain biological enhancements may help compensate for impairments and serve as treatments that support alternative modes of functioning. For example, gene therapy may be used to increase lipoprotein receptors above the normal range to compensate for the effects of hypercholesterolemia or to cause capillary formation above normal levels in individuals with arterial blockage. *See* Satz & Silvers, *supra* note 124, at 184.

145. SEN, COMMODITIES AND CAPABILITIES, *supra* note 23, at 9.

146. *Id.* ("$Q_i(X_i)$ represents the freedom that a person has in terms of the choice of functionings, given his personal features . . . and his command over commodities . . . . Q_i can be called the

individual chooses to know certain information, and this information diminishes her previous range of choice of functionings associated with not knowing the information, she may experience a loss of (well-being) freedom.[147] Such a loss of freedom pertains most strongly to diagnostic and predictive tests with high specificity. It may be exacerbated in instances where an individual is unable to obtain treatment for a certain condition. The majority of diagnostic and predictive tests provide partial risk information, however. Further, as discussed with regard to biological limits, loss is largely individual; such restrictions on capability sets may not affect health status based upon individual psychology or the ability to function.

Social preferences may restrict capability sets when, regardless of whether functionings may be valued differently by individuals,[148] widespread acceptance of certain functionings as having high (or low) worth limits the opportunity for individual valuation.[149] Consider social movements for the right to life, which have limited the availability of abortion, assisted suicide, and therapies from fetal stem cells. Like biological constraints, social choice restrictions, as well as commodity restraints, impact the process of evaluating capability sets. These are, however, issues to be addressed by political and policy leaders. Social and economic limits plague any distributive approach.

What if an individual makes choices that do not maximize her capabilities? These choices may be self-regarding or other-regarding. If they are self-regarding, this is a loss of freedom that basic capability accepts and that may be justified, based upon the arguments above (the social implications of bad choices are discussed below in Section B). If they are other-regarding, Sen's formal model cannot directly account for them as contributing to one's own well-being achievement.[150] Further, the model does not account for the value of the rejected

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'capabilities' of person *i* given those parameters.").

147. Sen makes distinctions between agency achievement, agency freedom, well-being achievement, and well-being freedom. Sen, *The Standard of Living: Lecture II*, *supra* note 75, at 26-29. Agency achievement is the attainment of goals one wants to achieve, possibly outside of one's own well-being, such as fighting for a cause. *Id.* Agency freedom is the ability to accomplish those goals. *Id.* Well-being achievement and well-being freedom are parallel concepts understood relative to one's own well-being, that is, the attainment of, and freedom to support, one's well-being, respectively. *Id.* The categories overlap insofar as an individual's well-being is affected by other-regarding preferences. *See infra* notes 150-55 and accompanying text. Thus, they cut across Sen's notions of well-being, quality of life, and standard of living. *See infra* note 155.

148. SEN, COMMODITIES AND CAPABILITIES, *supra* note 23, at 33.

149. *Id.* at 20.

150. Recall that the function v_i is defined on the achievable functionings, b_i, of the capability set $Q_i(X_i)$. The values of well-being that it is possible for one to achieve are represented by Sen as:

$$V_i = [v_i \mid v_i = v_i(b_i), \text{ for some } b_i \text{ in } Q_i].$$

self-regarding choice.

Genetic testing for linkage analysis, or testing for the presence of genetic markers indicative of diseases or conditions within certain families, provides an example of how these problems might arise.[151] Consider an individual, Rebecca, who does not wish to know her own genetic status but chooses to be tested in order to aid her pregnant sister, Sarah, who wants to know whether her fetus possesses the breast cancer mutation that runs in their family. Even if the test results are not disclosed to Rebecca, her own results may be indicated by her sister's decision to carry to term or terminate the pregnancy. To simplify matters, assume Rebecca's status is indeed indicated by her sister's actions, and this unwanted information negatively impacts Rebecca, preventing her from maximizing her capabilities.

Under Sen's formal model, only choices that affect Rebecca's well-being are integrated directly.[152] Rebecca's decision to aid her pregnant sister will support Rebecca's agency and well-being freedom but decrease her well-being achievement.[153] The problem is in accounting for the value that seems lost with regard to Rebecca's other-regarding choice. This problem may be mitigated partially by the fact that capabilities are maximized across populations. In this sense, contributions to the well-being of others may be integrated indirectly because the overall contribution to the well-being of the women's family is the same. In the example, Rebecca's well-being is increased while Sarah's is not

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SEN, COMMODITIES AND CAPABILITIES, *supra* note 23, at 8-9. The set V_i shows the range of well-being that an agent may achieve with the capabilities available to her. This formal representation has several implications for other-regarding choices. Consistent with Sen's model, one may choose not to maximize one's own well-being. For example, one may act to benefit another, out of obligation or for other purposes, and decrease one's own well-being achievement. This means that one acts to maximize, or to improve by some increment, another's well-being.

As Sen recognizes, the valuation function only evaluates choices with respect to the agent's own well-being, and an individual's well-being is fostered only when her agency is concerned with her own doings and beings. *Id.* Although he does not elaborate upon this point, one can infer that Sen's theory may experience difficulty in interpersonal comparisons, given the possibility for non-optimal choice with respect to one's own well-being achievement for the sake of others and the inability to account for this in an individual's own valuation function. Arguably, agency and well-being freedom are preserved, however. *See supra* note 147 and accompanying text.

151. In linkage analysis, several individuals with the disease or condition are tested for polymorphisms, which are certain normal variations in genetic sequences that are often present with an unknown disease gene. Presymptomatic individuals, people without clinical manifestation of the disease but who share these polymorphisms, may be at risk for the disease. For symptomatic individuals, those who are experiencing clinical symptoms, linkage analysis may confirm or disaffirm a genetic diagnosis.

152. SEN, COMMODITIES AND CAPABILITIES, *supra* note 23, at 9-10.

153. *See supra* note 147 and accompanying text.

(though Sarah exercises agency and well-being freedom in making her choice).[154] Regardless of whether Rebecca undergoes testing, the outcome, in terms of increasing familial well-being, is identical. One sister's well-being is increased while the other's is not, but the opposite choice will produce the same result. Perhaps the maximization of capabilities comes as close as possible to the maximization of the preferred capability range (the value-objects) for all individuals in a given population. This may be the best measure of individuals' choices, even if it cannot directly integrate other-regarding choices (or account for rejected self-regarding choices) in the valuation process.[155]

B. Social Role of Basic Minimums and Traditional Rationing

On a practical level, it may be argued that basic minimums and traditional rationing play an important social role in the distribution of health care services. There may be a sense that, even in a developed, western nation, universal access to traditional health care must come before access to high technology health care services, or that there is a need to build the health care service menu from the ground up. This claim might rest on the assumption that high technology health care is not important (or at least not as important as traditional health care services) for meeting the goals of basic health care. In the alternative, it is possible to believe that individuals should not be afforded an opportunity to choose from a set of health care services that contain high technology health care, even with self-rationing, because they may make bad choices, and these choices may be costly to society.

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154. *See supra* note 147 and accompanying text. Sen assumes other-regarding choices are made because they are of value to the agent. *See, e.g.*, SEN, INEQUALITY REEXAMINED, *supra* note 56, at 61-62. The premise being discussed is that they are of value to another individual and that the rejected (self-regarding) choice is of value to the agent. In addition, it is possible that both sisters in the example may benefit from the other-regarding choice, if the tested sister derives benefit from her sister's increase in well-being as a result of the testing.

155. Respecting these competing interests, Sen makes further distinctions about the scope of basic capabilities in different contexts. Sen defines quality of life as a broader category than well-being because it considers other-regarding commitments. Gasper, *supra* note 140, at 288. Well-being may entail other-regarding preferences of value to the *agent*, however. Standard of living, which does not consider such preferences, is understood as a component of well-being. *Id.* As some high technology health care, like predictive testing, generates shared genetic information that has implications for individuals other than the tested individual, well-being and quality of life, rather than standard of living, are relevant. This does not assume, however, that well-being should be measured in families or communities but not with respect to individuals, only that other-regarding choices may be made by individuals in furtherance of well-being. In fact, in his work on poverty and sex bias, Sen argues that equality requires a more just distribution of resources within families, that is, for each individual. SEN, RESOURCES, VALUES, AND DEVELOPMENT, *supra* note 23, at 364-65.

Part I of this Article argues that high technology health care may support the goals of basic health care and provides examples; the claim is further defended in Part II. In the latter Part, the flexibility of Sen's model to accommodate capabilities of varying degrees of importance and specificity is discussed. Nevertheless, it is worth saying more about how basic capability equality might contemplate the relative importance of different capabilities in light of the question: How important is high technology health care relative to traditional health care?

To start, Sen argues that the importance of capabilities may parallel degrees of command over commodities.[156] If social and economic barriers are low or removed, the importance of relatively higher-order basic capabilities may increase.[157] Sen cites Adam Smith's famous example of appearing in public without shame (of close relation to Rawls's primary good the social bases of self-respect).[158] This example is understood to support basic capabilities, such as the ability to be clothed, as well as less basic capabilities, like the ability to wear a linen shirt.[159] Bernard Williams is troubled by the idea that what Sen terms an invariant, or base-line, capability might entail different responses, for example, a luxury over a more standard response, to enable a particular capability.[160] This concern about providing sophisticated goods over more standard ones is frequently raised with regard to access to high technology health care. Williams tests the boundaries of the concept of a basic capability by asking whether the capability to wear a linen shirt washed with Bloppo, a favored laundry detergent, constitutes a basic capability.[161]

Is high technology health care, such as predictive testing, closer to washing with Bloppo, wearing a linen shirt, or wearing any shirt at all? In the instances where such testing enables basic health-related capabilities that are not supported by other diagnostics, it seems closest in analogy to the basic capability of wearing any shirt at all. When predictive testing confers the same benefits as traditional diagnostics but is less invasive or involves less frequent testing or monitoring, it may be closer to the capability of wearing a linen shirt, though it might still be considered basic given its advantages. Most conservatively stated,

156. Sen, *The Standard of Living: Lecture II*, *supra* note 75, at 17-18.

157. *Id.*

158. *Id.* at 16-17; *see also* RAWLS, *supra* note 83, at 440.

159. Sen, *The Standard of Living: Lecture II*, *supra* note 75, at 17-18.

160. Williams, *supra* note 74, at 98-102.

161. *Id.* at 98, 101-02. Sen argues instead that one does not need to assess the importance of capabilities before establishing capability sets because the valuation of capabilities will serve to eliminate the trivial ones. *See* SEN, INEQUALITY REEXAMINED, *supra* note 56, at 44-45. Regardless, Sen and Williams agree that convention or nature, or some combination of both, restrict capabilities within populations during capability set formation and valuation. *See id.* at 101-02; *supra* notes 91-97 and accompanying text.

there is a thin line in the basic health care context between the regular and linen shirt. For example, predictive testing for some forms of colon cancer may eliminate the need for repeated, invasive colonoscopies, which may also detect cancer risk. This does not seem like a luxury good. One approaches the analogy to the linen shirt only when using predictive testing to facilitate very marginal basic health benefits, like testing to predict a mild, temporary ailment. Presumably, the use of predictive testing to exceed the capabilities considered to be part of basic health would be akin to wearing the linen shirt or even washing the linen shirt with Bloppo.

The view that our legal and political structures should support access to only traditional forms of health care to further basic health is misguided. High technology health care may be more clinically efficient and derive better results than traditional care. Further, biological variation or different modes of functioning may be best supported by high technology health care. Examples include technologically advanced prostheses for persons who have lost limbs and super-oxygenation of the blood of individuals whose bodies experience difficulty with normal oxygen intake due to deformed erythrocytes.[162] Nevertheless, a patient may have to make a decision in a state of uncertainty about whether traditional or high technology services are best for their situation, and it is possible that the wrong choice will be made.

Concern about the social cost of bad patient choices is another reason people may argue that it is best to provide a basic minimum of traditional health care services or to ration them—making available a set of identified services known to be most effective in terms of typical effect on health status, functioning, or quality and length of life. In other words, basic minimum and traditional rationing schemes limit patient choice, possibly guarding against bad patient decision-making. The assumption is that if individuals make poor medical choices, they will likely require emergency or other additional costly medical interventions. If such health needs arise in the emergency context, under the Emergency Medical Treatment and Labor Act, most hospitals are legally required to address them.[163]

It is true that, by self-rationing, individuals may make choices that do not maximize their capabilities, either because the choices are bad ones or they are other-regarding (they increase the capabilities of someone else).[164] It is the first category with which we are concerned, since the latter arguably still contributes

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162. Satz & Silvers, *supra* note 124, at 185.

163. The Emergency Medical Treatment and Labor Act requires that hospitals accepting payment from Medicare and operating an emergency room engage in "appropriate medical screening" to determine whether a patient has an emergency medical condition and, if so, that they stabilize the patient. 42 U.S.C. § 1395dd *et seq* (2000).

164. *See supra* notes 150-55 and accompanying text.

to the maximization of capabilities across a given population.[165] Individuals may make poor health choices from among high technology and traditional health care services alike, however. Avoiding vaccinations, or failing to partake in preventative care for one's heart or for diabetes, are strong examples in the traditional health care context. Further, even if one is limited to traditional health therapies, one might still engage in risky social behaviors that dramatically affect one's health, like smoking, failing to wear a seatbelt or motorcycle or bicycle helmet, eating or drinking to excess, eschewing exercise, etc. If policy-makers are concerned with the cost of poor health care choices, these behaviors should be prevented as well. Further, the high technology health care discussed in this Article has the potential to support the goals of basic health care; thus, a poor choice in this context is more like a suboptimal, rather than an irrational or irresponsible, one.

Perhaps the biggest hurdle for making high technology health care available as basic health care is its cost for intense periods of care, such as that for premature infants and individuals at the end of life. It is here that utilitarian schemes, like the rejected cost-utility approach, provide a satisfying answer: Benefits are to be measured over a lifetime.[166] As one ages, one's entitlement to benefits under a QALY scheme decrease, guarding against excessive expenditures at the end of life.[167] But this may leave large expenditures at the beginning of life, if quality and length of life are expected to outweigh costs, and such services are prioritized by a population.[168]

Much remains to be resolved with regard to the application of basic capability equality to prolonged periods of substantial health care expenditures. Since capabilities are maximized over a population, the broader the population, the more difficult it is to sustain large costs that may affect only a minority of individuals. This may include care for some premature infants. As I discuss in Part I, I do not believe these forms of long-term treatment support the goals of basic health care. Nevertheless, the issue of resource drain at the beginning and end of life or during other periods of intense medical need is one that must be addressed in the future. I believe basic capability equality holds much promise for informing this area of decision-making as well. One possible solution, which I explore elsewhere, is to combine self-rationing under basic capability equality,

165. *See supra* notes 153-55 and accompanying text.

166. *See supra* notes 45-48 and accompanying text.

167. *See supra* notes 45-47 and accompanying text.

168. Contractarian frameworks fare worse than utilitarian ones in addressing this problem. Substantial resources may be diverted from some patients in order to assist others. *See, e.g.*, NORMAN DANIELS, AM I MY PARENT'S KEEPER? AN ESSAY ON JUSTICE BETWEEN THE YOUNG AND THE OLD 66-82 (1990) (suggesting it is necessary to determine entitlement to health care resources at each life stage).

for purposes of basic health care distribution, with a form of rationing or a basic minimum as applied to non-basic medical care.[169]

CONCLUSION

High technology health care that supports the goals of basic health care should be universally available. Basic capability equality provides strong normative support for this assertion, that is, for the ability of patients to self-ration, or choose amongst basic health care services. It is only by moving away from dominant economic, utilitarian, and contractarian approaches focused on supply, and toward an approach that directly considers patient demand, that it is possible to begin to understand the deprivation underlying the current health care crisis. This deprivation, based in part on demand for high technology health care, is not addressed by reforms that seek to expand the supply of traditional health care services. These reforms fail to understand the biological, social, and economic factors affecting patient choice as well as the range of basic health care benefits enabled by high technology health care.

169. Satz, *supra* note 49, at 216-21.

APPENDIX – VALUATION OF CAPABILITIES

For basic capability equality to function, it must be possible to evaluate and compare capability sets. Evaluation may involve intrapersonal or interpersonal comparisons. An intrapersonal comparison in this context is one in which an individual evaluates capability sets (capability-vectors or functionings-vectors) in order to choose one. Relevant interpersonal comparisons are those made between individuals in a given population. The possible mechanisms for both types of comparisons are essentially the same, with the exception that there are a host of classic, additional problems associated with making interpersonal comparisons. Although these issues cannot be addressed here, they are discussed thoroughly elsewhere.[170] The following text serves as a general discussion of possible methods for intrapersonal and interpersonal comparisons of well-being as part of basic capability equality. With the exception of Sen's formal expression of the valuation function for intrapersonal comparisons, the discussion applies to both intrapersonal and interpersonal comparisons.

I. WHAT IS ONE MEASURING?

The first step in making set comparisons is to determine what "units" are being evaluated. Sen speaks of these "units" in terms of "evaluative space" or objects of value for evaluation.[171] For utilitarians, individual utilities comprise the evaluative space; for Rawls, it is primary goods. With respect to basic capability equality, both functionings and capabilities constitute the relevant evaluative space. Functionings are a "larger" evaluative space than capabilities because they may represent conditions that are not possible for a given individual, that is, certain functionings cannot be capabilities. Functionings may be conditions that are unattainable, due to differences in personal characteristics or individual command over commodities. Capabilities are capability-vectors or functionings-vectors that may be achieved or are actually possible. By choosing certain capabilities, an individual selects the valued goods, value-objects, to be weighted. Implicit in this choice is that the chosen goods are of greater value to an individual than those that are not chosen.[172]

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170. *See* INTERPERSONAL COMPARISONS OF WELL-BEING (Jon Elster & John E. Roemer eds., 1991).

171. SEN, INEQUALITY REEXAMINED, *supra* note 56, at 42-44; Sen, *Capability and Well-Being*, *supra* note 75, at 32-33.

172. SEN, INEQUALITY REEXAMINED, *supra* note 56, at 42-44; Sen, *Capability and Well-Being*, *supra* note 75, at 32-33.

II. MECHANICS

Valuation in basic capability equality entails a comparison of capability-vectors or functionings-vectors, in order to make intrapersonal or interpersonal comparisons. For intrapersonal maximization to be meaningful, one must be able to make intrapersonal comparisons of capability-vectors or functionings-vectors, and for interpersonal maximization to have force, one must be able to make interpersonal comparisons of those vectors. The mechanics of valuation is perhaps the most contentious aspect of Sen's theory, as the flexible formal language does not provide much guidance in either the scope of the "units" of well-being to be valued or the process of valuation necessary to achieve practical outcomes.

Unlike utilitarianism, maximization under the capability approach does not amount to summation. As a result, the mechanics of maximization are much less straightforward for basic capability equality than for utilitarianism. For utilitarianism, all conditions are translated into utils, and the summation of these units provides a mechanism for maximization. Basic capability equality compares more than utilities, and due to this added complexity, capabilities cannot be summed. By starting with different "units," Sen creates the vexing issue of how to carry out such comparisons.

Sen believes this ambiguity is necessary to best capture the essence of well-being, which he believes is lost by adhering to more simple units of utility. Over-precision is, in fact, perceived by Sen as a danger in valuation,[173] since well-being, as captured by functionings, is too complex to allow for oversimplified comparisons. Sen stresses the need for flexibility in valuing elements of well-being and equality, which are "broad and partly opaque concepts."[174] He seeks to offer a pragmatic approach to interpersonal comparisons, preferring to rank what may be ranked through partial orderings, rather than forcing a complete ordering that may sacrifice the needed ambiguity of basic capability equality.[175] Although Sen argues that basic capability equality does not embrace a specific means of valuation, he offers partial ordering as an incomplete but viable method of maximization without summation.[176]

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173. SEN, INEQUALITY REEXAMINED, *supra* note 56, at 48.

174. *Id.*

175. *Id.* at 48-49.

176. Sen, *The Standard of Living: Lecture II*, *supra* note 75, at 29-31. Sen's discussion of partial ordering with respect to standard of living is cited here over other discussions of partial ordering that are not limited to the standard of living context because it is a more concise and clear explanation of the different types of partial ordering to which he appeals. This discussion has general application to broader well-being assessments. Recall that the difference is that standard of living does not take into account other-regarding preferences. *See supra* note 155 and accompanying text. This does not affect the mechanism for capability set comparison.

III. PARTIAL ORDERINGS

Sen speaks of evaluating capability sets on a spectrum, ranging from complete orderings to partial or incomplete orderings. He concentrates on partial orderings that provide the most practical methods to evaluate capability sets. Partial orderings themselves offer varying levels of completeness. What Sen terms dominance partial orderings amount to a minimum evaluation. Other partial orderings are closer to complete orderings, where exact values are known and possible to compare.

Sen defines a dominance partial ordering as one that does not require that each element b_i in the set $Q_i(X_i)$ be given a numeric value or a relative weight. A dominance partial ordering is created when certain capability sets (capability-vectors or functionings-vectors) are identified as valuable.[177] Dominance partial orderings may provide partial measures of overall living conditions or standards, for example.[178]

Other possible partial orderings involve assigning specific values or weights to capabilities.[179] These orderings also utilize dominance relationships, but since weights are involved, they are considered to be a higher level of evaluation than the dominance partial ordering. Value may be assigned in two different ways. It may be based either upon an individual's own judgments about her capabilities relative to what others possess, or, in the alternative, upon an assessment of an individual's own capabilities against the social standard. Sen refers to the first case as self-evaluation and the second as standard-evaluation.[180] He argues that the two approaches need not result in the same weight assignments, as they pose different questions serving varying purposes.[181]

More specifically, an ordering is a partial ordering if not all elements of the set on which the partial ordering is defined can be compared.[182] Consider, for example, a set that contains as its elements other sets. Some of those sets will be subsets of others and in that sense "smaller," and they can be compared to the "larger" sets. Other couples of sets may intersect without one being included in the other, or in the alternative, not intersect at all; these set elements cannot be compared by means of set theoretic inclusion.

An example of a partial ordering in the current context is the relation according to which one vector "dominates" another, if each component of the

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177. Sen, *The Standard of Living: Lecture II*, *supra* note 75, at 29-31.

178. *Id.*

179. Sen usually assigns weights to ranges of capabilities. *See, e.g.*, Sen, *The Standard of Living: Lecture II*, *supra* note 75, at 30-31 (and references cited therein).

180. *Id.*

181. *Id.*

182. The order of the components that are dominant is not significant for this type of ordering.

first is bigger than the corresponding component of the second. Consider the following two comparisons. The first is a comparison between $V_1 = (3, 6, 9, 10)$ and $V_2 = (1, 4, 7, 9)$. The components of V_1 are each larger than the components of V_2, and V_1 dominates V_2. But now consider $V_3 = (4, 8, 29, 10)$ and $V_4 = (2, 10, 27, 6)$. V_3 does not dominate V_4, and vice versa. This demonstrates that the dominance relation is a partial ordering, or incomplete ordering of the elements (vectors) of the set to which they all belong. There are also instances where functionings in two capability-vectors simply cannot be compared component by component. For these situations, the vector with at least one superior (in the relevant sense) component would be viewed as dominant over the other. The same reasoning applies to partial orderings of sets, although the comparison is between elements of the sets instead of vectors.

One significant criticism of dominance partial ordering is that it approximates the results of summation, a process Sen explicitly rejects. Parallel results hold for partial dominance sets where all values are known, as well as for those in which only some values are known or only some values are given within a range. In the first instance, if the elements of Set One each dominate the elements of Set Two, the sum of the elements of the first set obviously will be larger than the elements of the second, and Set One will be chosen in both cases. Where only certain elements have known values or ranges of values, summing the known values or comparing a summation of the extreme (low or high) possibilities of the range will obtain the same result as a dominance ranking that considers the same variables.

Although the distinction between utilitarian summation and maximization with regard to dominance ranking is difficult to see when both methods appear to yield the same result, summation over the elements of capability sets cannot be conceptualized in a meaningful way. Utils cannot simply be substituted for "capability units" because they represent different things. It is even unclear how practically one would convert capability units into utils. Of the possible functionings mentioned by Sen in various works, only one functioning, longevity, could easily approximate utility measure, that is, quantity of life. The rest—including having nourishment and basic health, avoiding epidemics, being literate, possessing the ability to interact socially and take part in community life, being able to live a life without being ashamed of one's clothing, having the ability to engage in cultural and intellectual pursuits and to travel—cannot be so easily converted. Further, even if such conversion is possible, it seems to violate the spirit of Sen's theory, which is to capture a robust form of well-being. In other words, a dominance ranking of Set One {3, 23, 74} over Set Two {6, 20, 69} may not necessarily yield the same result as a summation comparison of these two sets, if enough value is lost in the conversion of capabilities to utils.

IV. MAXIMIZATION WITHOUT SUMMATION

The ability to maximize without summation is a key difference between basic capability equality and utilitarianism, and it must be possible for basic capability to be a functional theory. Given this, it is worth exploring methods other than dominance ranking for maximizing without summation that are relevant to either exact or weighted ranges of values. Although not addressed by Sen, these examples help express the flexibility of Sen's formalism, that is, the general and abstract language that is needed to assess functionings in a broad range of cases.

One example of maximizing without summation is comparing the majority of elements in a set or the majority of components in a vector for a dominance relation. Imagine a vector V_1, in which components x_1, x_2, x_3, x_4, and x_5 are 1, 2, 8, 9, and 10, respectively. Now imagine a vector V_2 in which components x_1, x_2, x_3, x_4, and x_5 all have a value of 6. Even though summation would allow the choice of either vector, a comparison of components between vectors would result in the choice of V_1, because it is the vector in which the most components dominate. This differs from the partial orders discussed above because a known lesser value for $V_1(x_1)$ is chosen, and represents instead something more like "partial vector dominance." The same reasoning applies to set comparisons.

Another way to maximize without summation is lexicographic maximization. This approach compares the components of vectors or the elements of a set in order. Again consider comparisons of vectors, although the same method is applicable to set comparisons. If the first components are unequal, the vector with the component of largest value is chosen. If the first components are equal, the remaining components are assessed one at a time, until unequal companion values are reached, resulting in a dominance ranking. Consider the vector V_1 with components 2, 5, 6, 7, and V_2 with components 1, 7, 8, 9. Under the lexicographic approach, V_1 would be chosen. This result differs from the one obtained by summation, which would result in the choice of V_2. Similarly, if V_1 contains components with values in the order of 2, 3, 4, 1, and V_2 contains components with values in the order of 2, 3, 3, 4, a lexicographic approach would again result in the choice of V_1 and summation in the choice of V_2. In general, summation and lexicographical ordering will not deliver the same results.

The well-known Gini coefficient provides an alternative possibility for maximization without summation, although specifically within the domain of social welfare comparisons.[183] Briefly stated, the Gini coefficient is a social welfare measure that assesses inequality by measuring the distance, in a specific

183. *See* SEN, RESOURCES, VALUES AND DEVELOPMENT, *supra* note 23, at 434-36 (and sources cited therein).

sense, between the graph of a function expressing the actual distribution of income and a graph of a function expressing an equal distribution of the same.[184] If the x-axis of the A quadrant represents the percentage of individuals, and the y-axis is the percentage of income, a forty-five degree diagonal dividing the quadrant from the origin represents equality. The Gini coefficient is defined as the ratio of the area between the two curves and the area below the identity function. This quotient must be between zero and one; it is zero if the two functions coincide, that is, if the income is equally distributed, and it approaches one as income is distributed more unequally. Equality is maximized when there is no space between these two functions, that is, the Gini coefficient is zero on a scale of zero to one. The Gini coefficient remains at zero for each doubling of incomes for all individuals represented.

This measure of equality, as well as the other methods of maximization without summation proposed, provide support in addition to partial orderings that basic capability equality is functional as a theory. Maximization without summation allows for valuation of basic capabilities that extend well-being outside of the confines of utility measures. Much theoretical work remains, however, to determine how capabilities and capability sets should be ordered and what valuing capabilities and capability sets offers, in practical terms, over assessing other goods or preferences.

184. The first function assigns to each percentage *n* of the population the percentage of income held by the bottom *n* percent, whereas the second is the identity function in the A quadrant, which is the function that assigns to every value on the x-axis the same value on the y-axis (the diagonal).

NOTE

E Pluribus UNOS: The National Organ Transplant Act and Its Postoperative Complications

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* J.D., Yale Law School, 2007; M.A. (History of Science and Medicine),Yale University, 2005; B.A., University of Pennsylvania, 2002. This Note had its origins in the Beyond the Bungled Transplant Conference convened at Rutgers University on June 11 and 12, 2004, and draws on my essay *Playing with Matches without Getting Burned: Public Confidence in Organ Allocation*, *in* A DEATH RETOLD: JESICA SANTILLAN, THE BUNGLED TRANSPLANT, AND PARADOXES OF MEDICAL CITIZENSHIP 180 (Keith Wailoo et al. eds., 2006). I gratefully acknowledge the three inspired conference organizers: Julie Livingston, Peter Guarnaccia, and especially Keith Wailoo for his early encouragement. Along the way were thought-provoking conversations with friends and acquaintances including Morris Cohen, Ted Marmor, Richard Cook, Nancy Scheper-Hughes, Tom Diflo, Peter Schuck, Sue Lederer, Lesley Sharp, Dan Kevles, Bettyann Kevles, Naomi Rogers, James Blumstein, Art Caplan, Paul Root Wolpe, Prakash Kumar, Greg Lampros, Alistair Kwan, and Margaret Chisholm. Finally, I would like to express my profound gratitude to Emma Llanso and the rest of the YJHPLE editorial staff for their dedication, to Sumira Ohashi for bearing with me, to Jared M. Gross for living with me, and to my parents Herman and Maryalice Gross for their unwavering love and support.

INTRODUCTION

Thanks to George Orwell's dystopian novel, the year 1984 became a cultural reference point in Cold War America. When January of that iconic year finally arrived, Apple rolled out the Macintosh personal computer with an arresting Super Bowl advertisement, assuring viewers that "1984 won't be like *Nineteen Eighty-Four*."[1] As the introduction of new technologies generated excitement and apprehension in the mid-1980s, increasingly sophisticated organ transplantation practices seemed to embody the promise and the perils of medicine's future.[2] Orwell's novel remains a cultural touchstone in the twenty-first century, having outlived its immediate political context,[3] and the first Macintoshes, though today considered technological dinosaurs, ushered in the era of personal computing. The National Organ Transplant Act of 1984 (NOTA) likewise left a cultural imprint that would transcend its immediate historical context. The Act's motives, its text, and even its name have largely receded from the public's consciousness, to the extent that they ever were a part of that consciousness. The human organ allocation system that it spawned, however, supplies the news and entertainment media with a steady stream of inspirational stories, suspicious incidents, and ethical conundrums.[4]

Amid a persistent scarcity of transplantable organs, salient aspects of organ allocation in the United States—patients waiting for transplantable organs, shocked next-of-kin being asked to consent to the donation of loved ones' organs, institutional protocols for allocating available organs, and the ban on organ purchases—continue to draw academic and public scrutiny. Policy-oriented scholars are increasingly revisiting established features of the NOTA system, especially the provision of NOTA that prohibits commerce in human organs, and proposing various modifications.[5] But before this renewed critical

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1. *See* Ted Friedman, Apple's 1984: The Introduction of the Macintosh in the Cultural History of Personal Computers, http://www.duke.edu/~tlove/mac.htm (last visited Nov. 30, 2007) (discussing the memorable and oft-parodied Macintosh commercial that aired during the 1984 Super Bowl).

2. *See* Lindsey Gruson, *Center for Transplants and Pittsburgh Ascent*, N.Y. TIMES, Sept. 16, 1985, at A10 (quoting William R. Berry, Executive Director of the American Council of Transplant Physicians as saying "[w]hen you say medicine, I think transplant").

3. GEORGE ORWELL, NINETEEN EIGHTY-FOUR (1949).

4. *See, e.g.*, Chris Roark, *From One to Another*, CAROLLTON LEADER (Tex.), Apr. 25, 2007, *available at* http://www.courier-gazette.com/articles/2007/04/25/carrollton_leader/news/02front.txt (discussing a wife's organ donation to her husband).

5. *See, e.g.*, Eugene Volokh, *Medical Self-Defense, Prohibited Experimental Therapies, and Payment for Organs*, 120 HARV. L. REV. 1813 (2007).

interest can develop into an informed policy discussion, a more complete understanding of what NOTA was intended to do, and what it actually ordained, is needed.

A LexisNexis search of American and Canadian law journals for the phrase "National Organ Transplant Act" yields 232 articles. Clearly, the Act has generated substantial interest among legal scholars since its enactment in 1984. Much of this attention has focused on a provision of NOTA prohibiting the exchange of human organs for "valuable consideration."[6] Of the 232 results from the original LexisNexis search, 218 contained the word "market" or "sale." More than 120 contained the phrase "valuable consideration," mirroring the language of the Act itself.[7] Beyond the extensive debate surrounding this one controversial provision, the existing literature acknowledges the comprehensive nature of NOTA but does not provide a clear image of the statute's details.

Scholarly accounts of NOTA vary so greatly that, depending on which account one reads, one might absorb radically different understandings of the law's scope, import, and underlying motivations. One major point of disagreement concerns whether the organ allocation system established under the Act reflected the intent of its congressional supporters. Frank A. Sloan, an economist who has written extensively about health policy, suggests that Congress sought to establish "a national procurement and distribution system" and failed.[8] According to Sloan, "in spite of federal efforts to establish a uniform system," organ allocation remained, post-NOTA, in the hands of local or regional networks that were "decentralized, purely voluntary, lack[ing] criteria for sharing organs, and lack[ing] procedures for cross-matching before transporting organs."[9] Conversely, Vanderbilt Law Professor James F. Blumstein argues that the resulting network was far *more* centralized and uniform than NOTA's drafters envisioned.[10] In Blumstein's view, the original Act contained "distinct elements of a market perfecting orientation . . . compatible with a pluralistic, decentralized voluntary system."[11] What emerged subsequently, far different from the support structure envisioned by NOTA, was a tightly-coordinated, centralized network that played a "nongovernmental or quasi-governmental regulatory role . . . in virtually every facet of organ transplantation."[12] Sloan and Blumstein agree that

6. National Organ Transplant Act, 42 U.S.C. § 274e(a) (2000).

7. Search conducted April 3, 2007.

8. Frank A. Sloan et al., *Is There a Rationale for Regionalizing Organ Transplantation Services?*, *in* ORGAN TRANSPLANTATION POLICY: ISSUES AND PROSPECTS 115, 128 (James F. Blumstein & Frank A. Sloan eds., 1989).

9. *Id.*

10. James F. Blumstein, *Government's Role in Organ Transplantation Policy*, *in* ORGAN TRANSPLANTATION POLICY: ISSUES AND PROSPECTS, *supra* note 8, at 5, 22.

11. *Id.*

12. *Id.*

the network diverged from the legislative intent embodied in the Act, but their characterizations of that intent, and how the resulting network diverged from it, are diametrically opposed.

Accounts also differ about the concerns or desires that prompted NOTA. Descriptions of the Act's motivations, like the stories of its impact, are contradictory and, when taken together, opaque. According to Sloan, Congress's rationale for establishing the allocation system was twofold: to address the relatively low rate of organ procurement given the possibilities for transplantation, and to develop a national matching system for heart and liver transplants, since the existing computerized system matched only kidneys.[13] In stark contrast, medical ethicist Arthur Caplan suggests that the root problems were on the demand side of organ allocation, rather than the supply side. According to Caplan, "Congress insisted a national system be created" around notions of justice that would direct donated organs to "Americans . . . first," responding to a concern that American patients were being bypassed in favor of international patients who paid more.[14] Yet another theory, emphasizing the role of organized professional interests rather than public policy concerns, is offered by Jeffrey Prottas, a political scientist specializing in health policy who participated in the events leading to NOTA's passage.[15] According to Prottas, NOTA largely represented a response to lobbying by medical practitioners seeking an expansion of reimbursement for transplant therapy following the introduction of the powerful, but expensive, immunosuppressive drug cyclosporine. Additionally, "[a] split in the renal transplant community regarding organ sharing practices . . . brought a section of that community to the government for help."[16] Specifically, individual transplant programs' ability to "set their own rules" led to a collective action problem of organ hoarding.[17]

It is extremely difficult to reconcile all these interpretive accounts. Sloan and Blumstein's assessments of what NOTA sought to accomplish, if pushed sufficiently far, clearly conflict with each other: the legislation could not have created an organ allocation network that was simultaneously centralized and decentralized, voluntary and regulatory, top-down and bottom-up. However, if different elements of the legislation (and the resulting organ sharing network) embodied different tendencies, then depending on which provision of NOTA one looks at, one might see coercion or voluntarism, competition or hostility toward

13. Sloan et. al, *supra* note 8, at 128.

14. ARTHUR CAPLAN, MORAL MATTERS: ETHICAL ISSUES IN MEDICINE AND THE LIFE SCIENCES 142 (1995).

15. Jeffrey M. Prottas, *The Politics of Transplantation*, *in* ORGAN AND TISSUE DONATION: ETHICAL, LEGAL, AND POLICY ISSUES 3, 7 (Bethany Spielman ed., 1996).

16. *Id.*

17. *Id.*

competition. Likewise, the different accounts proffered for NOTA's underlying motivation are mutually exclusive in the sense that they cannot all be the paramount cause of the legislation. Nonetheless, because the legislation was comprehensive, addressing the procurement and distribution of human kidneys, hearts, livers, and other solid organs for transplantation, different elements of the law may have been responses to the different pressures described by Sloan, Caplan, and Prottas.

In this paper, I will attempt to elucidate the social and legislative history of NOTA, drawing upon documentary sources such as newspaper articles, congressional hearing transcripts, and law journal articles. Because there are already so many competing accounts of the Act's origins and impact, I will not test the validity of these theories one by one. Rather, I will present a narrative account that focuses on the concerns, aspirations, and effects (intended or unintended) that are most salient in the source materials. In addition, I will attempt to explain why these issues figured so prominently in the public discussion surrounding NOTA by considering how the legislation was the product of a specific technological, economic, political, and cultural context.

The first Section of the paper discusses the history of human organ allocation prior to the 1983-1984 congressional hearings that led to the passage of NOTA. This background should help provide a sense of how the interaction between technological change and social expectations created pressures to develop an organ allocation system that was both feasible (in light of evolving technical capabilities) and consistent with widely-shared American values (including prevailing notions of fairness). During this period, when organ procurement and allocation were governed by a heterogeneous matrix of legal doctrines and professional norms, a fundamental, recurring problem was that of "shortage." As more patients were able to benefit from transplant surgery, the available supply of organs did not keep up with the demand, prompting questions about who should receive transplants and how organ donation could be increased. The second Section of the paper describes how Congress intervened to address this perceived shortage and other issues raised by transplantation during the early 1980s. This Section argues that the major aims of NOTA were to increase efficiency in the use of transplantable organs, to improve the recruitment of organ donors, and to establish a task force process for resolving the ethical challenges posed by organ allocation. The legislation did less to address directly another concern frequently expressed in the media and in congressional hearings: the desire to regularize funding and eligibility rules for transplant surgery. Additionally, the legislative history suggests that the specific provision banning commerce in human organs was animated by multiple motives, ranging from beliefs about distributive justice, to repugnance over objectification of the body, to concerns about America's global image. The third Section of this paper examines NOTA's impact on organ procurement and allocation as the law's

mandates were carried out. This Section will attempt to show that Congress gave other institutional actors latitude in putting NOTA into practice, and that events subsequent to the passage of NOTA shaped understandings of the bill itself and how it was implemented. Finally, the concluding Section will bring the history up to date, showing that the institutional features of the NOTA system, by failing to alleviate the perceived shortage of transplantable organs, created pressures for further innovations in organ allocation policy. The most dramatic proposals for further reform would require amending or repealing NOTA, but many other innovations are being implemented without revising the legislation. The concluding Section will also survey the historical trajectory of organ allocation policy to re-evaluate scholars' understandings and assumptions about NOTA.

I. SOCIAL AND TECHNICAL ENVIRONMENT

Viable options for allocating health care are profoundly shaped by the technologies available to the individual, institution, or society responsible for allocation. For example, the ability to determine the presence of A and B surface antigens on red blood cells allows individuals with the same blood type to be matched with each other for transfusions and organ transplants. Before ABO blood-typing, doctors might have used any number of criteria in determining whether to attempt a transfusion when a patient was in dire straits, but no potential recipient would have been categorically ruled out in advance because of blood type "incompatibility." By the time organs (and not merely blood) were being transferred from donors to recipients, the known futility of ABO-mismatched transplants functioned as a constraint on allocation: A patient with O blood could not assimilate an AB kidney without suffering an acute rejection reaction, so such a patient must be ruled out as a recipient. Today, techniques are being developed that may be used to desensitize transplant recipients, so an O patient might actually benefit from an "incompatible" AB organ; in the future, such patients may eventually be considered as possible recipients for these differently-typed organs.[18] Likewise, if one has the technological means to preserve a human liver for twelve hours, there are more potential recipients to choose among than if one can only preserve the liver for six hours, because one can transport the organ across a larger geographical area before it deteriorates.

Although the technological state of the art in any given era is a powerful factor in the organ allocation calculus, technical limitations have never dictated who shall be a donor for whom. In the earliest days of transplantation, when the procedure was restricted to close genetic relatives, the question remained as to

18. *See, e.g.*, Roberto Troisi et al., *ABO-Mismatch Adult Living Donor Liver Transplantation Using Antigen-Specific Immunoadsorption and Quadruple Immunosuppression Without Splenectomy*, 12 LIVER TRANSPLANTATION 1412 (2006).

whether a transplant could be justified at all. For example, could the removal of one kidney from a healthy, assenting minor for the benefit of a dying sibling, with or without the consent of the parents, be morally and legally justified? The answer to such a question turned not on technical capacity, but on value judgments about tolerable medical risk, the rights of children, minors' need for protection, bodily integrity, the role of the state in relation to the family, and the slippery slope toward unethical experimentation. Further, as technologies of organ transfer—in particular, immunosuppression—developed, the general trend was to increase the number of potential recipients for any given organ, creating a larger space in which these value judgments could operate. Additionally, the line between social and therapeutic considerations is blurry, and a single criterion used in organ allocation can reflect both kinds of consideration. For example, hostility toward liver transplants for alcoholics probably reflects some combination of a value judgment that there are worthier recipients of scarce livers, a medical judgment (whether well-founded or not) that alcoholics who receive a new liver are likely to destroy this liver as well, and a public health judgment that this outcome would be wasteful when there is an organ shortage. The decision to label a culturally or politically charged condition such as alcoholism as a medical contraindication is a social process. Finally, on a more basic level, political decisions about the allocation of *funding*—for example, whether research and development capital is invested in antigen-matching or in immunosuppressive drugs—influence the development of technologies that, in turn, influence the allocation of organs.

The current organ allocation system in the United States, organized under the auspices of NOTA, is the product of a series of decisions that would have been difficult to predict in advance. While the American system relies on volunteers who have expressed their affirmative intent to donate, some liberal democracies obtain organs by presumed consent. Whereas American allocation policies are national in scope, many Continental European countries participate in a multinational Eurotransplant network. One cannot simply assume that such fundamental design decisions reflect Americans' general policy preferences. In 1984, when Congress effectively established a single, national organ distribution system, deregulation—not nationalization—was a watchword of the Ronald Reagan Administration.[19] As Richard Cook has noted, organ allocation is a "socio-technical" process.[20] The legislative history of NOTA reflected this

19. *See* Blumstein, *supra* note 10, at 6 (noting this divergence from the "procompetitive" orientation of contemporary politics).

20. *See* Richard I. Cook, *Hobson's Choices: Matching and Mismatching in Transplantation Work Processes*, *in* A DEATH RETOLD: JESICA SANTILLAN, THE BUNGLED TRANSPLANT, AND PARADOXES OF MEDICAL CITIZENSHIP 46, 68 (Keith Wailoo et al. eds., 2006) [hereinafter A DEATH RETOLD].

interaction between social and technical considerations. These concerns, however, did not emerge ex nihilo in the congressional hearings on NOTA. Rather, the ongoing interplay between social and technical aspects of organ allocation helped inspire NOTA's introduction and passage. This Section of the essay will provide the important historical context of the Act by examining the politics, economics, and technicalities of organ allocation prior to Congress's intervention in the process during the early 1980s.

A. The Socio-Technical Organization of Organ Matching

In the early years of transplantation, there was no formal allocation "system" to speak of, and public hope and confidence in the emerging, experimental system were linked to the specifics of whose organs were matched with whom. Solid organ transplants first became a viable clinical option in the 1950s, but generally only between identical twins.[21] Allocating organs according to genetic identity left little room for value judgments. From the start, transplant surgeons pushed the bounds of this narrow conception of the acceptable match. Genetically-distinct skin and renal grafts occasionally worked as bridges until patients regenerated their own skin or a faltering native kidney began functioning again. Nonetheless, the element of luck or fate in finding a suitable match seized the public imagination. Thus, a 1955 article in *Time* about a skin transplant recounted this hospital conversation: "It was *unfortunate*," the chief surgeon remarked, that patient Rodney Madeira "did not have an identical twin, since only skin from the patient's own body or from such a twin would do for a permanent graft. Replied Madeira, 'I have one.'" Similarly, the previous year, an airman had recovered from severe burns because "he *chanced* to spot his twin brother wandering around the hospital corridor."[22] Surgeon Francis D. Moore asserted that so "[m]any coincidences were necessary" for the successful first twin transplant that it initially struck doctors as "a medical freak."[23]

As immunosuppressive therapy and antigen matching technologies developed in tandem, they synergistically expanded the number of patients who could hope for long-term graft survival. Even so, technological constraints necessitated a reliance on living donors in solid organ transplantation's early years, and people invested in this project spoke of their hopes for it, rather than their confidence in it. The introduction of mechanical ventilators in the late 1950s

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21. Experimentation with animals suggested that transplants between fraternal twins would also be acceptable in the rare event that they shared a single placenta, exposing the twins' nascent immune systems to each other's tissue. *See* TONY STARK, KNIFE TO THE HEART: THE STORY OF TRANSPLANT SURGERY 33-34 (1996).

22. *Twins Under the Skin*, TIME, Oct. 17, 1955, at 84 (emphasis added).

23. FRANCIS D. MOORE, GIVE AND TAKE: THE DEVELOPMENT OF TISSUE TRANSPLANTATION 75 (1964).

and the medical endorsement of brain death in the late 1960s meant that, for the first time, organs could be temporarily maintained and oxygenated in a brain dead donor's body until the moment of need.[24] Until dialysis machines became widely accessible, patients with end-stage renal disease could not wait long until a cadaver kidney became available. Only with the development of effective techniques for preserving organs outside the body in the late 1960s did cadaveric kidney transplants become elective surgery rather than an emergency procedure.[25] Thus, even as the genetic compatibility requirement began to loosen, organ allocation remained contingent on coincidences of time and location in the lives of donors and recipients.

In kidney transplantation's early experimental period, the use of "penal volunteers"[26] and biologically-related living donors lessened pressures to enroll the public at large in the transplant enterprise. Whether the kidneys came from prisoners or relatives, medical professionals were selecting donors for kidney patients, not selecting recipients for available organs. This assumption could be seen in the published remarks of British transplant surgeon Roy Calne, who warned that matches between living people could be a burden as well as a blessing: "I fear that even if we do get a perfect method of tissue-typing we will be faced with new problems of finding a good donor who happens not to want to give his kidney."[27] Pioneering American surgeon Thomas Starzl abandoned the use of (consenting) prison donors after encountering intense criticism at an international symposium on transplant ethics.[28] While transplants between patients bound by family ties were not ruled out as coercive per se, a series of judicial opinions, largely stemming from predicaments involving potential donors who were legally incompetent, cemented the informed consent requirement for living donors.[29] "Public and Congressional outrage" over the

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24. *See* MARGARET LOCK, TWICE DEAD: ORGAN TRANSPLANTS AND THE REINVENTION OF DEATH 78 (2002).

25. *See* Folkert O. Belzer, Organ Preservation: A Personal Perspective, http://www.stanford.edu/dept/HPS/transplant/html/belzer.html (last visited Nov. 30, 2007).

26. Paul I. Terasaki et al., *Serotyping for Homotransplantation*, 129 ANNALS N.Y. ACAD. SCI. 500, 501 (1966).

27. Thomas E. Starzl et al., *Survival After Human Renal Homotransplantation*, 162 ANNALS SURGERY 749, 787 (1965).

28. *See* THOMAS E. STARZL, THE PUZZLE PEOPLE 147 (1992); Robert Platt, *Ethical Problems in Medical Procedures*, *in* CIBA FOUNDATION SYMPOSIUM, ETHICS IN MEDICAL PROGRESS: WITH SPECIAL REFERENCE TO TRANSPLANTATION 166 (G.E.W. Wolstenholme & Maeve O'Connor eds., 1966).

29. The exceptions at least in theory affirmed the rule: Courts regularly authorized such transplants between minor twins either on the theory that the transplant was in the donor's "best interest" given the dreary alternatives or on the basis of "substituted judgment," by counterfactually asking whether the person, if competent, would agree to donate. *See* Arthur Caplan et al.,

excision of pituitary glands from cadavers, without permission, to treat dwarfism in the 1960s revealed that the use of cadaveric organs was also contingent on public support.[30] Policymakers seeking to advance the transplant enterprise would need to allay cultural, religious and psychological misgivings about donation.

As a technical matter, some Americans questioned how well transplantation would work. A California homemaker, responding to a 1968 Gallup poll on public attitudes toward organ donation, remarked, "[t]hese transplants will perhaps stall death a week or a month, but I don't believe they'll ever be able to get a man back on his feet again."[31] Yet even here, the criterion for evaluating therapeutic success was not purely technical. The problems transplantation posed for the pre-existing cultural trope of "standing on one's own two feet" may help explain why variations on this theme were frequently invoked in public discussion of transplants—whether in reference to the sharing of body parts or the postoperative challenges awaiting immunosuppressed transplant patients. A relatively recent news article, focusing on attitudes toward donation among ethnic minorities, quoted an African-American donor recalling, "I remember my mother saying, 'I was born with two legs, let me die with two legs.'"[32] Another possible source for this figurative language was the legend of the twin Saints Cosmas and Damian, credited with replacing the gangrenous leg of a man (traditionally depicted as European and Christian) with the leg of a recently deceased North African.[33] In either case, ample evidence indicates that Americans did not evaluate transplantation as a matter of abstract logic; rather they assessed the new type of surgery in light of personal experiences, cultural traditions, and collective memories, which may or may not have been widely shared in society at large. At a minimum, organ donation was inconsistent with some conventional notions about respectful treatment of bodies. "Are kidney donors weirdoes?" asked one publication (rhetorically) as late as 1974.[34]

Within the legal academy, cadaveric organ donation as a donative transfer opened another line of discussion: It became the province of trusts and estates law. Prior to 1968, novel or unusual dispositions of dead bodies necessitated the

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Increasing Organ and Tissue Donation: What Are the Obstacles, What Are Our Options?, *in* THE SURGEON GENERAL'S WORKSHOP ON INCREASING ORGAN DONATION: BACKGROUND PAPERS 199, 202 (1991).

30. *Id.*

31. George Gallup, *The Gallup Poll: Majority Would Donate Organs*, L.A. TIMES, Jan. 17, 1968, at A5.

32. Christopher Heredia, *The Ultimate Offering: An Example for the Many Minorities Reluctant to Donate Organs*, S.F. CHRON., Jan. 11, 1999, at A13.

33. *See* Leonard Barkan, *Of Medicine, Miracles, and the Economies of the Body*, *in* ORGAN TRANSPLANTATION: MEANINGS AND REALITIES 221, 225 (Stuart J. Youngner et al. eds., 1996).

34. Arthur J. Snider, *Are Kidney Donors Weirdoes?*, SCI. DIG., May 1974, at 54.

navigation of perilous legal and cultural terrain. English common law, which continued to exert a strong influence in some states, granted the decedent a right to a decent burial that by default was inherited by the decedent's next-of-kin.[35] In the United States, when the disposition of the body was disputed, courts balanced such considerations as "the interests of the public, the wishes of the decedent, and the rights and feelings of those entitled to be heard by reason of relationship or association."[36] With the dawn of cadaveric organ transplantation, individual states supplemented this common law approach with positive legislation—for example, some statutes authorized anatomical gifts exclusively by will.[37] The liability risk for transplant centers was sufficiently acute that a hospital guidebook "caution[ed] against using organs from a body where there [we]re objections, even though the decedent had authorized such use" in the absence of specific enabling legislation.[38]

The limitations of this guarded approach—both public and personal—were dramatized by the death and burial of Grace Metalious, author of the novel *Peyton Place*, in 1964.[39] Metalious's will provided that her body should go to the Dartmouth School of Medicine for research; Harvard Medical School was her backup.[40] Neither school would accept the body after her survivors "reportedly" warned the institutions that they would bring suit.[41] As bodies came to be seen as sources of organs for clinical procedures, medical urgency pressed against legal complexity, uncertainty, and conservatism.

The National Conference of Commissioners on Uniform State Laws responded to these pressures with the Uniform Anatomical Gift Act (UAGA) of 1968. UAGA, in its attempt to clarify and standardize procedures for donating organs and tissue, enshrined the conception of organ donation as the bestowal of a gift. The original UAGA's conception of an anatomical gift was detailed and quite literal: Not only did the donee have a right to reject the gift, but the donee could also "transfer his ownership to another person."[42] This model legislation was quickly adopted in forty-one states,[43] and all fifty eventually enacted some

35. *See* E. Blythe Stason, *Uniform Anatomical Gift Act*, 23 BUS. LAW. 919, 922 (1968).

36. Yome v. Gorman, 152 N.E. 126, 128 (N.Y. 1926).

37. Stason, *supra* note 35, at 924.

38. Gary C. Randall & Janet Randall, *The Developing Field of Human Organ Transplantation*, 5 GONZ. L. REV. 20, 28 (1969).

39. *Id.*

40. Holland v. Metalious, 198 A.2d 654, 655 (N.H. 1964).

41. Randall & Randall, *supra* note 38, at 28.

42. HANDBOOK OF THE NATIONAL CONFERENCE OF COMMISSIONERS ON UNIFORM STATE LAWS 191-92 (1968).

43. *See* Jesse Dukeminier, Jr., *Supplying Organs for Transplantation*, 68 MICH. L. REV. 811, 817 (1970).

form of UAGA.[44]

As "anatomical gifts," organ donations fit into a larger movement in which trusts and estates scholars and practitioners expanded the field's professional jurisdiction by claiming jurisdiction over the human body. Between roughly 1940 and 1970, attorneys, clients, judges, and scholars embraced new concepts including "willed bodies" (i.e., cadavers donated for medical research) and "living wills" (i.e., advance directives regarding medical treatment) that applied trusts and estates law, with its equitable sensibility, to the care of the body in periods of unconsciousness, as well as post-mortem.[45]

In allowing salvageable organs to be buried for want of authorization to remove them, UAGA parted ways with the utilitarian, statist thrust of public health law (the body of jurisprudence and scholarship governing such exigencies as quarantines and compulsory vaccination). Intellectual strands within the legal field—respect for individual donors' autonomy, and the inherent conservatism of trusts and estates law—favored UAGA's gradualist, consensual approach to organ procurement, but they were not the only consideration. The need to build *public* support for transplantation in a majoritarian democracy also powerfully cautioned against rushing to impose a more aggressive "opt-out" procurement regime on an ambivalent public.[46] By providing a standard legal basis for the donation decision and recognizing the primacy of the decedent's wishes, UAGA paved the way for organizations like the National Kidney Foundation to distribute uniform organ donor cards on nationwide scale.[47]

B. Enlisting "The Public," but Not the Public As a Whole

Early efforts to promote organ donation, which were oriented toward building majority support for donation, emphasized rapidly expanding the scope of transplantation over serving all members of American society equally well. This majoritarian bias could be seen in tactical decisions made below the radar of public policy debate.

The development of the human leukocyte antigen (HLA) system for matching organs involved one such choice. As data on tissue compatibility

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44. Marjorie A. Shields, Annotation, *Validity and Application of Uniform Anatomical Gift Act*, 6 A.L.R. 6th 365, 365 (2005).

45. *See, e.g.*, Luis Kutner, *Due Process of Euthanasia: The Living Will, A Proposal*, 44 IND. L.J. 539 (1969).

46. *See* Platt, *supra* note 28, at 160 (quoting C.E. Wasmuth at panel discussion saying that "[w]e realize [an individual rights approach] is not the end, but at least it does give to a person a right which he does not now have . . . . We believe this is the correct approach in the United States, simply because with this we can educate the people").

47. *See* Nancy Hicks, *Kidney Fund Calls for Bequests of Organs for Transplant Uses*, N.Y. TIMES, Mar. 4, 1970, at A22.

accumulated unsystematically, transplant immunogeneticists recognized the need for antigen-matching tools that "residents, surgeons, and technicians" could use without confusion.[48] At a 1968 World Health Organization conference, immunologists Walter Bodmer and Jean Dausset cautioned that an ostensibly "monospecific" serum—a test that could identify a single antigen in a given population—might react to more than one antigen found in a different population. Dutch immunologist Jon van Rood similarly questioned whether the sera should be "studied in different races."[49] Duke University researcher Bernard Amos, a pioneer in the use of tissue-typing to select organ donors among siblings, countered that such exhaustive expectations would hinder the development of a working system for identifying antigens: "[A]s soon as [a serum]'s shown not to be monospecific in another population then we're forced to take it out."[50] Observing that three supposedly distinct antigens immunologists were testing for—D1, Mac, and LA2—turned out to be "identical within Caucasian populations," Amos emphasized the desirability of "some uniformity."[51] In other words, focusing on Caucasians would simplify the research and yield HLA characterizations that were, in Amos's view, good enough to operationalize. Genetic diversity across populations was seen not as something that needed to be taken into account at this stage in the research, but rather as a threat to the rapid deployment of a working system for allocating organs among white people.

To be sure, immunogenetic researchers sought to tissue type people of diverse ethnic backgrounds for scientific reasons, such as identifying rare antigens in far-flung places or studying isolated populations to simplify their research.[52] It is less clear to what extent the researchers' intellectual endeavors improved clinical outcomes for ethnic minority patients. The tissue typers' precise concern about different levels of antigen specificity across populations never materialized, but in the United States, serological tests were on average less effective at characterizing the immunogenetic makeup of racial minority patients decades later.[53]

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48. *See* Roy L. Walford, *First Meeting WHO Leukocyte Nomenclature Committee*, *in* HISTORY OF HLA: TEN RECOLLECTIONS 123, 130 (Paul I. Terasaki ed., 1990) (quoting Jon van Rood).

49. *Id.* at 126.

50. *Id.*

51. *Id.* at 128 (quoting D. Bernard Amos).

52. *See, e.g.*, Walter Bodmer & Julia Bodmer, *History of HLA: Recollections of A Golden Age*, *in* HISTORY OF HLA: TEN RECOLLECTIONS, *supra* note 48, 95, at 99 ("Oh, the fun in the bush of getting the Africans to help us by defibrinating [sic] the blood in the vacutainers by shaking them to the rhythm of the drums!").

53. *See, e.g.*, Howard Univ., Nat'l Human Genome Ctr., Milestones Leading to the NHGC, http://www.genomecenter.howard.edu/milestones.htm (last visited Nov. 30, 2007) (reporting that circa 1982, "44% of the AfricanAmerican [sic] panel, compared to only 2% of Caucasians, could

A similar, if less conscious, majoritarian bias played out in early donor recruitment campaigns, disadvantaging religious, linguistic, and other cultural minorities. As early as 1970, a *Michigan Law Review* article by a prominent trusts and estates scholar identified several specific religious doctrines, associated with diverse faiths, which could hamper donation: "A fundamentalist Christian might consider organ removal inconsistent with the principle of bodily resurrection. A Jehovah's Witness might object to the shedding of blood. Many orthodox rabbis have opposed autopsies, invoking a principle of Judaism that the body must not be violated."[54] In a predominantly Christian society, however, public discussions of organ transplantation have frequently invoked (vaguely or explicitly) mainstream Christian imagery. A majoritarian objective—securing the support of mainstream Christians—was more easily achieved than the egalitarian correlative—reconciling transplantation with America's myriad religious traditions. This religious orientation was largely a result of individual commentators' drawing on widely shared religious and cultural resources, rather than conscious policy choices. To cite a few recent examples, the *New York Times* described the transplant waitlist as "purgatory."[55] "What if one beloved child could resurrect another?" asked *Newsweek* contributing editor Anna Quindlen, employing the theme of bodily resurrection to promote donation.[56] While such metaphors may help many Americans (including non-Christians)[57] make sense of the unknown, their appeal is not necessarily universal. The now ubiquitous slogan, "[d]on't take your organs to heaven . . . Heaven knows we need them here," speaks to a particular set of religious concerns, but transplantation may raise a different set of concerns for a religious tradition

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not be HLA-D typed with reference typing reagents obtained primarily from multiparous Caucasian women"). While HLA polymorphism among African-Americans may have contributed to this disparity, it was also the logical consequence of a utilitarian approach that focused on serving a majority within society. *See* Patrick G. Beatty et l., *Impact of Racial Genetic Polymorphism on the Probability of Finding an HLA-matched Donor*, 60 TRANSPLANTATION 778, 780-81 (1995) (positing that "extensive heterogeneity in HLA among African Americans" has implications for HLA matching in this population). *See also* Laura G. Dooley & Robert S. Gaston, *Stumbling Toward Equity: The Role of Government in Kidney Transplantation*, 1998 U. ILL. L. REV. 703, 719 & n.90.

54. Dukeminier, *supra* note 43, at 836.

55. Jeff Stryker, *H.I.V. Patients Get Fresh Hopes for Donor Organs*, N.Y. TIMES, Dec. 11, 2001, at F6.

56. *See* Maureen Dowd, Op-Ed, *A Lyrical Gift*, N.Y. TIMES, Nov. 16, 2003, at 413.

57. One review of a film depicting Jesus as an organ donor noted that the film resonated with both Christian and Buddhist themes, and that "even to a viewer with no formal religious training, the images call upon deeply submerged, widely shared, often inaccessible beliefs about transplants." Wendy Doniger, *Transplanting Myths of Organ Transplants*, *in* ORGAN TRANSPLANTATION: MEANINGS AND REALITIES, *supra* note 33, at 194, 217.

holding that "[k]arma is encoded in . . . the body."[58] Another barrier to achieving a representative diversity of potential donors was the tendency for donor recruitment campaigns to be conducted only in English. Much as the availability of transplantable organs in a predominantly Christian society depended on the willingness of Christians to donate organs, the availability of organs in a predominantly English-speaking society depended on the support of donors who could comprehend English-language public service announcements.

In contrast to their efforts to sway the opinions of the majority, transplant professionals' attempts to understand and address the concerns of minority demographic groups got off to a clumsy start. As recently as 1996, a leading heart transplant surgeon called Jewish law "mysterious" and "difficult to understand," but elaborated upon the low donation rate among Orthodox Jews by remarking that they "behave sociologically like lower-class Asians, Blacks, and Hispanics."[59] Recognizing such a pattern, however, was still a step away from understanding the beliefs, anxieties, and motivations that influence willingness to donate among specific demographic groups with low donation rates. The moral and therapeutic hazards of these majoritarian biases included a possible disadvantage to minority patients in the short run, as noted in the discussion of approaches to antigen matching above, as well as the alienation of potential minority donors in the long run.[60]

C. Hearts, Minds, and Corneas in Geopolitical Context

The Uniform State Laws committee that drafted UAGA called transplantation a "new frontier of modern medicine."[61] This language, echoing the soaring rhetoric of President John F. Kennedy,[62] situated organ transfer in the political culture of Cold War America. Because organ transplantation transgressed conventional boundaries—between persons, between life and

58. *Id.* at 212-13.

59. Judy Siegel-Itzkovich, *Transplants: The Ultimate Act of Generosity*, JERUSALEM POST, July 28, 1996, at 5.

60. *Cf.* LOCK, *supra* note 24, 153-54 (noting that in Japan, where the concept of brain death remained controversial, "[a]n association [was] being made between the Christian culture of America and recognition of brain death" in a television presentation of the subject and that "[a]n implicit contrast [was] being set up between America and Japan").

61. HANDBOOK OF THE NATIONAL CONFERENCE OF COMMISSIONERS ON UNIFORM STATE LAWS, *supra* note 42, at 184 (quoting a prefatory note to the Uniform Anatomical Gift Act).

62. *See* Senator John F. Kennedy, Accepting the Democratic Party Nomination for the Presidency of the United States (July 15, 1960), *available at* http://www.jfklibrary.org/Historical +Resources/Archives/Reference+Desk/ (evoking a pioneer ethos of freedom, earnestness, and achievement that would enable Americans to conquer "the uncharted areas of science and space, unsolved problems of peace and war").

death—the new frontier was an apt metaphor, and one that easily came to mind in the 1960s era.[63] Yet it was not the only plausible way of understanding transplantation. The instrumentalization of cadaver organs might alternatively have been wrapped in Jeffersonian rhetoric of political revolution ("the earth belongs to the living"). In a political culture that embraced American voluntarism as an alternative to Communist coercion, however, rhetoric about radically revising the social contract between the dead and the living likely would have left many uneasy.[64] To be sure, the romance of the frontier also had a violent and destructive underside, but the ideal of a world "where no walls divide you"[65] was consistent with the liberalism that reigned over the American political scene in the mid-1960s. By 1970, discussion of transplant policy, as part of a larger American political discourse, included a more self-consciously radical, libertarian strand. One legal scholar suggested that allowing the sale of organs might be consistent with the same philosophy "underl[ying] much of the current trend to liberate 'sins,' such as private deviate sexual conduct and fornication by the unmarried, from criminal sanction."[66]

Metaphors often work in two directions, and if the frontier provided an accessible way of understanding organ transplantation, transplantation was also a fitting emblem for a society—or at least its policy elites—intent on breaking barriers imposed by nature, politics, and human history. Amid the geopolitical antagonism of the Cold War, the operating theater became one of many theaters in the "long, twilight struggle" between the superpowers.[67] Thus, in 1968, the *New York Times* envisioned "a Soviet-American race in the transplantation of . . . organs" akin to "the international competition to send the first men on a round trip to the moon."[68]

The envisioned beneficiaries of this rivalry were not just American and Soviet patients. The delivery of health care across national borders readily serves

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63. *See* Doniger, *supra* note 57, at 215 ("The moment of death, like personhood, is a boundary line that we must now newly construct.").

64. *See* JED RUBENFELD, FREEDOM AND TIME (1999) (presenting a Burkean critique of Jeffersonian revolutionary presentism in American culture).

65. JOHN BARRY & DON BLACK, BORN FREE (1966). By 1961, the construction of the Berlin Wall had given Winston Churchill's perception of an oppressive "iron curtain" a material manifestation. *See* Modern History Sourcebook: Winston Churchill: The Iron Circuit, http://www.fordham.edu/halsall/mod/churchill-iron.html (last visited Nov. 30, 2007).

66. Dukeminier, *supra* note 43, at 859.

67. *See* John F. Kennedy, President, Inaugural Address (Jan. 20, 1961) [hereinafter Kennedy, Inaugural Address], *available at* http://www.bartleby.com/124/pres56.html (announcing "a call to bear the burden of a long twilight struggle . . . against the common enemies of man: tyranny, poverty, disease, and war itself").

68. Harry Schwartz, *The Neglected Battleground in Heart Transplants*, N.Y. TIMES, Nov. 18, 1968, at 46.

as both a tangible expression of generosity and an awesome demonstration of power over life and death, and introducing organ replacement techniques to strategically important regions—specifically, East Asia—was consistent with Cold War internationalism.[69] An early example was New York's Mount Sinai Hospital's provision of plastic and reconstructive surgery, including skin grafting, for female Japanese atomic bomb survivors hosted by Quaker families during the mid-1950s. An opponent of this endeavor warned that "[it would be] very difficult for Japanese to comprehend pure altruism, since [purportedly] so very little of it existed in Japan among people who are not tied together by family bonds."[70] As described in American news coverage, the cultural exchange turned out be a triumph of friendship and good will on the part of participants from both nations, even while medical personnel cautioned that it was "too early" to evaluate clinical outcomes.[71] In 1961, American "eye specialists" planned a visit to Hong Kong, financed by the pharmaceutical industry, to assist blind refugees from mainland China. The reported purpose of the trip was not only to provide medical care, but also to promote attitudes conducive to corneal transplantation: "Team members will lecture on the whole field of eye surgery for Asian doctors, leave sets of highly specialized surgical instruments for operations and training by Chinese doctors, and set up an eye bank in hopes of overcoming Oriental taboos barring removal of eyes after death."[72] A later donation of pacemakers worth $7.6 million made by the American Friends Service Committee to Chinese authorities gave new meaning to winning hearts and minds. A nursing instructor from Minnesota "happily remarked, 'Can you imagine, 3,200 Chinese walking around with their heartbeats regulated by American pacemakers? It boggles the mind.'"[73]

Media coverage of such medical missions, by implicitly contrasting the generosity of American volunteers with recipient nations' difficulties in supplying organs for their citizens, probably reinforced a self-congratulatory progressive narrative, in which the benefits of transplantation were encoded as "ours," and the challenges encoded as foreign. In a letter to the editor critiquing the tone of a news article as insufficiently supportive of transplantation, one doctor wrote:

> I am sure that the editors of the *New York Times* did not intend to portray these hopeful advances in medical science as a savage gobbling up of one human

69. *See generally* CHRISTINA KLEIN, COLD WAR ORIENTALISM: ASIA IN THE IMAGINATION, 1945-1961 (2003).

70. Norman Cousins, *Interim Report on the Maidens*, SATURDAY REV., Oct. 15, 1955, at 22.

71. *Id.* at 23.

72. *Doctors Set Hong Kong Mercy Trip*, WASH. POST, Oct. 5, 1961, at C19.

73. Kathleen Teltsch, *Philanthropy from Friendly Persuaders*, N.Y. TIMES, Sept. 6, 1981, at 418.

> being by another. In the worlds of commerce, politics and international relations, where this is too often the case, the new surgery is actually promoting a new altruism. But in doing this, there must be a reduction and weakening of the Chinese shibboleth about the sanctity of tissue.[74]

The original article, about transplantation in America, did not mention China, traditional Chinese beliefs about the body, or Chinese attitudes toward organ donation.

So long as scientific progress did not sever the connection between organ substitution technology and the bodies of organ providers,[75] the field would remain haunted by a dualistic dance of life and death.[76] While legal and institutional developments could improve the coordination, regulation, and execution of organ transfer, they did not dissolve the paradox of routinized heroism; the limits of spontaneous generosity; the potential for exploitation on medicine's frontier; the awkwardness of recognizing individual autonomy over organs in order to promote their alienation; or tensions in the relationships of trust, trustworthiness, and the antitrust impulse. With a rudimentary procurement system in place and increased interest in transplant medicine, these concerns would eventually surface close to home.

D. Building on Hope and Built-in Dilemmas

The refinement of tissue typing, which was federally supported by 1965,[77] and the widespread adoption of UAGA facilitated the development of organ sharing networks, which institutionalized organ allocation and, by extension, the need for public support. Seven West Coast transplant centers established a

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74. Robert Seidenberg, Letter to the Editor, *On 'Cannibalizing'*, N.Y. TIMES, Sept. 25, 1968, at 46.

75. For a general discussion of how the treatment of dying persons can be managed respectfully through "structured ambivalence," see ROBERT A. BURT, DEATH IS THAT MAN TAKING NAMES: INTERSECTIONS OF AMERICAN MEDICINE, LAW, AND CULTURE 159 (2004). For ruminations on the dualism inherent in the transplant enterprise, see Renée C. Fox & Judith P. Swazey, *Leaving the Field*, HASTINGS CENTER REP., Sept.-Oct. 1992, at 9-15 (juxtaposing somewhat stereotypically transplant suregons' "adventurous, optimistic" outlook alongside their "bellicose, 'death is the enemy' perspective" and their "relentless, hubris-ridden refusal to accept limits"). *See also* Ruth Richardson, *Fearful Symmetry: Corpses for Anatomy, Organs for Transplantation?*, *in* ORGAN TRANSPLANTATION: MEANINGS AND REALITIES, *supra* note 33, at 66, 67-68 (noting that organ transplantation involves a "fearful symmetry").

76. *See* Richardson, *supra* note 75, at 80 (observing that "[r]edefinitions of death . . . seem always to revise it nearer to life"); *Id.* at 60 (referencing "medieval woodcuts of the Dance of Death").

77. *See* Paul I. Terasaki, *History of HLA: A Personalized View*, *in* HISTORY OF HLA: TEN RECOLLECTIONS, *supra* note 48, at 213, 215.

common computer-based system for matching organs and patients in 1968.[78] In 1969, a transplant surgeon from the Medical College of Virginia and a Duke University immunologist initiated the South-Eastern Regional Organ Procurement Program (SEROPP). SEROPP, which quickly entered a contractual agreement to link nine transplant centers between Baltimore and Atlanta, was incorporated as American Foundation for Donation and Transplantation (AFDT) in 1975.[79] AFDT's board took the lead in creating a national network by introducing the United Network for Organ Sharing (UNOS), originally a computerized matching system, in 1977, and establishing a "round-the-clock" kidney placement support center in 1982.[80]

With the support of these new institutions, the 1970s were a decade of quiet, steady technical refinement. A few determined individuals strived to expand clinical transplantation to organs other than the kidney. Between 1963 and 1980, American liver transplant surgeon Thomas Starzl "refined a bypass system that allowed blood to be diverted to the lower half of the body during surgery," which was vital to control bleeding, and "developed preservative solutions that extended the time the liver could survive outside the body from four to ten hours."[81] Yet despite Starzl's use of "10% of all the research dogs in the country" one year, an immunosuppressive regime that would prevent rejection without killing the patient remained elusive for organs other than kidneys.[82] Meanwhile, a few researchers persisted in their pursuit of cyclosporine, a fungal molecule identified through Swiss pharmaceutical company Sandoz's novel soil screening program. Although the molecule seemed promising as an immunosuppressant, the market for such drugs was then miniscule and support for further research and development could not be taken for granted.[83]

In the face of institutional resistance, individuals committed to transplant immunology had a shared stake in medical innovation: Transplantation required better postoperative therapy, and immunological research programs needed transplantation. In 1990, Paul Terasaki, the dean of American transplant immunogeneticists, estimated that "[p]robably as much as 80% of meeting and workshop expenses [in the field of human leukocyte antigen research were] covered by transplant-related sources." Terasaki speculated that professional

78. Harry Nelson, *For Organ Transplants: 7 Hospitals Here Plan Pool*, L.A. TIMES, Jan. 9, 1968, at 1.

79. South-Eastern Organ Procurement Found., Brief History, http://www.seopf.org/intro.htm (last visited Nov. 30, 2007).

80. *Id.*; United Network for Organ Sharing, History, http://www.unos.org/whoweare/history.asp (last visited Nov. 30, 2007).

81. BARRY WERTH, THE BILLION DOLLAR MOLECULE: ONE COMPANY'S QUEST FOR THE PERFECT DRUG 47 (1994).

82. *See id.* at 47; STARK *supra* note 21, at 130-34.

83. *See* WERTH, *supra* note 81, at 48.

organizations "would collapse if tissue typing were no longer considered necessary for transplantation."[84] Such relationships of sponsorship and patronage were maintained through a process of negotiation. Terasaki observed of the immunogenetic research community: "[T]he name that we chose for ourselves, 'histocompatibility [as in the "American Society of Histocompatibility and Immunogenetics] implied that the HLA antigens we were studying were part of a compatibility system in transplantation."[85] In 1964, the National Academy of Sciences hosted the first "International Conference on Histcompatibility Testing," and a year later, Congress authorized the establishment of a program within the National Institute of Allergy and Infectious Diseases (NIAID) that would fund tissue-typing research.[86]

Nimble cross-institutional marketing was likewise essential to the development of cyclosporine. According to one journalistic account, when Sandoz's management was disinclined to shoulder the costs of developing the drug as an immunosuppressant, transplant surgeon Roy Calne and immunologist David White flew from England to the company's headquarters in Switzerland at the request of Jean Borel, a Sandoz researcher who was committed to the project.[87] "We more or less had to sell them their own drug," White later remarked.[88] Although the drug might ultimately "create the very market . . . needed to justify [its] development costs," its advocates emphasized a different consideration: Even if the company never recouped these costs, transplantation's "high profile" could propel "Sandoz's name . . . to the forefront."[89] During this period, transplant professionals' goals and interests were not perfectly aligned: for example, there was a tension between tissue typers' desire to develop a method for matching organs and transplant surgeons' eagerness to break new boundaries.[90] However, a mutual interest in extending clinical transplantation to more patients, a shared commitment to scientific rigor, and close personal relationships kept these tensions in check. A series of events towards the end of 1970 powerfully demonstrated the potential for solidarity among transplant professionals with respect to organ allocation. Following a push in Italy toward legislatively requiring organ transplants to be tissue typed, immunogeneticist Terasaki presented data at an international conference indicating that tissue typing only improved patient survival among perfectly matched donors and

84. Terasaki, *supra* note 77, at 215.

85. *Id.*

86. *Id.* at 215, 221.

87. STARK, *supra* note 21, at 129-30.

88. *Id.* at 130 (quoting David White).

89. *Id.* at 131.

90. *See id.* at 112 (discussing a surgeon's evident delight in a study showing that antigen matching only improved outcomes in limited circumstances; the surgeon "[wouldn't] have to worry about that 'damn matching anymore'").

recipients, who were exceptionally rare.[91] Terasaki's UCLA laboratory's retrospective analysis of Starzl's liver transplants, while consistent with kidney transplant surgeon John Najarian's clinical observations, conflicted with the prevailing theory of a predictive "sliding scale of success" animating tissue typing.[92] Shortly thereafter, NIH representatives, apparently convinced that Terasaki's team "must [have been] doing something wrong," performed a site visit. By the end of the calendar year, Terasaki was informed that the NIH contract that supplied virtually all of the laboratory's funding would be terminated. Further, NIH would take direct control over the tissue-typing tray and reagent distribution program that Terasaki's lab had started. From 1970 through 1984, the UCLA lab, still under Terasaki's direction, stayed afloat by selling its tray system in competition with the NIH's version. According to Terasaki, the value proposition of the UCLA trays was their comparative "quality," but one can appreciate how such adverse experiences could also give rise to intense personal loyalties.[93]

In the area of renal transplantation, advances in tissue typing yielded tangible clinical results by the 1970s. In 1973, NIAID reported that "more than 60 per cent of all transplants now utilize cadaver kidneys . . . and the proportion is growing larger each year."[94] Another source reported that 50-70% of kidney transplants in 1977 involved cadaveric kidneys.[95] While transplant statistics were imprecise, transplant outcomes were also apparently improving. In 1974, the three-year survival rate for cadaveric kidney transplants reportedly surpassed 50%.[96] By 1977, roughly half of cadaveric kidney grafts lasted *five* years, as compared to 35% of cadaveric grafts in 1972, or 85% of living donations from siblings in 1977.[97] The sheer number of kidney transplants performed in 1973 (over two thousand), however, would not be matched during the next three years.[98] Experts began to contemplate the number of donors who would have to be enlisted to meet the need for transplants. These projections (kidneys for 8,000 to 10,000 patients per year if 70 to 100 million Americans carried donor cards)[99]

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91. *Id.* at 108-12.

92. *Id.* at 108-10.

93. *Id.* at 113 (quoting Paul Terasaki).

94. *U.S. Plans 2-Year Study on Kidney Transplants*, N.Y. TIMES, Apr. 15, 1973, at 56.

95. Lawrence K. Altman, *It's Not Unusual for Kidneys To Be Rushed from Country to Country*, N.Y. TIMES, May 29, 1977, at 124.

96. David Dempsey, *Transplants Are Common; Now It's the Organs that Have Become Rare*, N.Y. TIMES, Oct. 13, 1974, at 332.

97. Altman, *supra* note 95.

98. *Id.*

99. *See* Dempsey, *supra* note 96 (quoting Dr. Ira Griefer, Medical Director, National Kidney Foundation); *Kidney Foundation Plans Drive To Get Funds and Organs*, N.Y. TIMES, Mar. 1, 1972, at 11 (quoting transplant surgeon Samuel L. Kountz).

were extremely ambitious but theoretically not impossible. Professional transplant coordinators, whose roles included locating kidneys and "persuad[ing]" grieving relatives to authorize organ donation, represented an "aggressive[]" new organized approach to the need for transplantable organs.[100]

The ethical and political problem of allocating scarce human organs would not capture the public imagination, however, until the 1980s. The earliest transplant patients surely were unrepresentative of the general population facing organ failure: The first people to receive transplants lived near pioneering medical centers, were willing to risk undergoing an unproven procedure, and impressed treating physicians as determined, perseverant candidates.[101] Everything about transplantation was so extraordinary that concerns about elitism or impropriety in the recipient selection process typically did not figure into discussions such as "man on the street" newspaper interviews.[102] Scholarly articles on the legal questions posed by transplantation would mention that the Equal Protection Clause of the Fourteenth Amendment potentially applied to patient selection, but exactly what would constitute illegal discrimination was not analyzed in depth.[103] Organ procurement, however, was becoming more aggressive, raising new doubts about the system's trustworthiness, as American institutions were becoming more responsive to demands for civil rights and hearing new claims of entitlement. Suspicions of racial disparities in transplantation were occasionally voiced in a letter to the editor or a comedian's routine. These comments focused both on who was providing the organs and on who was receiving them.[104]

On the public policy level, in 1968 Senator Walter Mondale began advocating the establishment of a National Advisory Commission on Health, Science and Society that would examine "the ethical, social, and legal implications of advances in biomedical science and technology."[105] The financing of transplant surgery and allocation of organs fit squarely within Mondale's agenda.[106] When the Commission was finally convened in modified form in 1978, its charges were both broad (examining socioeconomic disparities in access to health) and, in some cases, highly specific (considering the social impact of voluntary genetic "testing, counseling and information and educational

100. *Ideas and Trends: The Transplant Coordinators*, N.Y. TIMES, May 29, 1977, at 124.

101. *See, e.g.*, CHRISTIAAN BARNARD & CURTIS BILL PEPPER, ONE LIFE 255 (1969).

102. *See, e.g.*, Snider, *supra* note 34, at 54.

103. *See, e.g.*, Frank P. Grad, *Legislative Responses to the New Biology: Limits and Possibilities*, 15 UCLA L. REV. 480, 497 (1968).

104. *See, e.g.*, Susan E. Lederer, *Tucker's Heart: Racial Politics and Heart Transplantation in America*, *in* A DEATH RETOLD, *supra* note 20, at 142.

105. George J. Annas, *All the President's Bioethicists*, HASTINGS CENTER REP., Feb. 1979, at 14, 14 (quoting Sen. Walter Mondale).

106. *See* Walter F. Mondale, *The Issues Before Us*, HASTINGS CENTER REP., June 1971, at 4.

programs").[107] Events had not brought the problems of transplanting organs to the fore and—with the exception of defining death[108]—they got lost in the shuffle.

Though activity to coordinate the transfer of organs between strangers focused primarily on enlarging the donor pool and improving immunological matching techniques through the early 1980s, the ethical and political problems of organ allocation were foreshadowed in the 1960s and 1970s, when *artificial* kidneys—i.e., dialysis machines—provided a (costly) new way of extending the lives of end-stage renal patients.[109] The allocation of access to dialysis machines, at a time when the number of patients in need of dialysis dwarfed the number of machine-hours available, quickly became a subject of scrutiny from journalists, legal scholars, other policy-oriented professionals, and the general public. One institutional approach was so widely criticized in the academic and professional literature[110] that it effectively stood as a model of how not to allocate scarce medical resources. The Seattle Artificial Kidney Center relied on a committee of community members, which seemed to consist largely of locally prominent figures (such as a minister and a labor leader), to select among candidates for dialysis based on social and psychological criteria. The popular magazines *Life* and *Redbook* reported on how the process worked: The Seattle committee deliberated in roughly the manner of a trial jury, favoring candidates with "a record of public service."[111] To critics, the committee "spared" individuals whose personal traits and forms of community involvement reflected committee members' "own middle class suburban value system." The very objective of selecting candidates based on putative "social worth" was highly controversial,[112] and the way the committee measured such vague and abstract notions was ripe for derision. In practice, "public service" was given highly specific meanings that

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107. Annas, *supra* note 105, at 14.

108. *Id.* at 14.

109. The dialysis machine was invented in 1943, but kidney dialysis did not become a practicable long-term therapy until the introduction of the arteriovenous Teflon shunt in 1960. *See* David Sanders & Jesse Dukeminier, Jr., *Medical Advance and Legal Lag: Hemodialysis and Kidney Transplantation*, 15 UCLA L. REV. 357, 360 (1968).

110. *See, e.g.*, Christopher R. Blagg, *The Early Years of Chronic Dialysis: The Seattle Contribution*, 19 AM. J. NEPHROLOGY 350, 353 (1999) (noting that the Seattle dialysis selection committee "became notorious as a result of" national media attention). But, for an appreciative discussion of the "Seattle God Committee" as emblematic of the "advantages and dangers" of using "parajuries" to allocate scarce goods, see GUIDO CALABRESI & PHILIP BOBBITT, TRAGIC CHOICES 187-88 (1978).

111. Sanders & Dukeminier, *supra* note 109, at 377. *See also*, Shana Alexander, *They Decide Who Lives, Who Dies*, LIFE, Nov. 9, 1962, at 102; John Robbins & June Robbins, *The Rest Are Simply Left To Die*, REDBOOK, Nov. 1967, at 80.

112. *See* Laura J. McGough et al., *Which Patients First? Setting Priorities for Antiretroviral Therapy Where Resources Are Limited*, 96 AM. J. PUB. HEALTH 1173 (2005).

represented the experiences of a particular subset of society and "scouts, Sunday school, Red Cross" counted in one's favor. Going to jail in a political protest, or devoting one's life to promoting atheism, seemed less likely to earn points.[113] In words that would often be quoted in subsequent law journal articles, psychiatrist David Sanders and trusts and estates scholar Jesse Dukeminier, Jr., remarked, "[t]he Pacific Northwest is no place for a Henry David Thoreau with bad kidneys."[114] However, since problem consensus is not the same as solution consensus, scholars who joined in this basic critique did not necessarily share a preferred alternative.[115]

In 1972, the scarcity necessitating a process for making such choices was ameliorated after President Richard Nixon signed a set of amendments to the Social Security Act that "extended Medicare coverage to [the vast majority of Americans] with chronic kidney failure."[116] Indeed, obviating deathly allocation dilemmas (in a society that prided itself on its abundance) was "the underlying rationale" for the legislation.[117] At the time, there was also considerable interest among policymakers, including Senate Finance Committee Chairman Russell Long, in providing limited national health insurance for "catastrophic" medical crises.[118] The Medicare End Stage Renal Disease (ESRD) program fit neatly into this paradigm: It mustered collective resources to make a "life-saving therapy" that was "beyond the [financial] means of practically all individuals" available to the segment of the population that needed it.[119] At the congressional staff level, the program was discussed "as a pilot for catastrophic health insurance."[120] The costs of the program, however, escalated more rapidly than anticipated, raising questions about the approach's sustainability on a large scale.[121]

Media coverage of the kidney amendments highlighted similar tensions. On the one hand, officials from the National Kidney Foundation characterized the

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113. Sanders & Dukeminier, *supra* note 109, at 377-78 (quoting and paraphrasing a description by Robbins & Robbins, *supra* note 111, at 133).

114. Sanders & Dukeminier, *supra* note 109, at 378.

115. Dukeminier and Sanders advocated a policy of presumed consent for organ removal. *See id., supra* note 109. *See also* Jesse Dukeminier, Jr. & David Sanders, *A Proposal for Routine Salvaging of Cadaver Organs,* 279 NEW ENG. J. MED. 413 (1968).

116. Richard A. Rettig, Inst. Of Med., *Origins of the Medicare Kidney Disease Entitlement: The Social Security Amendments of 1972, in* BIOMEDICAL POLITICS 176 (Kathi E. Hanna ed., 1991).

117. Roger W. Evans & Christopher R. Blagg, *Lessons Learned from the End Stage Renal Disease Experience: Their Implications for Heart Transplantation, in* ORGAN SUBSTITUTION TECHNOLOGY: ETHICAL, LEGAL, AND PUBLIC POLICY ISSUES 175, 176 (Deborah Mathieu ed., 1988).

118. Rettig, *supra* note 116, at 186, 191-93.

119. Evans & Blagg, *supra* note 117, at 176.

120. Rettig, *supra* note 116, at 186, 193.

121. Evans & Blagg, *supra* note 117, at 178-81.

legislation as "a model" for funding the treatment of "other chronic diseases."[122] On the other hand, the disease-specific nature of the legislative approach stirred unease about a system in which the availability of health care financing "seem[ed] to depend on how well a special interest group gets its message across to the public."[123] Ambivalence about the roles of individual initiative and organized lobbying would dog the field of organ replacement therapy as the scarcity of kidneys came to overshadow the scarcity of funds in public policy discourse.

E. Making Tragic Choices: The Domestic Politics and Economics of Organ Allocation

The development of cyclosporine therapy in the late 1970s and early 1980s would change the nature and salience of the scarcity of transplantable organs. In 1978, British transplant surgeon Roy Calne demonstrated the drug's efficacy in preventing kidney rejection. Although the drug has often been described as potent,[124] its advantages lie largely in its selectivity: It effectively targets the "small proportion of white blood cells . . . responsible for destroying transplanted organs" without devastating the patient's entire immune system.[125] Starzl achieved a similar effect in liver transplantation after taking the additional step of combining the drug with steroids.[126] Following "the introduction of the drug," one year kidney transplant survival rates "climbed" from 55% to 85%.[127] The breakthrough was more profound in liver transplantation, where the comparatively short time that livers could be kept viable outside the body had limited the feasibility of immunological matching.[128] "Prior to 1980, using azathioprine-steroid therapy, the reported five-year survival rate for 170 [liver] recipients was 18.2 percent. After 1980, using cyclosporine-steroid therapy, the projected five-year survival rate, based on 244 patients, had risen to 68 percent."[129] Outcomes for heart transplant recipients evidently also improved, despite the even shorter organ preservation time (four hours) for hearts.[130]

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122. Lawrence K. Altman, *Costs of Kidney Therapy: Two Fundamental Questions*, N.Y. TIMES, Jan. 23, 1973, at 13.

123. *See, e.g., id.*

124. *See, e.g.*, STARK, *supra* note 21, at 128.

125. *Id.* at 131.

126. WERTH, *supra* note 81, at 49.

127. STARK, *supra* note 21, at 133.

128. TASK FORCE ON ORGAN TRANSPLANTATION, U.S. DEP'T OF HEALTH & HUMAN SERVS., ORGAN TRANSPLANTATION: ISSUES AND RECOMMENDATIONS (Apr. 1986), 17-19.

129. *Id.* at 18.

130. *Id.* at 17-18. Although the preservation time for human hearts was reportedly only four hours, short term outcomes for heart transplant recipients were substantially better (roughly 65%

Like artificial kidneys, technological advances in immunosuppression presented new practical challenges and policy dilemmas, fitting into a pattern that policy analyst Theodore Marmor has dubbed the "paradox of progress."[131] One set of questions revolved around the costs and financing of transplant surgeries and post-operative therapy that were now medically advisable. The ESRD program, naturally, did not extend to "extrarenal" transplants; a spotty patchwork of public and private coverage existed for liver transplantation.[132] Financial pressures even bore on renal transplantation, because some who were eligible for reimbursement of surgical costs could not afford cyclosporine post-transplant.[133] Faced with a "growing divergence between financial and clinical considerations," transplant surgeons became acutely aware of the political economy of health care financing.[134] A similar problem confronted organ procurement agencies. These organizations had developed to serve renal transplant programs,[135] and many received all their funding from the Medicare kidney program, which "pa[id] only for kidney acquisition."[136] Supplying hearts, livers, and pancreases on a large scale would require funding for labor-intensive procurement and transport activities under tight time pressures. By enlarging the number of patients who stood to benefit from a given kidney, immunosuppression made the choice of recipients of cadaver organs a real social problem. The assumption that some, and perhaps many, patients would be an acceptable donee for virtually every donated kidney was implicit in the calculation of "kidneys procured" per capita to measure procurement agencies' "effectiveness" and in the use of kidney "discard rates" to measure wastage.[137] Every patient waiting for a transplant was plausibly a victim of the organ shortage, and not merely bad luck.[138]

Guido Calabresi and Philip Bobbitt's 1978 book *Tragic Choices* was a timely contribution to the burgeoning scholarly literature on allocating scarce

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survived one year or more) prior to the introduction of cyclosporine.

131. *See* THEODORE R. MARMOR, THE POLITICS OF MEDICARE 4-5 (1973).

132. By 1986, this included both federal and state financing. *See* TASK FORCE ON ORGAN TRANSPLANTATION, *supra* note 128, at 17-18.

133. *Id.* at 17. Note that the Task Force itself contended that there were "essentially no financial barriers to kidney transplants" in the United States.

134. Richard A. Rettig, *The Politics of Organ Transplantation: A Parable of Our Time*, *in* BLUMSTEIN & SLOAN, *supra* note 8, at 193.

135. TASK FORCE ON ORGAN TRANSPLANTATION, *supra* note 128, at 53.

136. OFFICE OF TECH. ASSESSMENT, BLOOD POLICY AND TECHNOLOGY 185 (1985).

137. *See* Prottas, *supra* note 15, at 48-49.

138. Thus, "[i]n contrast to 'statistical' low-visibility victims . . . organ transplants benefit identifiable victims whose plights are vivid, palpable, and can be dramatically represented in the media." Peter H. Schuck, *Government Funding for Organ Transplants*, *in* BLUMSTEIN & SLOAN, *supra* note 8, at 169, 175.

resources.[139] It examined how three societies, including the United States prior to the Medicare amendments, allocated access to dialysis machines. Calabresi and Bobbitt, two emerging legal scholars, perceptively recognized that scarcity engenders not only competition for material resources, but also conflicts of values. This thesis would hold true for organ allocation as well as the selection of patients for dialysis. Americans have long professed commitments to a set of values that can potentially conflict with each other: majority rule and equal citizenship, personal autonomy and democratic governance, laissez-faire and nationalism.[140] And plausible principles for allocating organs—equality of opportunity, medical need, therapeutic efficacy, ability to pay, putative social worth—can likewise conflict with each other. American society, however, has developed (or stumbled upon) effective ways of managing the contradictory impulses within our culture *in ordinary circumstances*. For example, a large scholarly literature explores how cultural norms (e.g., individual economic responsibility) and institutional structures (e.g., policies that modestly redistribute wealth) have kept in check the latent tension between egalitarianism and market capitalism.[141] Of course, these are not the only rivalrous ideals American society has managed to reconcile, but their harmonization is emblematic of the negotiated compromises that have been a persistent feature of American political culture.

In contrast, the frontiers of transplantation were not only technologically unstable, but presented some difficult and unusual social conditions. These conditions included dire scarcity amid material abundance (the primary problem in organ allocation is clearly stimulating supply, rather than demand),[142] a profound dependence on strangers (the transplant recipient "makes something of oneself" with another person's parts), a lack of reliable legal rules (an organ "futures market" presupposes its own future), and stubborn, seemingly innate

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139. CALABRESI & BOBBITT, *supra* note 110.

140. For a few intellectuals' assessments of tensions among Enlightenment values that resonate in contemporary America, see, for example, DANIEL BELL, THE CULTURAL CONTRADICTIONS OF CAPITALISM (1976); JAMES FITZJAMES STEPHEN, LIBERTY, EQUALITY, FRATERNITY (R.J. White ed., Cambridge Univ. Press 1967); Robert A. Burt, *Constitutional Law and the Teaching of the Parables*, 93 YALE L.J. 455, 455 (1984) ("[M]ajority rule is intrinsically at odds with the egalitarian principle."); Amy L. Chua, *The Paradox of Free Market Democracy: Rethinking Development Policy*, 41 HARV. INT'L L.J. 287 (2000); Richard A. Epstein, *Liberty Versus Property? Cracks in the Foundations of Copyright Law*, 42 SAN DIEGO L. REV. 1, 3 (2005) (examining a "tension between liberty and property within the natural law tradition of Locke"); Charles D. Gonthier, *Liberty, Equality, Fraternity: The Forgotten Leg of the Trilogy, or Fraternity: The Unspoken Third Pillar of Democracy*, 45 MCGILL L.J. 567 (2000).

141. *See* FREDERICK JACKSON TURNER, THE FRONTIER IN AMERICAN HISTORY 305, 342 (1958); Chua, *supra* note 140, at 292.

142. *See* Prottas, *supra* note 15, at 44.

inequalities (depending on one's blood group, one might be a "universal donor" or a "universal recipient").[143] Economist Lester Thurow put the predicament poignantly: "Being egalitarians, we have to give the treatment to everyone or deny it to everyone; being capitalists, we cannot deny it to those who can afford it. But since resources are limited, we cannot afford to give it to everyone either."[144] Organ allocation would involve "tragic choices" because, given the scarcity of organs and the constraints imposed by technological limitations, no allocation mechanism or criterion could fully satisfy the panoply of rivalrous values at stake, including equality of opportunity, democratic governance, individual choice, compassion for the least fortunate, nationalism and capitalistic entrepreneurship.[145]

Further, any allocation formula could be said to favor some transplant candidates over others. A system developed through majoritarian political processes is likely to disadvantage those without the political franchise, such as non-citizens. A system based on genetic compatibility may result in longer wait times for members of ethnic groups with lower donation rates and higher rates of organ failure. A laissez-faire approach to organ allocation would likely result in reduced access to transplants as one moved down the socioeconomic ladder. Where cultural identities or socioeconomic inequalities are already politicized, policies or techniques that tend to keep organs within identifiable groups (e.g., genetic matching) are vulnerable to allegations of clannishness, while approaches that allow transplantation across societal cleavages (e.g., immunosuppression) are vulnerable to allegations of conquest. Because the distribution of these scarce resources implicates cherished values, the politics of organ allocation cannot be reduced to material interests. But material considerations and high ideals would often converge so as to give critiques of organ transfer policies a standard, stylized form: Allegations that some group of patients is unfairly or improperly receiving "privileged access" to the nation's organs. On a higher level of abstraction, critics will contend that an allocation protocol violates some tenet of "the American way"—without acknowledging the extraordinary difficulty of reconciling these contradictory tenets in the transplant context. The next Sections of this essay examine how Congress and the Executive Branch grappled with

143. *Cf.* FRANCIS FUKUYAMA, OUR POSTHUMAN FUTURE 9 (2002) (basing political equality on our common humanity and quoting Thomas Jefferson's observation that "the mass of mankind has not been born with saddles on their backs, nor a favored few booted and spurred, ready to ride them legitimately, by the grace of God").

144. *See* Timothy J. McNulty, *Transplant Ethics a Matter of Life and Death*, CHI. TRIB., May 12, 1985, at C1 (quoting Lester Thurow). Of course, Thurow's version of egalitarianism was not the only equality-oriented approach. One might argue for a policy that maximizes the number of lives saved on the theory that all lives have equal worth. *See* RICHARD A. EPSTEIN, MORTAL PERIL: OUR INALIENABLE RIGHT TO HEALTH CARE?, 276-79 (1997).

145. *See* CALABRESI & BOBBITT, *supra* note 110.

such concerns as various stakeholders and the general public became increasing engaged with the problems of organ allocation.

F. Green Lights and Red Tape

One of Calabresi and Bobbit's claims in *Tragic Choices* was that, as resource scarcity forced a society to make value-laden allocation choices (e.g., "sickest first" versus "most likely to benefit from a transplant"), policymakers would often hide, deny, or smooth over the fact that a value-laden choice was being made (e.g., "science tells us this person is the best match"), temporarily helping the society to preserve its cherished values.[146] Then, as citizens realized that tragic choices were being made, pressure might build for increased social expenditures (e.g., the Medicare dialysis amendments) to address the scarcity and thereby alleviate the threat that such tradeoffs pose to their value system. The history of transplantation partially conforms to this two-part dynamic and partially complicates it.

Because the problem of organ allocation was an extension of the dialysis access problem, the fact that organ allocation necessitated morally difficult choices could hardly be papered over, although paper-pushing was not out of the question. As soon as better immunosuppressive drugs substantially improved outcomes in unrelated donor transplants, the politics and economics of organ allocation were thrust vividly into the public consciousness. Further, there was no straightforward way to relieve the underlying scarcity. Whereas Congress could simply appropriate more money to purchase dialysis machines and fund dialysis, the prospect of purchasing organs immediately raised a new set of anxieties. Nonetheless, the strategies policymakers employed to manage the allocation predicament—targeting inefficiencies and shifting decisional authority to more politically insulated agencies—were consistent with the theory of *Tragic Choices*.

Within the decentralized, loosely-coordinated institutional matrix of transplant centers, various factors—including personal resourcefulness, regional boosterism, and political patronage—facilitated the development of transplant surgery and influenced the allocation of organs. Tissue typers' work in uniting regional kidney transplant centers into expansive organ sharing networks was one example of this sort of individual and institutional initiative.[147] Savvy elected

146. *See* CALABRESI & BOBBITT, *supra* note 110, at 149-91.

147. *See, e.g.*, Paul I. Terasaki, *Histocompatibility*, *in* HISTORY OF TRANSPLANTATION: THIRTY-FIVE RECOLLECTIONS 513, 520-21, 524 (Paul I. Terasaki ed., 1991); *National Organ Transplant Act: Hearing on H.R. 4080 Before the Subcomm. on Health and the Enviroment of H. Comm. on Energy and Commerce*, 98th Cong. 16-29 (1983) [hereinafter *Energy and Commerce Hearing*] (providing statements of members of families interested in transplantation and doctors in support of a national network).

officials quickly became involved in helping constituents obtain access to the life-saving organs these networks could provide. In October 1983, North Carolina Senator Jesse Helms carried a jaundiced eight-month-old into a "packed" room during one of the Senate committee hearings that would ultimately lead to the passage of NOTA. "Josh is now first on the organ waiting list at the University of Minnesota Hospital," the Senator declared. Governor James Hunt, Jr., who was running against Helms in the 1984 election, said that "North Carolina had recently amended its insurance program to cover transplant surgery, which in Josh's case would cost about $200,000."[148]

Perhaps nowhere was the role of ambitious local enterprise more vivid than in the emergence of the University of Pittsburgh's Presbyterian Hospital as an international transplant hub. Pioneering liver transplant surgeon Thomas Starzl, reportedly "tired of chasing research grants" as surgery chair at the University of Denver, in 1980 "agreed with a handshake to set up a liver transplant program" in Pittsburgh. The city's location—within an hour's flight from 70% of the American population—was ideal for time-sensitive organ procurement, and by 1984, "Presby" surgeons were performing half of all liver transplants in the United States.[149] Multiple institutions and constituencies were part of the action as the growth of the city's health care sector partially offset manufacturing job losses. The *Pittsburgh Press* surveyed "thirty prominent Pittsburgh people" to see how many held organ donor cards.[150] In 1985, the *New York Times* described Pittsburgh as "a prime goal for surgeons, who compete for slots," noting that the Presbyterian "name on a resume [could] make a big difference in fees and status."[151] Transplant Recipients International Organization (TRIO) also made its home in the City of Bridges, where so many of its members had gotten their new lease on life.[152]

As transplantation became a realistic clinical option for more patients, transplant families and onlookers expressed frustration with one major aspect of America's diffuse, variegated, and informal organ transfer system: Access to transplant surgery depended on factors far removed from technical considerations, and many of these factors seemed needlessly unfair to individual patients. Public financing of extrarenal transplantation, particularly liver transplantation, was precarious and subject to decisions that participants in the process and close observers decried as inconsistent and arbitrary. The role of

148. Joey Ledford, *Washington News*, UNITED PRESS INT'L, Oct. 20, 1983.

149. *See* Gruson, *supra* note 2.

150. Andrew Schneider & Mary Pat Flaherty, *Donor Organs a Fragile Link Between Grief and Hope*, PITTSBURGH PRESS, May 26, 1985, at B9.

151. *See* Gruson, *supra* note 2.

152. Steve Twedt & Gayle McCracken, *U.S. Panel to Study Transplant Rules*, PITTSBURGH PRESS, May 13, 1985, at A1.

politicians in pressuring state health insurance programs to pay for operations "case-by-case,"[153] as well as the Reagan Administration's efforts to publicize individual patients' need for organs, struck critics as partial fixes to systematic and comprehensive gaps in organ procurement and allocation.[154] Additionally, less publicized at that time, the kidney shortage seemed to be getting worse following the introduction of cyclosporine.[155]

Some critics complained about the unpredictability and capriciousness of decisions determining patients' access to transplants. "These things can't be left to chance," said Charles Fiske, a hospital administrator whose own daughter needed a liver transplant in 1982.[156] Massachusetts Blue Cross had first agreed to cover the transplant, then reversed its position, and finally restored coverage after the state house speaker and the media took an interest in the case.[157] Others saw this mode of allocation as inherently biased. The *Washington Post* noted legislators' frustration with a "system that provides new organs to those who are savvy enough to go to the White House, resourceful enough to get themselves on television or lucky enough to live in the right state."[158]

For transplant centers, too, the lack of settled, consistent allocation rules consumed time and energy. UCLA's medical director explained how his institution haggled with out-of-state Medicaid programs over the cost of transplants: "Someone will say they're not going to pay, and we'll say, 'Well, we can't do it.' Then they'll come up with a little money and we'll lower our price a bit. . . . The stress on the patient and our institution is very great."[159] One result was that even relatively well-off transplant families—perhaps especially the well-off—felt they could not clear the process's hurdles with their dignity intact. Myron Teichholtz, described as an "affluent businessman," told a reporter that

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153. *See, e.g.*, H.R. REP. NO. 98-575, at 19 (1983) ("While the Committee believes that the decision to extend Medicaid coverage for one or more organ transplant procedures is appropriately that of each individual State, the Committee does not believe that this decision can equitably be made on a case-by-case basis. . . . Access to organ transplant coverage should not, in the Committee's view, be dependent upon a family's ability to draw sympathetic media coverage and favorable dispensation from elected officials.").

154. *See, e.g.*, *Energy and Commerce Hearing*, *supra* note 147, at 3 (statement of Rep. Thomas A. Luken) ("Air Force I isn't a national policy"); Howard Kurtz & James Schwartz, *Organ Transplants Turn into Form of Patronage*, WASH. POST, Apr. 23, 1984, at A1.

155. *See* Ronald Sullivan, *New York's Shortage of Organ Donors Grows Acute*, N.Y. TIMES, Sept. 8, 1985, at E26 (noting that the number of patients nationwide in need of dialysis or a kidney transplant was "growing, while the number of transplants has leveled off in recent years," despite a better "likelihood of [surgical] success").

156. Kurtz & Schwartz, *supra* note 154. *See also* Rettig, *supra* note 134, at 199.

157. Kurtz & Schwartz, *supra* note 154.

158. *Id.*

159. *Id.*

his offer of more than $100,000 "in personal assets" couldn't get his daughter into Presby.[160] Although Massachusetts Medicaid ultimately agreed to cover the daughter's transplant, the agency had initially denied the coverage, following the same pattern as in the Fiske case. "After working my whole life, they made a panhandler out of me," said Teichholtz.[161] "Here we were, a family draining every resource, and these people were playing with us like chips on a chessboard. Today yes, tomorrow no."[162] Put bluntly, patients, their loved ones, and transplant centers needed access to organs and adequate financing. By framing these pressures in terms of consistency and coordination, media coverage likely played to widely shared, relatively uncontroversial notions of procedural fairness.

The first federal efforts to rationalize the mechanics of transplant policy—specifically, financing—showed how desires to increase the availability of transplant surgery or, conversely, cost considerations could shape the new order being imposed. At the federal level, between 1979 and 1987, the availability of Medicare reimbursements for heart transplantation reflected factors such as the willingness of state Blue Cross intermediaries to pay for the procedure, the Social Security Administration's administrative law jurisprudence, and eventually the policy judgment of the Department of Health and Human Services (HHS).[163] A national study of heart transplant outcomes and costs, commissioned by HHS and conducted by the Battelle Memorial Institute, led to HHS's "determination . . . that heart transplants are medically reasonable and necessary" in certain circumstances.[164] In a roughly parallel process, the National Institutes of Health (NIH) in 1982 agreed to convene a conference on the state of liver transplantation at the urging of Surgeon General C. Everett Koop. Although a determination that liver transplants were no longer "experimental" would have implications for Medicare coverage, there was little overlap between the population experiencing liver failure and the population eligible for Medicare. Nonetheless, if NIH gave liver transplantation its "imprimatur" and Medicare agreed to finance the procedure, "state Medicaid agencies . . . Blue Cross and Blue Shield plans, and . . . commercial health insurance firms . . . . would have little choice but to follow."[165]

Richard A. Rettig, a social scientist commissioned by the Institute of Medicine to evaluate the ESRD program, observed that the scientific and policy

160. *Id.*

161. *Id.*

162. *Id.*

163. *See* Rettig, *supra* note 134, at 196-97. *See also* Criteria for Medicare Coverage of Heart Transplants, 52 Fed. Reg. 10,935 (Apr. 6, 1987); Notice of HCFA Ruling To Discontinue Medicare Coverage of Heart Transplantation Procedures, 45 Fed. Reg. 52,297 (Aug. 6, 1980).

164. Criteria for Medicare Coverage of Heart Transplants, 51 Fed. Reg. 37,164 (Oct. 17, 1986).

165. Rettig, *supra* note 134, at 202.

controversy surrounding liver transplantation was unusually politicized when compared to previous experiences concerning other organs. Rettig attributed this politicization to "well-organized" advocacy by interested persons and to the concentration of public attention on pediatric liver cases.[166] Several other factors may have helped further explain liver cases' absorbing effects on policymakers and the public at large. Once dialysis became broadly available, extrarenal transplants provided a clearer example of transplant medicine's life-or-death stakes than did the clinical choice of how to treat ESRD patients. Whereas human heart transplantation was first attempted overseas and had begun to diffuse across the United States by the mid-1980s, the routinization of liver transplantation was occurring largely within a single American medical institution, Starzl's Pittsburgh program.[167] Then, the sudden, dramatic clinical impact of cyclosporine on liver transplantation may have helped thrust the procedure into the public's consciousness. Starzl's role may have contributed to White House interest in pediatric liver transplantation, since Starzl's professional mentor, Dr. Loyal Davis, was also the father of First Lady Nancy Reagan.[168] Finally, whereas procuring beating hearts was a culturally freighted activity, candid discussion of the need for human livers, and even aggressive pleading for them, may have been more acceptable to the public.

II. LEGISLATIVE RESPONSE

A. Congressional Inquiry

As the bureaucratic gears began to turn, complaints about the existing system of organ allocation took on a new sense of urgency when entrepreneurs outside the system offered an alternative that many Americans found unpalatable—the purchase of organs domestically or abroad for sale in America. In September 1983, one such proposal caught the attention of the national media. De-licensed Virginia physician H. Barry Jacobs contacted the Food and Drug Administration to "inquir[e] whether he needed a license to import organs." Jacobs claimed that hospitals had "expressed interest in removing kidneys" from

166. *Id.* at 199.

167. *Compare id.* at 196-97 (describing the expansion of heart transplantation beyond Dr. Norman Shumway's pionnering program at Stanford), *with id.* at 199 (describing Starzl's program and several others in Europe and North America).

168. *See Thomas Starzl*, 21 ENCYCLOPEDIA OF WORLD BIOGRAPHY SUPPLEMENT (2001) (documenting Davis's great influence on Starzl's life); Anita Srikameswaran, *Pioneer Without Peer: Hard-Driving Surgeon Has Made Life-Saving Transplants Almost Common*, PITTSBURGH POST-GAZETTE, June 11, 2000, at A16 (mentioning Starzl's "long friendship with professor and neurosurgeon Dr. Loyal Davis, father of former first lady Nancy Reagan").

paid donors whom he would "solicit."[169] Both the supply and demand sides of the business plan provoked objections: The plan would advantage economically privileged kidney patients over those who were not wealthy, and it would potentially exploit or injure desperate organ sellers.

Practical objections to the proposal were based on scant evidence of an adequate informed consent process and doubts that the living donors would receive needed follow-up care.[170] Several ethical objections were leveled at the proposal as well. A surgeon who had become active in private-sector transplant policy efforts spoke of "honorable alternatives" for "increas[ing] the availability of tissues and organs"—presumably excluding Jacobs's alternative as dishonorable to those involved.[171] To the extent that organ sales would exacerbate or enshrine economic inequalities in the allocation system, the proposal contradicted the egalitarian ethics of many reformers.[172] From one communitarian perspective, it represented "the expansion of unfettered commercialism into dimensions of life which could just possibly provide us the opportunity to achieve a greater sense of community and of national purpose than we have previously known, except in the face of external threat."[173] The high stakes of transplantation, both existential and symbolic, evoked strong feelings and passionate language.

Jacobs's nascent business, the International Kidney Exchange (IKE), was not well-liked, and commenters frequently connected shortcomings of the present system of organ allocation to the space left for commercial ventures. A resolution condemning the sale of human organs, introduced by Massachusetts Senator Paul Tsongas in October 1983, illustrated this point, beginning, "whereas the . . .

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169. Margaret Engel, *Va. Doctor Plans Company To Arrange Sale of Human Kidneys*, WASH. POST, Sept. 19, 1983, at A9. As Jacobs's plan developed, it focused on purchasing organs from living providers, as opposed to purchasing cadaveric organs. *See MD Sets Up Kidney-Selling Business*, GLOBE & MAIL (Toronto), Oct. 8 1983 (contemplating protections for living sellers).

170. *See Procurement and Allocation of Human Organs for Transplantation: Hearings Before the Subcomm. on Investigations and Oversight of the H. Comm. on Science and Technology*, 98th Cong. 377 (1983) (statement of Samuel Gorovitz, Department of Philosophy, University of Maryland, College Park) [hereinafter *Science and Technology Hearing*] (noting that "the scheme makes a mockery of informed consent, as is evident to anyone familiar with Federal regulations protecting human search subjects"). *See also id.* at 269 (statement of Oscar K. Salvatierra, M.D., President, American Society of Transplant Surgeons).

171. *Energy and Commerce Hearing*, *supra* note 147, at 257 (statement of Gary E. Friedlaender, M.D., Interim President, American Council on Transportation).

172. *See Science and Technology Hearing*, *supra* note 170, at 340 (statement of Robert M. Veatch, Ph.D., Professor of Medical Ethics, Georgetown University Kennedy Institute of Ethics) ("Any scheme that distributes lifesaving organs on a basis of ability to pay is discriminatory and, therefore, in my mind unethical.").

173. *Id.* at 379 (statement of Samuel Gorovitz, Department of Philosophy, University of Maryland, College Park).

pressures caused by a lack of national policy have encouraged the practices of the sale of human organs for profit."[174] In a country burdened by the historical subordination of some human beings into the category of others' property, this new kind of commodification was quickly condemned as akin to "slavery."[175]

Earlier that year, Representative Gore, Chair of the House Science and Technology Committee's Oversight Subcommittee, had convened the first of a series of hearings that would culminate in the enactment of NOTA.[176] Published sources have attributed Gore's interest and growing involvement in transplant policy to multiple origins. The Congressman had "learned that the most pressing problem in caring for end-stage renal disease was availability of suitable organs for transplant" during 1982 congressional hearings on dialysis and diet.[177] The Congressman's exposure to the problem also became more personal "when one of his constituents sought Gore's help in securing an organ."[178] Around the same time, a Yale pediatrics professor, Dr. Myron Genel, was "assigned" to Gore through the Robert Wood Johnson Health Policy Fellows Program. This new staff affiliate reportedly "press[ed] Gore to use his position as chair of an investigative subcommittee to highlight problems [regarding transplantation] and develop a federal government solution."[179] Now, "after being sent a brochure from a New England company that offered to register donors, offering them the potential of a $10,000 payment if one of their organs was used in a transplant," Gore sought to ensure that the legislation developing under his watch would quash this emerging industry.[180]

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174. S. Res. 251, 129th Cong. (1983).

175. The article quotes Representative Gore as stating that, "putting organs on a market basis . . . seems to be something inconsistent with our view of humanity . . . . Prostitution is illegal for reasons that are similar. So is slavery." *See* Engel, *supra* note 169. The analogy has been sharply questioned in recent scholarship, which suggests that the defining moral failing of slavery was not property rights in human tissue, but rather whom was allowed to own and alienate whom. *See, e.g.*, MICHELE GOODWIN, BLACK MARKETS: THE SUPPLY AND DEMAND OF BODY PARTS 198 (2006) (noting that "many slaves were given away as gifts," including the African-American Harriet Jacobs, who was inherited by a three-year-old). At a minimum, the theory implicit in the analogy needs more explication if it is to survive. After all, discourses about diversity and affirmative action that characterize people of color or their labor as valuable in a global market have not engendered the same degree of outrage from the same critical positions. *But see* Grutter v. Bollinger, 539 U.S. 306, 329 (2003) (Thomas, J., concurring in part and dissenting in part) (criticizing law schools' racialized conception of student body diversity as an "aesthetic" sensibility).

176. Rettig, *supra* note 134, at 199.

177. Keith J. Mueller, *The National Organ Transplant Act of 1984: Congressional Response to Changing Technology,* 8 POL'Y STUD. REV. 346, 346 (1989).

178. *Id.* at 347.

179. *Id.* Note that this source consistently misspells Genel's name as "Ganel."

180. Engel, *supra* note 169. *See also* Victor Cohn, *New Federal Help for Transplants Pressed*

In July and October 1983, the House Committee on Energy and Commerce's Subcommittee on Health and the Environment held further hearings on transplant policy. Under the direction of Subcommittee Chairman Henry Waxman of California, the hearings brought together two legislators who shared an unusually deep familiarity with transplantation. Waxman first attempted to improve the accessibility of transplantation as a member of the California State Senate.[181] At the hearings, Thomas Starzl recalled speaking with Waxman around 1981 about the implications of improved immunosuppression for the ESRD program.[182] Representative Gore, though not a member of Waxman's Subcommittee, played a leading role in its hearings by providing extensive testimony about the challenges of organ allocation and transplant financing.[183] Gore's Oversight Subcommittee continued its inquiry in November 1983,[184] and over the next year, hearings concerning organ transplantation were held by the Senate Committee on Labor and Human Resources in Oklahoma City, with Oklahoma Senator Don Nickles presiding as Acting Chair of the Committee,[185] and the House Ways and Means Committee's Subcommittee on Health.[186] In contrast to Gore's Subcommittee on Investigations and Oversight, these bodies had the authority to enact legislation and appropriate funds.[187]

The institutional preconditions for this series of hearings had been set in the 1970s, when the "proliferation of [congressional] subcommittees" enlarged the opportunities for legislators with relatively little seniority to emerge as policy "entrepreneurs."[188] As the news media and the White House took an interest in transplantation, often focusing on individual cases, the subject became a logical candidate for this kind of policy entrepreneurship. Indeed, some critics "[spoke]

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by Gore, WASH. POST, Oct. 6, 1983, at A17 (reporting that Gore described his effort to ban commerce in human organs as "a response . . . to two new efforts—one in Reston [i.e., Barry Jacobs's Virginia plan] and one in Maine").

181. *Energy and Commerce Hearing*, *supra* note 147, at 301-02 (statement of Oscar K. Salvatierra, M.D., President, American Society of Transplant Surgeons).

182. *Id.* at 225 (statement of Thomas E. Starzl, M.D., Ph.D., Professor of Surgery, University of Pittsburgh).

183. *See id.* at 7-11 (statement of Rep. Albert Gore, Jr.).

184. *Science and Technology Hearing*, *supra* note 170.

185. *See, e.g.*, *Organ Transplantation: Hearing Before the S. Comm. on Labor and Human Resources*, 98th Cong. (1983) [hereinafter *Human Resources Hearing*].

186. *National Organ Transplant Act: Hearing on H.R. 4080 Before the Subcomm. on Health of the H. Comm. on Ways and Means*, 98th Cong. (1984) [hereinafter *Ways and Means Hearing*].

187. *See* Mueller, *supra* note 177, at 348 (describing the oversight subcommittee as "non-legislative"). Jacobs's business plan probably provided some of the impetus for legislating, transforming "Oversight" questions into "Commerce" and "Labor and Human Resources" problems.

188. *Id.* at 347-48.

wearily of politicians using mortally ill children to enhance their public images." When Gore began promoting legislative intervention in transplant policy, his favored legislation was labeled "the Gore for Senate bill."[189] Coast-to-coast media coverage, as well as the way that actors closer to the scene framed the problem as one of "piecemeal aid [that] must be replaced by a national policy,"[190] gave the policy discussion a certain tenor: Members of transplant families stood as representatives of a grand problem implicating moral precepts and the interests of the public at large. To the extent that politicians self-consciously played to a nationwide public audience, they accentuated this timbre. By Gore's account, "individuals and families" were "get[ting] a very human response and some help" from the Executive Branch, but "there [was] an inability to see the national dimension of the problem."[191] Presumably, congressional hearings, mustering the testimony of transplant families, health care workers, public officials, and professional moral philosophers, would bring this dimension to light.

Interested members of Congress, in mapping the terrain, explored the problem from many vantage points. The issues that emereged ranged from blood pressure rates of living related kidney donors[192] to the amounts of HCFA kidney retrieval reimbursements that were passed on to lenders as interest payments.[193] Several major challenges to the transplant enterprise, however, emerged as focal points of the hearings. As bioethicist Roger Evans testified before members of the House, with the introduction of cyclosporine, "the lack of two vital resources[,] money and donor organs," was "likely to limit the number of persons who w[ould] benefit from organ transplantation."[194] Also missing was the organizational infrastructure needed to coordinate organ transfer efficiently, lest the organs and dollars that were available be wasted.[195] Where the organs and dollars would come from, and how to organize the sharing of organs and information, were at the heart of the matter. Concerns about differential access to

189. Elizabeth Wehr, *Dying Children Prompt Legislation: National Health Policy Sought for Organ Transplant Surgery*, CONG. Q. WKLY., Feb. 25, 1984, at 453.

190. *Id.*

191. *Id.*

192. *Science and Technology Hearing*, *supra* note 170, at 338 (statement of Barry Brenner, M.D., Harvard University Medical School, Brigham and Women's Hospital).

193. *Energy and Commerce Hearing*, *supra* note 147, at 120 (statement of Rep. Albert Gore, Jr.).

194. *Id.* at 56 (statement of Roger W. Evans, Research Scientist, Health and Population Study Center, Battelle Human Affairs Research Centers).

195. In a statement to the Senate Committee on Labor and Human Resources, North Carolina Governor James Hunt elaborated a similar tripartite analysis, identifying "three very serious obstacles" to liver transfer: the absence of a "reliable system for rapid, standby transportation" of organs and recipients, the spottiness of insurance coverage, and the lack of a "national computer network" to match organs with recipients. *Human Resources Hearing*, *supra* note 185, at 247.

transplant surgery and distributive justice also surfaced repeatedly as legislators probed the problems of procurement, financing, and organization.

B. Organs

Because solid organs are part and parcel to the human body (unlike dialysis machines) and non-renewable (unlike blood), the means of procuring organs presented a conundrum, as did the problem of choosing a method of allocation. Given the unprecedented nature of this problem and the Cold War political climate, public discussion of the options turned less on empirical data than on notions of what kind of system was most consistent with "American" values. For Barry Jacobs, laissez-faire market exchange was the American way of allocating goods, and rules prohibiting market alienation were tantamount to state ownership. In a *USA Today* guest column, Jacobs wrote that "[c]ompensating the donor for blood or a kidney is the American way. . . . When it comes to deciding what to do with our bodies, Congress is not a better judge than the individual. . . . Only in the Soviet Union do human organs belong to the State."[196] Others relied on notions of equality or dessert. "Any millionaire with cirrhosis of the liver will gladly pay a half million dollars," stated one opponent of organ sales. "That's not considered to be the American way."[197]

Opponents of this approach pointed to the geopolitical significance of the American way of obtaining and allocating organs. A Red Cross official who previously headed the American Association of Tissue Banks called the commercialization of organ procurement "immensely damaging."[198] It threatened not only the status and reputation of transplant professionals, but also America's image in the world. As bioethicist Samuel Gorovitz asserted:

> At a time when we urgently need to nurture good relations with the nations of the third world, our international credibility would be dealt a severe blow by our tolerance of a plan according to which the poor in underdeveloped countries were exploited as a source of spare parts for rich Americans. Our antagonists behind the iron curtain would love such a public relations windfall—and they would be right.[199]

On a purely descriptive level, opponents of commercialization correctly

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196. H. Barry Jacobs, Guest Column, *Let Consenting Adults Sell Their Kidneys*, USA TODAY, Sept. 27, 1983, at 8A.

197. Engel, *supra* note 169 (quoting Dr. Harold Meryman).

198. *Id.*

199. *Energy and Commerce Hearing*, *supra* note 147, at 282 (statement of Samuel Gorovitz, Department of Philosophy, University of Maryland, College Park). *See also* Nicholas Wade, *The Crisis in Human Spare Parts*, N.Y. TIMES, Oct. 4, 1983, at A26 (noting that some critics claimed the Jacobs plan incorporated "the worst features of . . . colonialism").

understood that *some* Americans clearly were donating organs altruistically. In the hearings, speaker after speaker emphasized that introducing payment could undermine the existing system before its full potential was realized. "The realization of profit from the retrieval and sharing of donated organs and tissues," Keith Johnson of the Association of Independent Organ Procurement Agencies testified, "could very rapidly turn off public acceptance of the concept of organ donation."[200] In contrast, although for-profit firms were volunteering corporate jets and beepers in service of transplantation,[201] there was little precedent for commercialized organ procurement. References to Richard Titmuss's research on paid blood donation, with its attendant health risks, presented words of caution.[202] Thus, anyone seeking to supplement or substitute a new mode of organ procurement for organized voluntarism would have faced an uphill battle since hopes and careers were thoroughly invested in a strategy based on public confidence and altruistic donation.

Jacobs's business plan was sufficiently unusual and sufficiently advanced that it demanded attention in the hearings. However, the focus on this hasty scheme and the man himself—who was prone to jarring and offensive comments as a witness[203]—may have distracted policy makers from their erstwhile emphasis on broad questions of system design. Public inquiry into the facts of organ procurement and allocation was motivated by the potential for abuses and improprieties in these processes. Robin Cook's 1977 fiction bestseller *Coma*, adapted to film by Michael Crichton, had publicly linked this potential for abuse to organ sales; this speculative literary insight was duly noted in congressional testimony.[204]

Yet, "[s]cenarios contemplating the instrumentalization" of human organs frequently raise moral and existential questions about coercion, exploitation,

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200. *Energy and Commerce Hearing*, *supra* note 147, at 224 (statement of Keith Johnson, President, Association of Independent Organ Procurement Agencies).

201. *See Ways and Means Hearing*, *supra* note 186, at 39.

202. *See, e.g.*, *Science and Technology Hearing*, *supra* note 170, at 345 (statement of Robert M. Veatch, Ph.D., Professor of Medical Ethics, Georgetown University Kennedy Institute of Ethics). The outbreak of the AIDS epidemic heightened this concern. *See id.* at 355 (statement of Arthur L. Caplan, Associate for the Humanities, Hastings Center) ("Plasmapheresis centers, the major purchasers of blood in this country today, are now enormously and . . . publicly concerned about the incentive payment gives to donors to conceal facts about their sexual practices, practices which may be implicated in the transmission of various viral diseases through blood transfusion.").

203. For example, Jacobs, prompted by Representative Gore, toyed with the idea of taking a Boeing 747 airplane and "fill[ing] it full of Bangladesh [sic] people," presumably to serve as living donors. *Id.* at 297-98.

204. *See Energy and Commerce Hearing*, *supra* note 147, at 288 (statement of Bernard Towers, Co-Director, UCLA Program in Medicine, Law, and Human Values; and Robert B. Ettenger, President, American Society of Transplant Physicians).

justice, risk, and trauma in the absence of any quid pro quo payment for organs.[205] Jacobs represented transplantation out of control, and anxieties about the misuse of medical power latched onto him, his business plan, and the entire notion of putting a monetary value on organs.[206] A 1983 law review comment called for "[a]dditional legislative guidelines" constructing a market for human organs, arguing that because this commerce would raise "issues not involved in the transfer of ordinary fungible goods, some specific standards . . . must be defined."[207] Non-market approaches to organ allocation, of course, provoked much the same sentiment. Ironically, one aspect of Jacobs's congressional testimony that triggered intense opposition was his insistence that all living kidney donors, whether paid or not, should be required to pass a psychiatric examination. "Do I have to make what I consider a humanitarian decision, then defend that before a psychiatrist or psychologist?" asked one Congressman.[208]

Since the start of the hearings, donor awareness (of transplantation) and medical professionals' awareness of donors were on the policy agenda. In October 1983, one journalist spoke of the potential for a "federally led effort to increase life-saving organ transplants by 5,000 or more a year" through mechanisms such as upgrading organ-matching infrastructure.[209] New Mexico Republican Representative Joe Skeen spoke about how his sister had died of a kidney disease as a young adult, and how his niece received a kidney transplant at about the same age. "I know we need a broader effort," he remarked at a news conference with colleagues from across the aisle.[210]

Innovative approaches to organ procurement pressed Americans to identify points where efforts to enlarge the donor pool bumped into other human values. Many were uneasy about what looked like a new form of flesh peddling.[211] Some

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205. Jed Adam Gross, *Gray Not Red: The Hue of Neoconservative Bioethics*, AM. J. BIOETHICS, Oct. 2007, at 24.

206. *See, e.g.*, *Ways and Means Hearing*, *supra* note 186, at 26 (statement of Rep. Henry Waxman) (discussing the prospect of commercialization and asserting that "[h]uman organs should not be treated like fenders in an auto junkyard").

207. David E. Chapman, Comment, *Retailing Human Organs Under the Uniform Commercial Code*, 16 J. MARSHALL L. REV. 393, 408 (1983).

208. *Energy and Commerce Hearing*, *supra* note 147, at 244 (statement of Rep. Howard C. Nielson).

209. Cohn, *supra* note 180.

210. *Id.* (quoting Rep. Skeen).

211. *See, e.g.*, *Energy and Commerce Hearing*, *supra* note 147, at 246 (quoting Rep. Gore asking Barry Jacobs, "could they put up their kidney as a collateral on a loan of some kind?"). Within a few years, a prominent policy-oriented scholar proposed government financing of transplant surgery through a combination of loans and grants. "A share of [the] private benefits [of receiving a transplant]—perhaps calibrated according to an age- or income-related sliding scale—arguably should be returned to the public whose investment made them possible." Schuck, *supra*

were also skeptical that a new, efficient bureaucracy could eliminate the frustrations of the old system of informal, personal contacts without introducing new bases for mistrust. Initially, members of the Senate spoke enthusiastically about the need for "a national registry for those who are waiting for organs and those who are suitable donors" or "an organ procurement and transplantation registry."[212] After receiving input from transplant professionals, however, Representative Gore pointed out that some strongly opposed such a registry, quoting a letter from the American Society of Transplant Physicians that warned that "our experience has been that maintenance of a 'living bank' adds nothing to organ and tissue retrieval, is expensive, and can actually obstruct obtaining organs and tissue if there is a requirement to consult the registry before acting on available donors."[213] Whereas the surgeons were interested in obtaining quick and legally reliable consent to remove organs, would-be donors were likely more concerned about who had access to their medical information (if it could still be called theirs) and for what purposes. Within the House, there was substantial support for a carefully controlled, small-scale trial registry of potential bone marrow donors, which was understood to be a practical necessity for unrelated bone marrow transplantation.[214] Supporters of the trial registry spoke to the importance of "safeguards to protect the confidentiality of those who have agreed to become donors, so that they retain their right to decide in each case whether they still want to donate and so they are protected from unfair coercion."[215] As for a policy of presumed consent for cadaveric organ removal, "the idea [had] no champions in Congress. Americans," observed one journalist, "[had] read enough MAN, DEAD SIX HOURS, SITS UP stories to be squeamish about opening a body while the organs are still fresh."[216] As with marketization proposals, the movement to increase the organ supply through population surveillance ran into different points of resistance, but in the latter case, legislators were able to adapt the approach to these limits.

More generally, once the moral complexities and tensions between competing aims were recognized, legislators could work out compromises while tending to the concerns of affected interest groups. A major zone of negotiation was the interface between organ procurement and allocation, on the one hand, and transplant support services, on the other. After getting wind of the movement to ban payment for organs, the President of the Arizona Kidney Foundation,

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note 138, at 185.

212. 130 CONG. REC. 30,724 (1984) (statements of Sen. Don Nickles and Sen. Mark Andrews).

213. *Id.* at 17,656 (1984).

214. *Id.* at 17,650 (1984) (statement of Rep. Henry Waxman).

215. *See, e.g., id.* at 17,651 (statement of Rep. Albert Gore, Jr.). *See also* Head v. Colloton, 331 N.W.2d 870 (Iowa 1983) (rejecting a public right of access to bone marrow registry information under Iowa's public records statute).

216. Bill Keller, *Gut Issues*, NEW REPUBLIC, Mar. 19, 1984, at 15, 16.

James F. Pfenning, wrote to Arizona Representative John McCain, expressing concern that a tight restriction on the transfer of private funds might hamper ongoing activities that facilitated transplantation or "penalize" organ donors and recipients.[217] "Reimbursement should be allowed for those costs associated with removal, storage and transplant of human organs. In addition, legislation should allow for individual and/or nonprofit organizations to cover reasonable costs of travel, housing, lost wages and other direct or indirect expenses incurred by a living donor and/or recipient."[218] These services, which more or less directly aided patients and transplant programs, would lack economic value in the absence of transplantable organs, hence the difficulty of disentangling payment for the services and payment for organs. Conversely, donated organs would lose much of their use-value to the broader public without these labor-intensive services, hence the impulse toward compensation.

Transplant professionals responded to incentives, including market incentives. Aligning these incentives with the interest of patients and the general public remained a challenge. Barry Jacobs's bold market proposition showed one place that these incentives could lead, but in arguing that the clinical management of organ failure needed an injection of entrepreneurship, he also hinted at what state subsidization could solidify: "The kidney specialists in this country, the nephrologists, control the flow of $2 billion of their private dialysis centers . . . . They have a reason to maintain the status quo."[219] On this point, Gore and Jacobs were unusually of one mind: After hearing testimony that "[t]he transplant list should be three times as large as it is," Gore pressed Dr. Ira Griefer, medical director of the National Kidney Foundation, as to the "troubling" possibility that "people who should be on the transplant list are not being listed because their doctors—in this case, nephrologists—are not that eager to surrender control of their patients to a specialty that will actively consider a transplant strategy as the treatment for those patients."[220] So long as Congress was committed to supporting biomedical dynamism while maintaining a mixed system of voluntary organ donation, a workforce of paid professionals, and limited federal financial support, the impulse to ban organ purchases would have to work itself into rules directing the flow of money, prohibiting self-dealing, and possibly even setting a just price.

C. Dollars

The price of extrarenal transplant surgery in 1983 was high: by one estimate,

217. *Ways and Means Hearing*, *supra* note 186, at 178.

218. *Id.*

219. *Id.* at 250 (statement of Barry Jacobs, M.D., Medical Director, International Kidney Exchange, Ltd.).

220. *Science and Technology Hearing*, *supra* note 170, at 251.

liver transplants cost between $54,600 and $238,000, while heart transplants cost between $37,000 and $110,000.[221] For patients in need of a transplant, these dollars were nearly as vital as organs. As a source of financing, insurance arrangements, sometimes negotiated under intense pressures, were augmented with bake sales, "Shop and Share" days at local supermarkets, and the occasional church spaghetti dinner.[222] In 1983, after the first round of congressional hearings, the NIH conference organized by Surgeon General Koop offered its "qualified statement of support" for liver transplantation.[223] By February 1984, Medicare coverage was theoretically available to pediatric liver patients if they met an arduous set of medical criteria and insurance eligibility requirements, but since this decision did not lead to actual reimbursements, "the basic financing question [remained] largely unresolved."[224] As momentum built for expanding the federal role in organizing and financing extrarenal transplantation, friction would arise in questions about cost, parity in public insurance coverage, and governmental entanglement in the practice of medicine.

In a climate of federal fiscal restraint, reformers, including Gore, tried not to set their sights too high. Gore's approach was "not exactly socialized medicine," noted the *New Republic*—indeed, he was not proposing a new ESRD-like program to support solid organ transplantation.[225] By seeking to support and streamline the loose existing matrix of transplant institutions, while "slightly broaden[ing] the federal insurance coverage of transplant surgery," Gore envisioned a congressional intervention that might win over "policymakers haunted by the memory of the kidney dialysis program, which started small and grew into a $2 billion a year drain on Medicare's troubled trust fund."[226]

As the spectral presence of the ESRD precedent hinted, the problems broached by dialysis and kidney transplantation were not entirely dissimilar to those now arising in the extrarenal fields. To the extent that livers were available—and effectively declared priceless—the fates of sympathetic patients who might get a new lease on life but for want of the full down payment were psychologically gripping, even amid anxieties that expanding the federal health care financing commitments would prove to be budget-busting.[227] In the

221. Mueller, *supra* note 177, at 347.

222. *See Fundraisers to Benefit 3-Year-Old Aurora Girl*, CHI. TRIB., Oct. 14, 1983, at SD14.

223. Rettig, *supra* note 134, at 203.

224. *See id.* at 204 ("[T]he child . . . would have to have worked, contributed to Social Security for a minimum of six quarters, and then lived another two years, unable to work because of his disability.").

225. Keller, *supra* note 216, at 15-17.

226. *Id.* at 17.

227. Public appeals for charitable donations by families of pediatric patients evidently found both private financial support and public political support. *See* Ledford, *supra* note 148; Frank Thorsberg, *Domestic News*, UNITED PRESS INT'L, Apr. 13, 1983 ("Mrs. Hall said she had no way to

extrarenal context, the interaction between disease manifestations and cultural values took a different turn than in the Seattle dialysis committee protocol. As the medical need was simultaneously associated with vulnerable infants and adult alcoholism, the allocation process hinged on collateralizing the steep cost of the therapy. An Illinois legislator testified that two constituents "faced $100,000 liver transplant bills that their insurance companies would not pay," and, she ruefully claimed, they were not "'cute and cuddly' enough for the fund raising campaigns sparked by very young transplant patients."[228] Members of Congress struggled with the ethics of making sure their constituents got a fair try when so many others were similarly situated, but this undertaking was draining, and dogged by a suspicion that devotion to individual patients might be counterproductive social policy.[229] "This is not the job of politicians," insisted Arkansas Senator Dale Bumpers.[230]

Congressional reformers contemplated two strategies for rationalizing and potentially expanding coverage and access to extrarenal transplantation. The first was to grant Medicare, which made coverage determinations for medical procedures on an "all-or-nothing" basis, the authority to designate certain provider institutions—and perhaps specific health conditions—as eligible for reimbursement of "transplants [and] other sophisticated procedures."[231] Several considerations argued for a conditional or incremental approach. Treatment options, technical capabilities, and risk did vary by center within a system that tolerated and encouraged surgical innovation on the individual and institutional level.[232] At the same time, selective coverage was responsive to concerns that government subsidization would induce a proliferation of "glamorous, high-tech medicine" regardless of financial wisdom or patient safety.[233] The "centers of excellence" approach gave a new twist to the liminal concept of an experimental procedure invoked by insurers: Costs could be controlled by curbing inappropriate utilization.

The American Society of Transplant Surgeons, which represented a broad

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finance the complex operation until a small religious radio station in her hometown began a campaign that raised $80,000.").

228. Wehr, *supra* note 189.

229. Elizabeth Wehr, *System Manipulated to Get Transplants for Kids*, CONG. Q. WKLY., Feb. 25, 1984, at 455. *See also* 130 CONG. REC. 29,980 (1984) (statement of Sen. Orrin Hatch).

230. Wehr, *supra* note 229.

231. *Compromise Organ Transplant Bill Passed*, 1984 CONG. Q. ALMANAC 476, 477.

232. To cite an extreme example that occurred after the NOTA debate, pharmaceutical company Fujisawa's immunosuppressant drug FK-506 was initially available for clinical use only at the University of Pittsburgh, which was actively involved in the drug's development from the basic research stage and eventually obtained FDA permission for human trials. *See* WERTH, *supra* note 81, at 52-53.

233. *See* Keller, *supra* note 216, at 17.

cross-section of transplant surgeons, endorsed this strategy. Oscar Salvatierra, the Stanford transplant suregon who was president of the society, explained its publicly minded logic: "We are very optimistic, at this time, that our success with organ transplantation at relatively few centers can be expanded to more centers. However, we are mindful of the need for planned and managed expansion that makes the most of economies of scale and enhances quality. . . . We perceive this to be . . . without the risk of excessive cost that would be incurred by [an ESRD-like] program . . . ."[234] Lurking within the designation system was the implicit threat of high-stakes, government-promoted competition based on price as well as quality. In the short run, however, it did not take a brain surgeon to get a sense of whose finances and prestige were most likely to be strengthened by government certification. Chairman Waxman, whose district included Beverly Hills, introduced one panel of witnesses as "a virtual Who's Who in the field of organ transplantation. We have four of California's, if not the Nation's, most prominent and experienced authorities in this emerging area of medicine."[235]

Whereas established centers and elite surgeons were poised to accrue the financial and reputational gains of a center of excellence designation, the conceivable burdens of increased federal involvement in the medical market threatened physicians generally. The American Medical Association (AMA), which represented these diffuse and diverse practitioners, stridently expressed its opposition to federal certification.[236] Dr. James E. Davis, speaking for the AMA, vividly described the extended implications of shifting control of professional standards to political actors: "It would authorize the 'cookbook' approach to medical practice, with chapter and verse written by the secretary of HHS."[237] By speaking to the continuous refinement of medical technologies and practices, the AMA offered an antidote to claims—perhaps exaggerated—that high-tech surgery introduced unprecedented moral and political problems, necessitating a radical break with conventional financing and technology policy. The AMA warned that had such a policy been in place, "the existing widespread benefits of the CAT scanner might not be available today and its cost effective diagnostic benefits might have been denied to patients across the country."[238]

Although the centers-of-excellence strategy would have increased the power and fiscal discretion of the Executive Branch, the Reagan Administration resisted

234. *Energy and Commerce Hearing*, *supra* note 147, at 195 (statement of Oscar K. Salvatierra, M.D., President, American Society of Transplant Surgeons).

235. *Id.* at 301 (statement of Rep. Henry Waxman).

236. *See* J.K. Iglehart, *The Politics of Transplantation,* 310 NEW ENG. J. MED. 864, 868 (1984).

237. *Id.*

238. *Ways and Means Hearing*, *supra* note 186, at 114 (statement of James E. Davis, M.D., American Medical Association).

this opportunity for aggrandizement.[239] Carolyne K. Davis of HCFA expressed a general concern about undertaking a major policy shift when Medicare's hospital fund was in a precarious state.[240] Assistant Secretary of Health Edward N. Brandt expressed principled opposition on much the same grounds as the AMA; his own views were bolstered by "the volume of . . . correspondence" on the certification issue.[241]

Of course, government was not only regulating access to organ transplants but also subsidizing them. Private insurers that looked to Medicare for signals about the appropriateness of reimbursements also provided feedback about federal policies. "The Health Insurance Association of America . . . and the Blue Cross-Blue Shield Association . . . both adopted positions that favor[ed] the limitation of sites for organ transplantation . . . ."[242] Without sufficiently stringent means of monitoring and regulating how tax dollars would be spent, the case for federal financing remained enveloped in the hazy dread of bottomless outlays.

Alternatively, state agencies, which were already pressured to finance extrarenal transplants in high-profile cases, might take on this challenge systematically, setting consistent financing policies. One option, proposed by Gore, was to "[r]equire state Medicaid programs to adopt written policies" with respect to transplant coverage;[243] those that failed to do so would be compelled to follow Medicare's policies.[244] This measure had the virtues (and vices) of transparency and consistency. In the glare surrounding coverage decisions, the measure was also aligned with the ambitions of those advocating increased insurance coverage of extrarenal transplants. At the state level, where transplant financing was evidently spotty, agitation for greater support brought transplant financing into direct competition with other social priorities. Michigan's Director of Social Services, Dr. Agnes Mansour, was disinclined to disperse funds for $200,000 liver transplants "until the hard-pressed state restore[d] its many recent cuts in welfare payments."[245] Whether Congress could or should attempt to tilt this balance was an open but complex question.

A related financial dilemma confronting policymakers was whether the federal government should reimburse the cost of immunosuppressive drugs, "break[ing] with Medicare's policy of not funding drugs for outpatients."[246]

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239. *See* Iglehart, *supra* note 236, at 867.

240. *Id.*

241. *Ways and Means Hearing*, *supra* note 186, at 41 (statement of Edward N. Brandt, Jr., M.D., Assistant Secretary for Health, Department of Health and Human Services).

242. Iglehart, *supra* note 236, at 868.

243. Wehr, *supra* note 189.

244. *See Ways and Means Hearing, supra* note 186, at 73 (statement of Carolyne K. Davis, Ph.D., Administrator, Health Care Financing Administration).

245. Wehr, *supra* note 189.

246. Elizabeth Wehr, *House Panel OKs Transplant Measure*, CONG. Q. WKLY., March 10,

Immunosuppression improved transplant outcomes, and—so long as the vast majority of transplant recipients were kidney patients eligible for the ESRD program—the increased volume of clinically successful transplants would save the public fisc. Testimony from the Executive Branch confirmed that, against the baseline Medicare outlay of $2 billion to provide dialysis for 70,000 patients in 1982,[247] renal transplantation represented a net reduction in entitlement expenditures. Although the initial cost of a kidney transplant was about $30,000,[248] Dr. Oscar Salvatierra, President of the American Society of Transplant Surgeons, estimated that 10,000 kidney transplants would save $500 million over four years.[249] The anticipated cost savings did not merely reflect the difference between the cost of immunosuppression and the cost of maintaining dialysis patients' health; research indicated that only 39% of kidney transplant recipients collected income support from the federal government, as compared to 60% of the dialysis patients.[250]

In the context of an ESRD program that would become increasingly oriented toward transplantation, reimbursing the costs of surgery but not the $5000 annual bill for cyclosporine had troubling social implications. Such a policy would provide for the welfare of the financially secure, but the remaining financial requirement might effectively screen low-income patients off the transplant list. Alternatively, low-income patients might get on the transplant list only to experience the ravages of histological rejection because of inadequate follow-up. Gore cited a Congressional Budget Office study finding that a program reimbursing cyclosporine for three years post-transplant would yield net savings, "because it cuts way down on rehospitalization and repeat procedures."[251] Repeat procedures, of course, presented a different spectre—not the waste of dollars, but the waste of scarce organs. The personal and fiscal impact of reimbursement policies for cost-saving technological innovations had already been demonstrated by "the ESRD program's . . . policy of reimbursing for center-based therapy, . . . but not for the cheaper but no less effective home dialysis," which was rectified in 1978.[252] As transplantation became a therapy of choice, reimbursing outpatient immunosupression seemed to be the next logical step. Less optimistically

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1984, at 564.

247. *See Ways and Means Hearing*, *supra* note 186, at 84 (Rep. Charles B. Rangel).

248. *Energy and Commerce Hearing*, *supra* note 147, at 60 (statement of Roger W. Evans, Research Scientist, Health and Population Study Center, Battelle Human Affairs Research Centers); *id.* at 74-75 (estimating cost of kidney transplant at $25,000 and $35,000).

249. *Id.* at 28 (statement of Oscar K. Salvatierra, M.D., President, American Society of Transplant Surgeons).

250. *Id.* at 66 (statement of Roger W. Evans, Research Scientist, Health and Population Study Center, Battelle Human Affairs Research Centers).

251. *Ways and Means Hearing*, *supra* note 186, at 35 (statement of Rep. Albert Gore, Jr.).

252. Schuck, *supra* note 138, at 185 n.48.

officials at HHS's Health Care Financing Authority (HCFA), responsible for administering Medicare and Medicaid, and spokespeople at the Health Insurance Association of America warned of the burgeoning potential cost of financing cyclosporine therapy for extrarenal transplants. Although transplant surgeon Folkert O. Belzer conjectured that extrarenal transplantation would be appropriate for a relatively modest number of patients over the next five years,[253] HCFA administrator Carolyne K. Davis projected the total cost of the proposed cyclosporine coverage to reach $80 million in the 1989 fiscal year.[254]

Regardless of the exact cost, the prominence of kidney transplants in examinations of immunosuppression was striking against a backdrop of concern about extrarenal transplants, partly triggered by the impact of cyclosporine on these therapies. While kidney operations were expected to remain a staple of transplant medicine (and hence drive the need for immunosuppression), discursive shifts and elisions between renal and extrarenal transplantation may have reflected a strategic manipulation of the public analysis.[255] The proposed Medicare outpatient immunosuppression program "was recommended to the [Energy and Commerce C]ommittee by Representative Douglas Walgren, a Democrat whose constituency include[d] the University of Pittsburgh," the nucleus of liver transplantation in America.[256] Nonetheless, since the expanding range of transplantable organs implicated many common technical, economic, and moral issues, there was a principled basis for contriving to build support for comprehensive policies.

Comprehensiveness, however, would prove to be a relative concept. Congressional resistance to reimbursing immunosuppression ultimately stemmed less from the costs or risks associated with cyclosporine than from the broad challenges posed by venturing into outpatient drug reimbursement. On the Senate floor, Indiana Senator Dan Quayle "objected to the creation of a disease-specific program because he could not justify 'singling out immunosuppressive drugs when there are other expensive drugs needed by many individuals with life-threatening illness.'"[257] Even if the decision could be justified philosophically, it might stimulate further demands on the budget as other interest groups demanded no less. Representative Henson Moore of Louisiana asserted that "lobbyists for the elderly" were seeking funding for a different list of "lifesaving drugs" on an

253. *Energy and Commerce Hearing*, *supra* note 147, at 42 (statement of Folkert O. Belzer, M.D.) (conjecturing that 4,000 patients per year might receive liver transplants in 1988, and that the number of medically appropriate heart transplants would not be "astronomical").

254. Wehr, *supra* note 189.

255. *See Energy and Commerce Hearing*, *supra* note 147, at 41 (statement of Folkert O. Belzer, M.D.).

256. Iglehart, *supra* note 236, at 866.

257. Blumstein, *supra* note 10, at 6 n.1 (quoting Quayle in 134 CONG. REC. 15,088 (1988)).

outpatient basis.[258] Viewed in this light, the problem was the same as that confronting state-level agencies: deciding where transplant-related expenditures should fit within an overarching fiscal framework.

When Gore's subcommittee first turned its oversight powers toward transplantation, existing federal arrangements for financing transplants were flush with ironies. Because the Medicare ESRD program entitled kidney patients to full Medicare coverage (and not just reimbursement for dialysis and renal transplantation), patients with end stage renal disease were eligible for Medicare-financed heart transplants on the basis of their kidney disease. Patients who *merely* experienced heart failure, on the other hand, were not categorically eligible for heart transplants.[259] Further, public insurance programs, such as the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), which provided health care to civilian family members of military personnel, were not forthcoming with funds for liver transplantation "on the grounds that the procedure was still experimental."[260] The irony here was that highly experimental transplant surgery had received at least some funding as scientific research; patients were turning to ordinary health insurance as the procedure was moving beyond the experimental stage and into a new coverage gap.[261] Finally, institutions dedicated to the serving the public often pursued these ends by seeking to capitalize on other parties' resources. The Battelle and NIH studies, for example, were prospective evaluations for the purpose of Medicare coverage eligibility, but they were also "retrospective review[s]" of completed surgeries that had received funding from somewhere.[262] A starker example of resourcefulness by an institution that was itself expected to be a resource could be seen in what one legislator would decry as the "bizarre spectacle of the Defense Department providing public relations guidance to mount public fundraising drives for the children of . . . military personnel [in] need [of transplants]."[263] The ultimate irony of transplant provisioning was that Congress picked up the same soft tools favored by the White House, using its political clout and cultural status to spotlight the need for organs and to pressure insurance programs to cover extrarenal transplants. A further similarity lies in the envisioned center certification apparatus, which was frequently compared to governmental policies toward clinical research and the experimental use of drugs

258. Wehr, *supra* note 246.

259. *See* Rettig, *supra* note 134, at 198.

260. *Id.* at 199.

261. *See* TASK FORCE ON ORGAN TRANSPLANTATION, *supra* note 128, at 109-10.

262. *Id.* at 108-09 (noting that rapid technological change could "render [exhaustive evaluations] essentially moot").

263. *Science and Technology Hearing*, *supra* note 170, at 498 (statement of Rep. Albert Gore, Jr.).

and devices.[264] Congress's engagement with transplant financing differed from the Executive Branch's in one important respect, though. While the Administration induced reimbursements for select individual cases while maintaining restrictive federal reimbursement guidelines, congressional action pressured payors—including federal programs—to make coverage available on a policy level.[265]

The relationship between the focal point of these proposals—the need for organs—and the corresponding need for financial resources was complex. For extrarenal transplantation, so long as organs remained scarce, this constraint on surgical volume kept costs in check and kept the need for organs in the spotlight. But if the public could be persuaded to donate more cadaveric livers (which had few uses aside from transplantation), would health care budget outlays (which were more fungible) simply become the next highly visible tragic choice?[266] Although directly converting dollars into organs was taboo, constraints on the availability of either of these resources could bottleneck organ transfer, increasing the practical and symbolic importance of each relatively scarce input. Congressional examination of another set of relationships—those between American transplant institutions and patients from abroad—shed light on the roles of different *sources* of funding, and the values attaching to them.

Gore's oversight committee, not surprisingly, found that individual transplant centers took radically different stances on extending access to non-resident aliens. In a professional society's survey, seventy of the eighty-two responding transplant centers reported giving some "priority" to U.S. citizens; Louisiana State University at Shreveport refused to accept nonresident aliens as a matter of policy.[267] In contrast, fifteen of Washington Hospital Center's thirty-five transplants had gone to nonimmigrant aliens so far in 1983—and all the nonimmigrant aliens were from Saudi Arabia.[268] Also not surprisingly, referral patterns and agreements often originated in personal contacts. Dr. George E. Schreiner, director of nephrology at Georgetown, recalled how a pioneering Greek nephrologist held a fellowship at Georgetown, and while Schreiner was

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264. *See, e.g.*, Wehr, *supra* note 246.

265. *See* Mueller, *supra* note 177, at 347 ("The means of getting Congressional attention was quite common; the difference with Gore was that he was in a position to push for general legislation, not merely to resolve a single case.").

266. *See* Henry Hansmann, *The Ethics and Economics of Markets for Human Organs*, *in* BLUMSTEIN & SLOAN, *supra* note 8, at 57-85.

267. *Science and Technology Hearing*, *supra* note 170, at 71 (statement of Nicholas J. Feduska, M.D., Chairman, American Society of Transplant Surgeons Committee on Organ Sharing and Preservation); *Id.* at 83 (statement of John C. McDonald, President, South-Eastern Organ Procurement Foundation).

268. *Id.* at 201 (statement of Jimmy Light, M.D., Director, Organ Procurement and Transplantation, Washington Hospital Center).

president of the International Society of Nephrology, it convened in Athens. When the Greek Ministry of Health approached Schreiner's program, Georgetown reached an agreement to treat suitable kidney transplant candidates sent (and apparently funded) by the Greek government. These patients, who were "not given any preferences and [might] wait a very long time," especially if they had type O blood, were hosted by local Greek Orthodox Churches.[269] Greek-American community organizations were also viewed as a potential source of donor organs.[270]

The relationship between citizenship and participation in America's transplant system may have been empirically complex, but it was susceptible to analysis and organization according to rational principles. In 1983, Georgetown professor of bioethics Warren Reich submitted testimony on the moral implications of allocating organs as "citizens of a global community." In his accompanying oral remarks, Reich distinguished between the ethical issues posed by "the financially capable alien, whom I will call the wealthy alien," and those posed by "the poor alien" or "the destitute alien."[271] The former group of patients needed surgery and had the wherewithal to pay for it; the latter group needed financial support to gain access to surgery. The ability of wealthy patients—whether aliens or U.S. residents—to finance their own transplants exposed the tension between notions of egalitarian access and notions of financial self-sufficiency. Treating patients eligible for Medicare ESRD coverage alongside patients whose kidney transplants could be financed out-of-pocket or by foreign governments implicated a set of tradeoffs governing the movement of dollars and organs. Because Medicare was a large and reliable payer, kidney transplant centers had an incentive to accept Medicare's partial reimbursements of surgical fees as payment in full. But if a center did this, then the center could collect higher payments from patients outside the ESRD program, creating an incentive to shift organs toward these patients.[272] These financially-independent patients, however, did not truly constitute a self-sustaining pool, because they depended on the general population for cadaveric donor organs, just as ESRD program beneficiaries did.

From a financing standpoint, dollars represented *contribution*, but so long as financial contributions were crucial, dollars also represented allocational *control*. A "differential fee structure" could be defended in terms of contributory fairness:

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269. *Id.* at 213 (statement of George E. Schreiner, M.D., Director, Nephrology Division, Georgetown University Hospital).

270. *Id.* at 65-66 (statement of Warren T. Reich, Director, Division of Health and the Humanities, Georgetown University).

271. *Id.* at 26, 29 (statement of Warren T. Reich, Director, Division of Health and the Humanities, Georgetown University).

272. *See id.* at 202 (providing a discussion of reimbursement policies).

compared to permanent U.S. residents, non-residents did not make the same "contribut[ion] through the payment of taxes or in other ways to the costs of research and development that made it possible for U.S. institutions to develop [transplant] technology."[273] The financial risk to transplant programs was delinquent debt and the "abuse of ESRD funds."[274] From an allocational standpoint, however, "[t]his argument would seem to suggest that surgeons may, without authorization, collect funds on behalf of the republic and then perhaps appropriate" these funds according to their own prerogatives.[275] Increased organ procurement would help solve this issue by making organs less dear in America and abroad;[276] increasing Medicare reimbursement rates would tilt the incentive structure in favor of American patients at the expense of American taxpayers. One proposed structural reform that would have an immediate impact—using "profits" from transplants to "foreign nationals who are able to pay" surgical expenses to finance organ procurement activities for the benefit of "poor foreign nationals"—revealed the extent to which the expenditure of money was integrated into the moral and political economy of organ procurement in spite of the International Kidney Exchange uproar.[277]

D. Coordination

The White House's charismatic, individualized involvement in transplant awareness and financing suited a "presidency dedicated to revitalizing the sacrificial center of American society."[278] In civic rhetoric, such as speeches acknowledging the destruction of the space shuttle Challenger or commemorating the Allied taking of Normandy, Reagan mythologized America

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273. *Id.* at 27 (statement of Warren T. Reich, Director, Division of Health and the Humanities, Georgetown University).

274. *Id.* at 99 (statement of Paul I. Terasaki, Director, Southern California Regional Organ Procurement Agency).

275. *Id.* at 27 (statement of Warren T. Reich, Director, Division of Health and the Humanities, Georgetown University).

276. *See, e.g.*, *id.* at 99 (statement of Paul I. Terasaki, Director, Southern California Regional Organ Procurement Agency) (noting that after kidneys were shipped from the U.S. to Japan, "cadaver donor donations from the Japanese population . . . increased [by] 100%").

277. *Id.* at 54 (statement of Warren T. Reich, Director, Division of Health and the Humanities, Georgetown University) (emphasis omitted). *See also id.* at 306 (statement of George J. Annas, Professor of Public Health, Boston University) (cautioning that banning the sale of organs under the Constitution's interstate commerce clause "seems to concede . . . that organs can properly be viewed as commercial commodities").

278. David Chidester, *Saving the Children by Killing Them: Redemptive Sacrifice in the Ideologies of Jim Jones and Ronald Reagan*, 1 RELIGION & AM. CULTURE 177, 179 (1991).

as a "giant country prepared to make so many sacrifices."[279] Attributing redemptive power to the ultimate "sacrifice of the body, the physical, or the material," Reagan celebrated the quotidian generosity of "voluntary gifts" when organ transplantation was offering grieving families new ways to experience the meaning of giving.[280] "'Do this one for the Gipper,' [Reagan] told Air Force officials when they resisted his plea to transport a boy to Tennessee for liver surgery."[281]

No matter how bracing such moments were, Normandy had been an operation that fit a broader war plan, whereas White House aide Michael Batten candidly acknowledged with respect to transplantation, "'[w]e're looking at events in search of a policy.'"[282] A fundamental difference between the Administration and reformers was over precisely how to characterize this policy vacuum. Dr. Brandt of HHS and Dr. Davis of HCFA emphasized the complexity of coordinating organ procurement, the value of ongoing study to identify best practices, and the importance of "utiliz[ing] the most recent information."[283] Gore relentlessly barraged the Administration officials with accusations of paralysis by analysis: "You have had studies; you have had recommendations on how to deal with transplants . . . . Are you studying [a previous] study? . . . [W]hen [the most recent] study is completed, you would be reluctant to act on it, because the most relevant one would then be the one you started next . . . . [Y]our whole approach has been to wait and wait and drag your feet and hope that the problem will solve itself."[284]

One theme running through the hearings, made more powerful because it was readily explicable by market and public policy dynamics, was the private sector's lack of initiative in procuring and sharing organs other than kidneys. As extrarenal transplants that involved these other organs became more effective from a therapeutic standpoint, patients pressured federal, state, and private insurers to cover extrarenal transplantation. But federal support for an organ sharing infrastructure remained focused on kidney allocation.[285] Transplant centers themselves, which had initiated kidney sharing arrangements, were stuck

279. *Id.* at 186, (citing Reagan's 1981 commencement address at the University of Notre Dame, in which Reagan quotes Australian Prime Minister John Gorton's characterization of the United States. RONALD REAGAN, THE QUEST FOR PEACE, THE CAUSE OF FREEDOM: SELECTED SPEECHES ON THE UNITED STATES AND THE WORLD 45 (1988)).

280. *Id.* at 184.

281. Keller, *supra* note 216, at 17.

282. Eugene L. Meyer, *Tax Money for Transplant Operations: Who Pays?*, WASH. POST, Sept. 12, 1984, at C1 (quoting Michael Batton).

283. *Energy and Commerce Hearing*, *supra* note 147, at 183 (statement of Carolyn K. Davis, Ph.D., Administrator, Health Care Financing Administration; and Edward N. Brandt, Jr., M.D., Assistant Secretary for Health, Department of Health and Human Services).

284. *Id.* at 182-83 (statement of Rep. Albert Gore, Jr.).

285. *Id.* at 182 (statements of Rep. Albert Gore, Jr. and Carolyne K. Davis, Ph.D., Administrator, Health Care Financing Administration).

in a Catch-22: Until liver transplantation became both larger in scale and more lucrative, there were few incentives to invest in infrastructure for allocating livers, and this lack on infrastructure hindered liver transplantation. Moreover, the growth of independent organizations dedicated to kidney procurement and allocation activities rendered the direct involvement of transplant centers in these activities institutionally out of place. Pittsburgh surgeon Thomas Starzl insisted that "[t]he procurement agencies cannot be little cottage industries devoted to only the kidney transplant programs. There is only one set of donors for all the needed organs and the organs are a resource of the entire United States. This concept has to be built into the system."[286]

Indeed, the existing system for allocating *kidneys* was in a state of flux, lacking an overarching design and, in the view of close observers, suffering from disorganization. The basic contours of the system were clear: "approximately 140 hospitals operate[d] some aspect of an organ procurement system," and procured organs ultimately made their way to 157 Medicare-recognized transplant centers.[287] By one count, an additional thirty-six independent organ procurement agencies removed kidneys in the hospital setting, participated in computerized kidney matching systems, and preserved and transported the organs. All of these independent agencies, as well as independent tissue typing laboratories, used a single financial intermediary, Aetna Life and Casualty, to process claims.[288] Much as the establishment of independent procurement agencies began to separate procurement activities from hospital organizations, the apparatus of organ matching was increasingly removed from transplant and procurement programs. SEOPF, the regional organ sharing program that originated in arrangements among transplant centers with in-house procurement programs in the southeastern United States, moved in this direction in 1977 when it made its UNOS computer matching system accessible to transplant programs nationwide. The network, which reportedly served 144 transplant centers by the time Congress intervened, was organized into regions including SEOPF itself.[289] Thus, UNOS had evolved into a tool for locating organs, with "some loose guidelines for sharing" built in. UNOS was functionally and geographically distinguishable from SEOPF's regional procurement efforts, despite being operated by SEOPF.[290]

Gaps, redundancies, and bottlenecks within this loose system were obvious. Brandeis University researcher Jeffrey M. Prottas, whose evaluation of organ

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286. *Id.* at 228.

287. *Id.* at 152 (statement of Carolyne K. Davis, Ph.D., Administrator, Health Care Financing Administration).

288. *See id.*

289. *See id.* at 212-13.

290. *Id.* at 213 (statement of Gene Pierce, Executive Director, South-Eastern Organ Procurement Foundation).

procurement activities was cited approvingly by Gore and Waxman,[291] found that "[w]hile some regions [were] underserved [by organ procurement agencies], others [had] several competing agencies."[292] Some of these agencies may have "grown too large to effectively service their catchment areas," while "many . . . [were] too small to do so."[293] As for the sharing of organs among agencies, SEOPF Executive Director Gene Pierce reported in a written statement that although articles of incorporation and bylaws for UNOS were being drafted, "[t]here [were] currently no funds to officially establish . . . UNOS" as a distinct organization.[294] Despite federal support for these services' involvement in kidney allocation, federal officials did not seem to have a grip on how these funds were being utilized. Prottas reported that in 1982, "the Federal Government spent about $40 million on kidney acquisition, yet most organ procurement agencies receive neither direction nor assistance from the funding agency [HCFA]."[295] The hearings gave federal officials an opportunity to gather basic information about the problems of organ sharing from interested professionals in the field. As Congress contemplated authorizing additional funding to enhance procurement activities, representatives of SEOPF pointed out that "[t]he amount of funds appropriated seems excessive in light of the revenue that will be generated from the procurement of organs within the first year."[296] The organization's vice president provided an assessment of how much funding an independent procurement organization would need during its first two years for "capitalization items and operating expenses" to become self-sustaining.[297]

If the memes of waste, lack-of-coordination, and lack-of-public-accountability became a permanent part of the public's conventional wisdom, they could affect donation rates. After the *Los Angeles Times* ran an article titled "Donor Organs Lost through Inefficiency" in 1982, one reader wrote to the editor that she signed an organ donor card "believ[ing] . . . that there was a system in which the donor organ would reach the transplant patient. . . . I am sure glad that my mother, who chose to donate her kidney to aid in the survival of her brother,

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291. *Ways and Means Hearing*, *supra* note 186, at 21 (statement of Rep. Albert Gore, Jr.); *Energy and Commerce Hearing*, *supra* note 147, at 181 (statement of Rep. Henry Waxman).

292. *Energy and Commerce Hearing*, *supra* note 147, at 47 (statement of Jeffrey M. Prottas, M.D., Senior Research Associate, Brandeis University).

293. *Id.*

294. *Id.*

295. *Id.* at 47 (statement of of Jeffrey M. Prottas, M.D., Senior Research Associate, Brandeis University). Gore estimated that the 1983 federal expenditure to finance kidney procurement was "almost $70 million." *Ways and Means Hearing*, *supra* note 186, at 21 (statement of Rep. Albert Gore, Jr.).

296. *Energy and Commerce Hearing*, *supra* note 147, at 216.

297. *Id.* at 209 (statement of Charles Carter, M.D., Vice President, South-Eastern Organ Procurement Foundation).

did so in person or he may have never received it."[298] While the funding of extrarenal transplants by government insurance programs remained controversial, horror stories about the lack of coordination in allocating available livers put pressure on Congress to organize a national, multi-organ network for matching donated organs and recipients, facilitating extrarenal transplantation and perhaps priming it for expansion.[299]

The most visible non-legislative response to these concerns was the American Council on Transplantation (ACT), which developed in response to the recommendations of a Surgeon General's workshop and received start-up funding from HHS.[300] Some members of ACT were appointed by the Administration, and others were chosen by constituent private organizations;[301] orthopedic surgeon Gary Friedlaender, the president of the American Association of Tissue Banks, had been elected interim president of ACT by its membership.[302] The Council's steering committee set out a list of goals "includ[ing] ensuring equitable access to available donated organs; promoting effective use of multiple organ donations; improving donor identification and referral; and motivating the public to donate organs."[303] Almost as soon as the ACT was created, it was riven by internal disagreements. Transplant surgeons "questioned the motives of the administration in pressing the interests of a private organization so hard, wondering whether ACT [was] serving mostly as a stalking-horse to head off legislation."[304] The American Society of Transplant Surgeons (ASTS) would not join ACT, and ASTS president Oscar Salvatierra "resigned from ACT's interim executive committee," citing the appearance of partisanship in its opposition to legislative intervention.[305] Of course, changing prospects for extrarenal transplant financing gave surgeons a monetary interest in ensuring that an industry council would not supplant government involvement in transplant policy.[306]

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298. Laura L. Johnson, Letter to the Editor, *Donor Organ Inefficiency*, L.A. TIMES , Dec. 24, 1982, at B4.

299. *See Energy and Commerce Hearing*, *supra* note 147, at 74.

300. Phil Gunby, *Organ Transplant Group Formed*, 250 JAMA 2103, 2103 (1983); Keller, *supra* note 216, at 17.

301. *See Energy and Commerce Hearing*, *supra* note 147, at 267.

302. *Id.*; Gunby, *supra* note 300, at 2103.

303. Gunby, *supra* note 300, at 2103.

304. Iglehart, *supra* note 236, at 867.

305. *Id.*

306. In October, 1983, four members of Stanford's transplant program wrote a letter to Salvatierra in anticipation of his testimony before the House of Representatives, asserting that "comparable therapeutic results" for kidney and extrarenal transplantation "amply justified" an "evenhanded approach" and specifically calling for "reimbursement . . . on an equal basis." *Energy and Commerce Hearing*, *supra* note 147, at 236 (quoting Letter from Dr. Edward B. Stinson, Professor, Department of Cardiovascular Surgery, Stanford University et al. to Dr. Oscar Salvatierra, President, American Society of Transplant Surgeons (Oct. 13, 1983)).

Nonetheless, disaffection and dissatisfaction with ACT reflected broader policy concerns than surgeons' narrow economic interests or legislators' ambitions to seize the mantle of progress. ACT's industry-council structure and its stated agenda, focusing on operational difficulties, lacked the architectural vision that some reformers felt was sorely needed. Not only was ACT in disarray, but constituencies that were only tangentially related to solid organ transplantation, such as tissue banks, seemed to be holding the center.[307] The Council's leadership sought to pattern ACT after a similar entity, the American Blood Commission,[308] a questionable model at a time when blood banks were stressed—though perhaps not stressed enough—by the social and medical implications of HIV transmission and identification.[309] The interim status of ACT's initial leadership did not project solidity, either: Friedlaender stated forthrightly that he did not desire to "remain at this task full time beyond [ACT's] next meeting."[310] Thus, strategic considerations of policy, and not just tactical calculations, contributed to the prevailing assumption that congressional reformers would be working around the Council, rather than with it.

Elected officials, in contrast, were well-positioned to coordinate health care financing, which did not require the construction of new procurement agencies to raise revenue and allocate funds on the spur of the moment. In a system where many patients traveled out of state for extrarenal transplants, fiscal considerations not only posed a direct challenge for transplant financing; differential reimbursement rates among the states, and the mistrust and resentments they spawned, could trap covered patients in a logistical nightmare, even though transplant centers approved for federal Medicare funding were already required "to accept [state-aided] Medicaid patients."[311] Members of the House sought to align reimbursement policies and procedures with this commitment to therapeutic access by requiring state Medicaid programs that financed transplants to cover them at the Medicare rate. "The purpose of this [initiative was] to avoid unnecessary disputes over reimbursement levels between States and facilities that might compromise the access of Medicaid eligibles to these life-sustaining procedures."[312]

Organizing the sprawling web of institutions involved in the transfer of

307. *See* OFFICE OF TECH. ASSESSMENT, *supra* note 136, at 187 (noting that four organizations representing "the blood banking community" were eligible to submit director nominations for ACT).

308. *Energy and Commerce Hearing*, *supra* note 147, at 259 (statement of Gary E. Friedlaender, M.D., Interim President, American Council of Transplantation).

309. *See* Ann Cooper, *The High-Stakes Race Is On To Develop Blood Test To Detect AIDS Virus*, NAT'L J., Aug. 4, 1984, at 1470-71.

310. *Energy and Commerce Hearing*, *supra* note 147, at 268 (statement of Gary E. Friedlaender, M.D., Interim President, American Council on Transportation).

311. H.R. REP. NO. 98-575, at 20 (1983).

312. *Id.*

human organs was another matter. In the congressional spotlight, egregious instances of poor coordination in the existing system made for easy targets. Gore asserted that in Pittsburgh, "[t]here were 300 livers that could not be used and were disposed of principally because . . . the transplant teams were otherwise occupied when the liver became available, or they were exhausted. . . . [T]here was great difficulty in getting them to the right place in the proper time."[313] Another Congressman alleged, "even though [pediatric liver patient Ashley Bailey] was on the Minneapolis University Hospital priority list, and had two previous mentions by the President of the United States, [she] was not included on one of the main computer donor lists until just about two weeks ago."[314] Some of the testimony emphasized the difficulty any one patient or family would have coordinating the elements necessary for a successful transplant—funding for hospitalization, funding for immunosupression, and the surgery itself. Congressman Dan Glickman suggested a "bill to direct the NIH to establish within a set timeframe at least a Federal information network along the lines of what Congress directed the Justice Department to do with regard to missing children,"[315] reinforcing the sense that organs were being lost.

Astonishment and anger over glaring inefficiencies, as well as broad and potent opposition to the commercialization of organ donation, may have temporarily masked tensions between competing allocational values that were implicit in congressional testimony. Patient organizations, formed around a common medical condition rather than the interests of an economic class, adamantly opposed the sale of organs, which threatened to divide these associations' constituencies. These advocacy groups, however, did not necessarily share a common philosophy of distributive justice. "What happened to *equal opportunity* when the rich can live and the poor must die?" asked Gail Rempell of the American Liver Foundation.[316] David Ogden of the National Kidney Foundation discussed the Foundation's support for a system that distributed organs "based on *medical need* and criteria without discrimination based on race, sex, social, or economic status."[317] Participants in the hearings did not naively believe that allocation based on medical criteria would always result in equal opportunity, but there remained a hope that these two ideals could be reconciled by eliminating waste and addressing collective action problems to increase the supply of organs. Gore observed in reference to the earlier decision

313. *Ways and Means Hearing*, *supra* note 186, at 33 (statement of Rep. Albert Gore, Jr.).

314. *Energy and Commerce Hearing*, *supra* note 147, at 74 (statement of Rep. Charles W. Stenholm).

315. *Id.* at 74-75 (statement of Rep. Dan Glickman).

316. *Ways and Means Hearing*, *supra* note 186, at 119 (statement of Gail Rempell, Board of Directors, American Liver Foundation) (emphasis added).

317. *Energy and Commerce Hearing*, *supra* note 147, at 360 (statement of David A. Ogden, M.D., President, National Kidney Foundation) (emphasis added).

to fund kidney transplants,

> [t]wo things happened to the patient mix once the government became involved in treating end-stage renal disease . . . . First, the availability of care became more equitable. This is demonstrated by a patient mix that more closely parallels the incidence of kidney disease within the general population. Second, doctors abandoned the use of medical practice standards that . . . had been in place prior to government intervention. . . . [P]atients who were once medically deemed unsuitable for this type of treatment were now being treated. [318]

In this way, proponents implied that public support and private resourcefulness might obviate the allocation dilemmas made pressing by the scarcity of donated organs.

The consensus commitment to a system based on voluntary donation pointed toward a certain differentiation of labor within the emerging public-private partnership. Persistent, hortatory activities to persuade the public to donate organs more naturally fell to non-governmental community organizations, while policy questions about the organization and regulation of the private sector fell within government's recognized powers to regulate commerce and protect public health and safety. Organ sharing policies, which reflected judgments about feasibility and fairness, logically fell somewhere between policy-level architectural decisions and procurement strategies in local communities. This mezzanine-level activity of developing a working allocation network also demanded logistical expertise. Dr. Henry Krakauer of the NIH Institute of Allergy and Infectious Diseases observed that SEOPF, the New England Organ Bank, the United Kingdom Transplant Service, and Euro-transplant gave different weight to factors such as "medical urgency" and antigen matching.[319] Describing this lack of "consensus" in technical terms, Kraukauer highlighted the degree of "medical uncertainty about utility"—a concept that is apparently also subject to great moral uncertainty.[320]

While critics may not have agreed—or even formed definite opinions—about how organs should be shared, legislative reformers did see a need for the consistent application of principles. Thus, when immunologist Paul Terasaki described the regionalized approach to organ matching in Southern California, Gore interjected, "You can't tell me that these scientific criteria are useful for purposes of assigning priorities within the region, but they're meaningless when it comes to deciding outside the region."[321] Of course, the optimal geographic

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318. *Ways and Means Hearing*, *supra* note 186, at 25 (statement of Rep. Albert Gore, Jr.).

319. *Science and Technology Hearing*, *supra* note 170, at 101 (statement of Dr. Henry Krakauer, Institute of Allergy and Infectious Diseases, National Institutes of Health).

320. *Id.* at 102.

321. *Id.* at 120 (statement of Rep. Albert Gore, Jr.).

organization of organ sharing was a function of socio-technical factors such as the improvements in match quality that could be gained by enlarging the network and the diffusion of self-reliance and transparency that resulted from the same enlargement. Less certain was whether the existing (and evolving) political economy of organ sharing was facilitating optimization based on these factors.

Questions of public morality pressed hard on officials making policy at the architectural level, and logistical challenges pressed hard on regional organ sharing programs developing allocation networks at the infrastructure level. At the level of direct interaction with potential donors, institutional politics pressed hard on those attempting to organize procurement activities. Transplant professionals, dissatisfied with the White House's ad hoc encouragement of organ donation and transplant financing, also recognized that one-shot policy-level interventions and "national TV exposure" would not substitute for the day-to-day work of cultivating donations from grieving families.[322] "We need people in the grassroots talking to the constituents, if you will, of your areas that can encourage people to donate. It is a people-to-people problem. It is not something that can be handled at upper levels."[323] While there was no substitute for hard work on the personal level, hard work could lead to radically different outcomes, especially if some procurement efforts were working against each other.

Jeffrey Prottas, reporting his findings on progress in organ procurement, emphasized the need to identify and replicate the best organizational structures and practices for obtaining donations. "If the entire Nation were served as well as the most effective [procurement] organizations serve their own regions, the number of available organs would double."[324] Because this seemingly uncontroversial prescription had an organizational dimension, however, institutional politics and localism meant that it would be difficult to put into practice. Not only had the private sector failed to organize itself along efficient lines, but state and national political structures were also organized in a way that only gave voice to local interests. When Representative Waxman asked Prottas how the federal government could "encourage the establishment of stronger local procurement agencies," Prottas responded that attempting to strengthen all of the 110 agencies presently receiving reimbursement for kidney procurement would not necessarily improve the effectiveness and accountability of the system.[325]

The possibility of a governmental role in selecting among agencies or

322. *Energy and Commerce Hearing*, *supra* note 147, at 229 (statement of Charles Carter, M.D., Vice President, South-Eastern Organ Procurement Foundation).

323. *Id.*

324. *Id.* at 46 (statement of of Jeffrey M. Prottas, M.D., Senior Research Associate, Brandeis University).

325. *Id.* at 69 (statements of Rep. Henry Waxman and of Jeffrey M. Prottas, M.D., Senior Research Associate, Brandeis University).

pressuring them to consolidate revisited the issue underlying the centers-of-excellence question that arose in connection with surgical reimbursements, in a slightly different cultural and political context. Dr. Charles R. Baxter, President of the American Association of Tissue Banks, and Ellen Heck, who oversaw the organ procurement program at the University of Texas at Dallas, submitted a prepared statement urging Congress not to "ignore" or "usurp" the existing procurement and standards-setting roles of voluntary organizations. The activities they highlighted ran the gamut from the UNOS kidney matching system to "the ham radio net for eye tissue placement."[326]

Compared with the medical profession or organizations such as the Joint Commission on Accreditation of Healthcare Organizations, traditions of professional autonomy and self-regulation were less established in the field of organ procurement. Dr. Keith Johnson, President of the Association of Independent Organ Procurement Agencies, urged Congress not to "disrupt the existing structure" of the independent agencies by stipulating organizational structures that would minimize providers' involvement in the agencies' procurement policies.[327] Additionally, Johnson argued that procurement efforts by "individuals and organizations whose primary motive is entrepreneurial" were inconsistent with the strategy of procurement by "donation," perhaps alluding to Barry Jacobs's International Kidney Exchange, and perhaps recognizing that fewer people would participate in a purely altruistic donation system if procurement agencies were exploiting their altruistic donations for private gain.[328] On the issue of structural organization, however, Johnson was vague. He stated that bringing organ retrieval expertise to every acute care hospital in the country "may require the establishment of new organ retrieval organizations where none currently exist or the consolidation of ineffective organizations into a single effective one"—without clearly delineating who should carry out this reorganization or how.[329]

Legislatively requiring organ retrieval efforts in sparsely populated areas or demanding the consolidation of existing agencies would have disrupted the civic voluntarism that Johnson assumed to undergird organ retrieval. Setting goals and rules for procurement activities, or authorizing HHS to develop criteria for designating certain procurement organizations for federal financing, could potentially give private sector efforts clearer direction toward the public good.[330]

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326. *Ways and Means Hearing*, *supra* note 186, at 140 (statement of Charles R. Baxter, M.D., President Burn Association; and Ellen Heck, University of Texas Health Science Center at Dallas).

327. *Energy and Commerce Hearing*, *supra* note 147, at 222, 225 (statement of President, Association of Independent Organ Procurement Agencies).

328. *Id.* at 224.

329. *Id.* at 223.

330. *Ways and Means Hearing*, *supra* note 186, at 82 (speculating about whether procurement

Indeed, many of the reformers' goals—improved coordination with other procurement agencies, hospitals, and the distribution apparatus—were horizontal and relational in nature and perhaps less attainable through a unipolar, top-down approach to implementation. Prottas had argued that the "cooperation of medical professionals" in hospitals without a transplant program was vital to increasing organ procurement, and that large procurement agencies that were "operationally independent" of any transplant program were most easily oriented toward this goal.[331] A national strategy, whether developed and implemented by the public or the private sector, would transcend the collective action problems associated with localism. But even a concerted effort to replace the procurement patchwork with a coordinated network of "independent" procurement agencies would not obviate delicate questions of who was accountable to whom for what.[332] These questions intersected with the overarching debate playing out in the Capitol regarding how the federal government should intervene to increase the efficiency and effectiveness of organ transfer. After all, even the private-sector council established by HHS adopted the acronym "ACT."

E. Legislative Process (and Product)

Policymakers committed to reforming the organ transfer system approached the task of drafting legislation with a set of foregone conclusions and a set of unanswered technical and political questions. Members of the 98th Congress (1983-1984) introduced a series of bills reflecting consensus principles that included a crackdown on commercialization, fiscal restraint in insurance coverage, and the use of seed money to expand extrarenal organ procurement. As for the points of uncertainty, legislative proposals frequently relied on two strategies. One, addressing logistical issues, was to empower some kind of national agency or private contractor to effectively manage and coordinate organ *procurement* organizations' activities, much as SEOPF's UNOS system managed organ *sharing* among transplant centers. The other strategy was to convene a task force that would develop organ transfer policies on a temporary or permanent basis by drawing on multidisciplinary expertise. To the extent that these judgments concerned moral or policy decisions, as opposed to complex scientific questions, this legislative delegation to unelected authorities arguably entailed some passing the buck. Nonetheless, elected officials would remain responsible for deciding whether to implement the panel's recommendations, and some

organizations that did not receive federal support would, in the words of Rep. Charles B. Rangel, "go out of business").

331. *Energy and Commerce Hearing*, *supra* note 147, at 48 (statement of Jeffrey M. Prottas, M.D., Senior Research Associate, Brandeis University).

332. *Id.* at 48 ("Organ procurement agencies do not work for their local hospital or surgeon. They work for a national program designed to serve a national need.").

insulation from the ordinary political process could be justified on pragmatic grounds. Further, members of Congress were incessantly tugged by a wide range of social, economic, and military issues, but a task force could devote its material and intellectual resources to one area of policymaking. Both of these strategies bore some resemblance to ACT's approach, but the coordinating body would be responsible for actively managing the network, and the task force would be charged with the broader goal of making *architectural* recommendations in the public interest and structured to represent a broader array of stakeholders. The end result of the legislative process, NOTA, would reflect an amalgamation of decisive and delegatory elements distilled from the contending proposals.

Perhaps the first transplant-related bill introduced in the 98th Congress, before the kidney purchasing schemes provoked outrage, was "[t]o amend the Internal Revenue Code . . . to provide income and estate tax deductions for decedents who donate organs for use as transplants."[333] Representative Philip Crane of Illinois introduced this proposal, H.R. 540, which could be characterized as an incentive or a reward, along with twenty other tax provisions, generally aiming to provide a measure of tax relief.[334] Numerous subsequent bills, of varying degrees of comprehensiveness, were more clearly propelled by arguments that resonated in the hearings.

In August, 1983, a bipartisan group of Senators, including two Democrats from Massachusetts and two Republicans from Pennsylvania, sponsored legislation, S. 1728, that would "provide for the establishment of a National Task Force on Organ Procurement and Transplant Reimbursement."[335] The Task Force would meet for six months to evaluate procurement and allocation efforts, and it would "develop a plan for a permanent body to make recommendations" regarding insurance coverage.[336] Pennsylvania Republican Don Ritter introduced a corresponding bill, H.R. 3977, in the House the following month.[337] During the next two months, October and November of 1983—as the hearings continued—legislators diverged on the scope of federal intervention.

On October 5, 1983, Gore introduced H.R. 4080 as the "National Organ Transplant Act."[338] Title I of this bill authorized grants to organ procurement organizations that met specified "eligibility criteria;" established a SEOPF-like

333. [2 98th Cong.] Cong. Index (CCH) 28,181 (Jan. 6, 1983) (describing H.R. 540, introduced by Rep. Philip Crane). *See also* discussion *infra* Sections III.A & III.B.

334. *Id.* at 28,180.

335. *Id.* at 14,235 (Aug. 2, 1983). As Massachusetts and Pennsylvania were both homes of pioneering transplant programs, public officials in these states may have had an especially acute awareness of the political economy of transplantation.

336. 129 CONG. REC. 29,564 (1983) (statement of Sen. Ted Kennedy, describing S. 1728).

337. [2 98th Cong.] Cong. Index (CCH) 28,374 (Sept. 22, 1983).

338. 129 CONG. REC. 27,395 (1983).

"United States Transplantation Network" that would maintain a registry of transplant candidates and coordinate organ sharing using a "national computer system;" and created a "National Center for Organ Transplantation . . . within [HHS] to administer" the grant program, oversee the organ sharing network, and promote organ donation.[339] In congressional testimony, Gore had previously called for a "National Center for Human Organ Acquisition;"[340] this more "acquisitive" approach was evidently softened as his initial proposal developed into a comprehensive bill with cosponsors. Title II contained a number of measures designed to facilitate the financing of transplantation. It exempted procurement activities from Medicare's diagnosis-based cost containment strategy, required state Medicaid programs to develop reimbursement policies and to work with transplant centers designated by the Federal Medicare program, and required transplant programs to accept Medicaid patients. Title III criminalized the purchase of human organs.[341] Officials representing procurement organizations and SEOPF, surgeons including professional leader Oscar Salvatierra, and social scientists Jeffrey Prottas and Roger Evans collaborated with Gore and his aide Jerold Mande in putting together legislation.[342]

Later that month, Republican Representative David Daniel Marriott of Utah introduced a fiscally modest alternative, H.R. 4180, authorizing the establishment of patient registry and a "Task Force of Organ Procurement and Transplantation."[343] In contrast to the designation of the original task force proposal, this one contained no express reference to reimbursement or financing. Meanwhile, a bipartisan cadre of four Senators including Sen. Kennedy of Massachusetts and Sen. Heinz of Pennsylvania supplemented the previous Senate task force proposal with S. 2018, which Heinz described as "the Senate version" of Gore's bill.[344] Heinz asserted his belief that the bill would provide vital support to the private sector without "unnecessary regulation" or ballooning federal expenditures, citing the strong endorsement of transplant surgeons, including Thomas Starzl, from his home state.[345] A few days later, on November 3, 1983, five Republican Senators introduced S. 2048, which paralleled Marriott's House bill, "provid[ing] for the establishment of a Task Force on Organ Procurement and Transplantation and an Organ Procurement and

339. *Id.* at 27,394-95.

340. *Energy and Commerce Hearing*, *supra* note 147, at 9.

341. 129 CONG. REC. 27,395-97 (1983) (providing a summary of bill).

342. Mueller, *supra* note 177, at 351; Dena Bunis, *Lions Club Thwarted Tissue Safety Standards*, ORANGE COUNTY REG., Apr. 19, 2000, at A10; Marianne Costantinou, *Miracle Workers*, S.F. CHRON., June 1, 2003, (Magazine), at 12.

343. [2 98th Cong.] Congressional Index (CCH) 28,386 (Oct. 20, 1983).

344. 129 CONG. REC. 29,565 (1983).

345. *Id.*

Transplantation Registry."[346] Although inattentive to questions of "resource allocations," this bill did stretch further than Kennedy's original Task Force proposal, S. 1728, in a few respects: It "add[ed] provisions for the establishment of a transplant registry, assistance for organ procurement activities and a prohibition on organ purchases," while adding a narrow bioethical dimension to the Task Force's ambit.[347]

The following day, Representative Marriott again introduced a task force and registry bill, H.R. 4320, this time joined by three House colleagues.[348] Members of the House were effectively greeted with a menu of options; Republican Representative Edward R. Madigan of Illinois ended up sponsoring Marriott's task force and registry proposal as well as an initiative authorizing financing for organ procurement later introduced by Gore, H.R. 4474.[349] Reportedly, "he became a supporter of Gore's broader proposal during its consideration by the [House] Energy and Commerce Committee."[350]

In a series of convoluted machinations, a streamlined version of Gore's comprehensive proposal gained momentum through a combination of popular support and procedural maneuvering. Gore's original National Organ Transplant Act, referred out of its originating subcommittee in amended form on November 8, 1983, garnered the approval of the House Energy and Commerce Committee on November 17, with ninety co-sponsors.[351] Pennsylvania Representative Doug Walgren's call for coverage of outpatient immunosuppression had been incorporated into this bill through an amendment authorizing it within the existing Medicare inpatient drug reimbursement framework.[352] Because the comprehensive legislation "affect[ed] Medicare financing," however, it would also have to get through the House Ways and Means Committee and the Senate Finance Committee to be enacted into law. These committees, which had not participated in the initial Congressional inquiry into transplant policy, would introduce "new and unsympathetic actors into the deliberations."[353] Representative W. Henson Moore, ranking Republican on the Ways and Means Subcommittee on Health, was seen as an opponent of NOTA, but "the leading

346. [2 98th Cong.] Congressional Index (CCH) 14,253 (Nov. 3, 1983) (describing of S. 2048).

347. Howard S. Schwartz, *Bioethical and Legal Considerations in Increasing the Supply of Transplantable Organs: From UAGA to "Baby Fae"*, 10 AM. J.L. & MED. 397, 415 (1985).

348. [2 98th Cong.] Cong. Index (CCH) 28,394 (Nov. 4, 1983).

349. *Id.* at 28,394 & 28,403.

350. Iglehart, *supra* note 236, at 866.

351. *See id.* at 865 (erroneously stating that the committee approved the bill by voice vote on November 18); Wehr, *supra* note 189 (stating that the voice vote actually occurred on November 17). *See also* H.R. REP. NO. 98-575, at 24 (1983) (tracing the history of the bill in detail and stating that the voice vote occurred on November 17).

352. H.R. REP. NO. 98-575, at 22 (1983).

353. Mueller, *supra* note 177, at 352.

candidate to fashion a compromise."[354] On March 6, 1984, the Ways and Means Subcommittee rejected Moore's gesture toward a task force and registry-only approach, instead waving Gore's bill on to the full Ways and Means Committee—minus the outpatient immunosuppression coverage.[355]

Advocates of immunosuppression coverage, apparently ranking this priority high in relation to the other proposed changes to the Medicare program, were not content with this compromise. The day after the comprehensive bill had been *approved* by the Energy and Commerce Committee, Gore, perhaps sensing what was coming, had introduced a pared-down alternative to his own bill. This bill, H.R. 4474, "authoriz[ing] financial assistance to organ procurement organizations," eliminated the controversial centers-of-excellence designation system and the attempt to direct state Medicaid policymaking.[356] It also represented an ingenious end run around by the Finance and Ways and Means Committees: By deleting these provisions and by shifting the outpatient drug financing from the Medicare program to the HHS Secretary's office, the revisions cast the remaining provisions outside the jurisdiction of these budget-sensitive committees.[357]

In the months that followed, the Senate and House both passed transplant bills. The Senate's "Organ Procurement and Transplantation Act," S. 2048, closely identified with Utah Republican Orrin Hatch, developed through a process of engagement across the aisle. Massachusetts Democrat Ted Kennedy's reimbursement-oriented task force bill, S. 1728, had been the basis for the Labor and Human Resources hearings that led to the introduction of S. 2048, originally a task force and registry bill.[358] As reported out of committee, the Hatch Bill authorized limited direct government assistance to organ procurement and sharing initiatives, in addition to fashioning a strategic planning Task Force and a registry of potential organ donors and recipients. This version was evidently acceptable to Kennedy, who gave it his backing before the decisive Senate voice vote on April 11, 1984.[359] In the House, a clean copy of Gore's streamlined bill, re-introduced as H.R. 5580, left the House Energy and Commerce Committee just days after the Ways and Means Committee approved the other Gore bill

354. Iglehart, *supra* note 236, at 868.

355. *See* Wehr, *supra* note 246.

356. [2 Cong. 98th] Cong. Index (CCH) 29,403 (Nov. 18, 1983) (describing H.R. 4474); Meuller, *supra* note 177, at 352. The move to designate certain transplant centers for reimbursement was met by an "increasing number of academic medical centers . . . announcing their plans to develop transplantation programs. With each such announcement, the prospect [grew] increasingly remote that Congress [would] enact—in the short run—a policy that would limit which of these centers would be eligible" for reimbursement. Iglehart, *supra* note 236, at 868.

357. Mueller, *supra* note 177, at 352-53.

358. 130 CONG. REC. 8740-43 (1984) (reading the full text of the bill into the record).

359. *Id.*

without drug coverage.[360] On June 21, 1984, the House approved an amended version of H.R. 5580, which had bypassed the Ways and Means Committee, by a lopsided vote of 396 to 6, with 31 representatives not voting.[361]

Representative Skeen, a co-sponsor of the House bill, called transplantation "a totally bipartisan issue that transcends politics,"[362] but the impulse to "do something" followed slightly different channels in the Capitol's two chambers.[363] Apart from the Task Force and procurement seed money provisions, both bills banned organ purchases, directed the HHS Secretary to contract with the private sector to improve organ matching and sharing, mandated the maintenance of a master list of transplant patients, and required the HHS Secretary to report annually "on the scientific and clinical status of organ transplantation."[364] On the whole, however, the Senate bill implied a smaller federal role in transplantation, a less hierarchical approach to governance of the transplant enterprise, and more policy involvement by identifiable stakeholders among the general public.[365] The most obvious difference was the inclusion of an immunosuppression reimbursement program in the House bill alone. In another sign of fiscal restraint, the Senate bill capped government assistance to procurement organizations at $15 million over three years for start up activities, while the House bill authorized expenditures of up to $40 million over four years for start-up and expansion financing.[366]

Subtle structural variations also operationalized different ideas about who should be organizing, coordinating, and regulating the organ transfer system. The House bill, unlike the Senate's, imposed detailed structural and staffing requirements on procurement agencies as a condition for federal grants, apparently to promote cooperation among stakeholders and ensure

360. [2 Cong. 98th] Cong. Index (CCH) 34,553 (1984) (summarizing H.R. 5580).

361. 130 CONG. REC. 17,668 (1984).

362. 129 CONG. REC. 27,396 (1983).

363. *See* 130 CONG. REC. 29,982 (1984) (statement of Sen. Kennedy) (urging that "[s]omething must be done" about transplant availability).

364. *Compare id.* at 8740-42 (reading S. 2048 into the record) (bill of Sen. Orrin Hatch) *with id.* at 17,648-50 (reading H.R. 5580 into the record) (bill of Rep. Albert Gore, Jr.).

365. Not every difference between the House and Senate bills was consistent with this pattern; some differences suggested that the House bill was the product of a more thorough drafting process. For example, it provided a larger express safe harbor from the ban on commerce in human organs, allowing reasonable reimbursement of donor expenses such as lost wages, as well as "reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ." *See id.* at 17,670 (reading Title II of H.R. 5580 into the record).

366. *See id.* at 17,669 (indicating House authorization); *id.* at 8742 (indicating Senate authorization).

communication with the general public.[367] Similarly, the House bill called for the appointment of a twenty-two member Task Force to examine questions of financing and access, consisting of sixteen specialists in organ procurement, histocompatibility, and transplant medicine; four "people who are not physicians or scientists and who as a group have expertise in the fields of law, theology, ethics, health care financing, and the social and behavioral sciences" (a role that could have been designed for the burgeoning bioethics community); and three "members of the general public."[368] In contrast, the Senate bill contemplated a nineteen member Task Force largely comprised of professionals with relevant expertise and individuals representing various constituencies, such as patient advocates and insurers.[369] For reasons that were not transparent, the House bill would decommission the Task Force a full year after it was to report its findings, but the Senate bill provided only one month until the Task Force would disband.[370] While the House moved slightly away from creating a named government center to administer organ procurement and allocation policies, the House bill nonetheless required HHS to "maintain an identifiable administrative unit" within the Public Health Service to oversee the government's new role in organ procurement and allocation.[371] In contrast, the Senate continued to envision federal support performing a largely informational function. The Senate bill described the network as an "Organ Procurement and Transplantation Registry," suggesting that its central feature was to maintain and verify information about prospective donors who were willing to be listed and about potential transplant recipients.[372]

When combined with the Registry's obligations to promote donation awareness and develop a national matching system, these charges gave the Registry an active role in increasing the availability of organs for transplantation. Other variations, though, suggested that the Senate's system would not go so far in imposing centralized external coordination of organ allocation. The Registry was not required to have representatives of the general public on its board of directors, as was the House's "United States Transplantation Network." While the House bill required the network to "coordinate, as appropriate, the transportation" of donated organs,[373] the Senate bill somewhat less directly required the network to "*promote* the coordination, as appropriate," of organ transport.[374]

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367. *Id.* at 17,670.
368. *Id.*
369. *Id.* at 8740-41.
370. *Id.*
371. *Id.* at 17,649.
372. *Id.* at 8741.
373. *Id.* at 17,669.
374. *Id.* at 8741.

In several respects, the Senate bill reflected a greater degree of neutrality and openness, while the House bill reflected a greater degree of decisiveness and demand for execution. Thus, the Senate simply required "private sector" operation of the network, while the House required that a single, nonprofit private entity fulfill this role.[375] The House bill alone directed the network to distribute sera for tissue typing. Similarly, the Senate bill called on the Task Force to examine a broad array of cultural, technical, logistical, and economic issues, while the House gave the Task Force a more focused set of charges. While both bills required the HHS Secretary to publish annual reports on "the scientific and clinical status of organ transplantation," the House's reporting requirement was clearly drafted with an eye toward reimbursement.[376] It directed the Secretary to "make the report and other related information available to" payors such as health insurance companies and "service benefit plans."[377] In contrast, the Senate bill did not order the delivery of the report to any specific person or entity, making the purpose of this reporting requirement opaque.

In both houses, legislative debate was succinct and generally supportive. Texas Republican Representative Ron Paul, known for his iconoclastic libertarianism, took a stand against the conventional wisdom by arguing for a market-based approach to organ allocation, ostensibly speaking "as a physician."[378] In the end, the maverick's appeal to professional authority did little to enhance his argument, which largely drew on economic philosophy, rather than medical expertise. When confronted with transplant surgeons' active support for NOTA, Paul responded that "there are physicians who do not understand economic allocation."[379] More commonly, purported deficiencies and improvements in the proposed legislation were framed as constructive criticism.

The House bill, which arrived ten weeks after the Senate's despite Waxman's and Gore's urgent shepherding, emerged after more thorough review and revision on the public record. The House bill's structure for delivering outpatient immunosuppressants exposed strains between the aspiration of bringing transplantation under the control of centralized, national management and a political system predicated on the representation and accommodation of states and localities. Perhaps in order to differentiate this program from a general outpatient drug benefit, the bill as drafted authorized HHS to furnish immunosuppression through facilities that performed twenty-five or more transplants per fiscal year. As Republican Representatives from Maine and Vermont pointed out, transplant centers in those two states, as well as Arkansas, Hawaii, New Mexico, Vermont, and Puerto Rico, were performing at least fifteen

375. *Id.*

376. *Id.* at 8742; *id.* at 17,670.

377. *Id.* at 17,670.

378. *Id.* at 17,663.

379. *Id.* (responding to Rep. Albert Gore, Jr.).

transplants per year, but no center in these jurisdictions reached the threshold of twenty-five. Vermont Representative James Jeffords noted that HHS had adopted a volume criterion of fifteen transplants per year "as one factor in determining eligibility" for federal reimbursement of renal transplant surgery.[380] Maine Representative Olympia Snowe explained the foreseeable effect of this inconsistency on patients from the liminal jurisdictions: "[they would] be forced to either absorb the very sizable expense of these medications or assume the added financial and emotional burden of traveling to other centers where the drugs are available."[381] Maine Representative John McKernan, Jr.'s proposal to lower the immunosuppression reimbursement threshold to fifteen transplants per year was approved with Chairman Waxman's endorsement. The influential California Democratic stated that the criterion was not intended to "impact disproportionately . . . rural States that only have a single transplant center."[382]

The need to build a broad political coalition was not the same as all-inclusiveness, as evidenced by the implications of *any* volume requirement for incipient transplant programs. Maryland Democrat Representative Parren Mitchell expressed concern about the bill's impact on "small, progressively expanding medical transplant centers that are located in predominantly black and lower income communities."[383] Because African-American patients experienced a relatively high incidence of post-operative complications and the cost of medication was especially burdensome for low-income patients, coverage that left out communities with these demographics would ill serve some of the patients most in need of affordable immunosuppression. Representative Mitchell's analysis, however, focused on the policy's implications for *hospitals*, especially the District of Columbia's Howard University Medical Center, which had averaged just over fourteen transplants per year over a ten-year period.[384] If the paramount purpose of the immunosuppression program was ensuring *patients'* access, Mitchell's arguments were only indirectly apposite.[385]

Congress did manage to develop strategies for reordering the scattershot organ procurement arrangements without reigniting apprehensions about the political, equitable, and health consequences of creating a transplant establishment or privileging a medical elite. H.R. 5580's eligibility criteria promoted coordination and consolidation by requiring procurement agencies to *include* sufficient geographical territory, a sufficient donor population, and a

380. *Id.* at 17,651.

381. *Id.* at 17,651.

382. *Id.* at 17,651-52.

383. *Id.* at 17,660.

384. *Id.*

385. Although numerous high-volume transplant programs were located in economically struggling urban centers, Howard may have been exceptional in its commitment to serving "high risk, generally low-income patients." *See id.*

sufficient percentage of the medical institutions within their service areas. By forbidding the HHS Secretary from disbursing grants to procurement organizations "serv[ing]" the same geographical area, the bill clearly disfavored redundancy while creating a space for market-like forces to sort out the institutional map.[386] The Senate bill took a different step toward dividing the network into (theoretically non-exclusive) catchment areas. By prohibiting funded procurement organizations from operating in "part" of a metropolitan area, the bill prepared the way for coordinated metropolitan procurement programs, but created a risk of leaving entire areas uncovered.[387]

Another point of agitation was the relationship between Congress's efforts to organize solid organ transfer and the clinical use of other human tissue. After the House distanced itself from the disputed strategy of tracking potential organ donors, but before the vote on H.R. 5580, Waxman successfully introduced an amendment instituting, on a demonstration basis, the confidential volunteer registry needed for unrelated bone marrow transplantation.[388] Waxman credited Maryland Democratic Representative Barbara Mikulski, reportedly unable to be present, as the amendment's "catalyst."[389] This innovation apparently also reflected the initiative of an able and highly motivated constituent of Mikulski's. Attorney Bart Fisher, whose seven-year-old son needed a bone marrow transplant from an unrelated donor, learned of Gore's foray into transplant policy a month after the boy was diagnosed with aplastic anemia. Fisher, who knew of a marrow registry in England but found none in America, sought out Mikulski, accompanied by four of his son's doctors from Johns Hopkins in Baltimore. Fisher also met with members of Gore and Waxman's staff and, by his uncontroverted account, played a role in drafting the legislation.[390] The House bill, as passed, provided for the distribution of outpatient immunosuppression through transplant centers with a greater sensitivity to the circumstances of states where renal transplantation was being carried out on a small scale. The bill also directed HHS officials to establish, oversee, monitor, and report on the bone marrow registry.

Integrating organ procurement and allocation initiatives into the larger ecology of anatomical gifts had the effect of winnowing down immediate congressional ambitions as well as augmenting them. Preliminary plans to set standards for organ and tissue transplantation in the same bill provoked vigorous resistance from tissue banking organizations, which were wary of government

386. *See id.* at 17,648 (reading H.R. 5580 into the record).

387. *Id.* at 8742 (reading S. 2048 into the record).

388. *See supra* note 214 and accompanying text.

389. 130 CONG. REC. 17,650 (1984) (statement of Rep. Henry Waxman).

390. Bart S. Fisher, Letter to the Editor, *The National Marrow Donor Program with Emphasis on the Early Years*, 47 TRANSFUSION 1101 (2007).

intervention in their established industry. After the Lions Club, a public service organization that promoted corneal transplantation, began a nationwide letter-writing campaign, Gore narrowed the bill's focus to organ transplantation, the more pressing concern, and the Club relinquished its objection.[391] This separation of tissue and solid organ policy raised a disturbing prospect, which Gore acknowledged. "There would be nothing worse for both organ and tissue retrieval," he said, "than to have a situation where the family of a potential donor is approached by a long line of individuals each seeking a different organ or tissue."[392] Different classes of anatomical gifts presented different logistical issues, but cooperation would be essential to humane procurement. H.R. 5580, as passed, required qualified organ procurement organizations to make arrangements with their counterparts in the tissue banking field as appropriate, but not every member of Congress was convinced that the bill adequately addressed "the need for coordination and cooperation between these two efforts."[393] This concern was one manifestation of a larger problem: Although the process of putting together the House bill evinced and incorporated tremendous collective knowledge of the issues at hand, the bill itself seemed hastily put together. The bill's structure pointed to the same conclusion as the "Prohibition of Organ Puchases" stood distinct from the rest of the bill as Title II. All the other provisions, intended to solidify and bolster the emerging public-private organ transfer system, were lumped together as Title I, and not necessarily in the most logical order.[394]

Movement toward an enanctable consenus began even before the House passed its bill. The day before the House enacted H.R. 5580, California Republican Representative William Dannemeyer proposed an amendment that was tantamount to a substitute bill.[395] By reducing the amount of money available to procurement organizations from $40 million to $15 million over three years and eliminating the immunosuppression financing program, Dannemeyer's amendment "would have brought the measure in line with [the] leaner transplant bill . . . approved April 11 by the Senate."[396] Dannemeyer's substitute adopted the Senate bill's language, referring to an "organ transplant registry" rather than a national transplant network, but he argued for the amendment in terms of fiscal responsibility and program flexibility rather than legislative harmonization—in the process, providing perhaps the most detailed rationale for the Senate's

391. Bunis, *supra* note 342.

392. 130 CONG. REC. 17,662 (1984) (statement of Rep. Albert Gore, Jr.).

393. *Id.* at 17,661 (statement of Rep. Bruce Morrison).

394. *Id.* at 17,668-70 (reading S. 2048 into the record).

395. *Id.* at 17,340.

396. Janet Hook, *Drug Funds Authorized: House Passes Bill To Improve Organ Transplant Network*, CONG. Q. WKLY., June 23, 1984, at 1491.

approach.[397]

The House was evidently not persuaded, and the day the House passed its Organ Transplant Act, H.R. 5580, Representative Waxman proceeded along a different path toward reconciliation: emptying the Senate's old bottle and refilling it with the House's new wine. He moved, without objection, to strike the entire text of the Senate's Organ Procurement and Transplantation Act, and replace it with the text of H.R. 5580. Waxman requested a bicameral conference on the legislation, and the House members appointed to the conference committee included the major participants in crafting NOTA—not only Waxman and Gore, but also Mikulski, Walgren, and Dannemeyer.[398] Eight days later, on June 29, 1984, the Senate rejected the House "amendments" and "agree[d] to the conference." The Senators meeting with future Vice President Gore at the conference would include future Vice President Dan Quayle, former presidential candidate Ted Kennedy, and future presidential aspirant Orrin Hatch.[399]

As summer turned to fall and the end of the legislative session marched toward its conclusion, "the drug-funding issue held up agreement on the bill."[400] State legislatures, on guard against fledgling commercial adventurism, had already begun enacting statutes that would exclude such dubious business from their jurisdictions.[401] The most innovative of these approaches was probably an addition to the California Penal Code. In 1984, California's governor signed an act that partially tracked the language of the Federal House and Senate bills, declaring "it . . . unlawful for any person to knowingly acquire, receive, sell, promote the transfer of, or otherwise transfer any human organ, for purposes of transplantation, for valuable consideration."[402] In contrast to the proposed federal legislation, however, the California Act contained a safe harbor disclaiming the Act's applicability "to the person from whom the organ is removed, . . . the person who receives the transplant, [and] those persons' next of kin who assisted in obtaining the organ for purposes of transplantation."[403] Legal scholarship has interpreted the statute consistently with its plain meaning, as "criminalizing brokering" but not direct sales from the person giving up the organ to the

397. 130 CONG. REC. 17,340 (1984).

398. *Id.* at 17,668-71.

399. *Id.* at 20,059.

400. *Compromise Organ Transplant Bill Passed*, *supra* note 231, at 476.

401. *See* Susan Hanklin Denise, Note, *Regulating the Sale of Human Organs*, 71 VA. L. REV. 1015, 1026-29 (1985).

402. CAL. PENAL CODE § 367f (West 1999). The federal bills, as passed, stated, "[i]t shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer for valuable consideration any human organ for use in human transplantation if the transfer affects interest commerce." 130 CONG. REC. 8742 (1984) (Senate bill); *Id.* at 17,670 (House bill).

403. CAL. PENAL CODE § 367f(e) (West 1999).

transplantee.[404]

That September, medical events again began to drive the movement toward federal legislation. "The *New England Journal of Medicine* reported that cyclosporine had caused fatal kidney failure in two heart transplant patients," reviving attention to ongoing medical assessment of the drug's "relative benefits and risks" and highlighting the perils of crystallizing public policy in a dynamic field. The article strengthened the Senate position and "Gore agreed to drop the drug funding" in a compromise that designated medical and policy questions surrounding immunosuppression as the envisioned Task Force's "top priority."[405]

The National Organ and Transplant Act reported out of the conference committee on October 2, 1984, was neatly organized into four Titles. Title I called on the HHS Secretary to commission a twenty-five member Task Force on Organ Transplantation within ninety days. The qualifications for the twenty-one people comprising the Task Force's *appointed* membership reflected the House's interest in public participation and humanistic input and the Senate's interest in payor representation. Additionally, the Surgeon General, the NIH Director, the FDA Commissioner, and the HCFA Administrator were given ex officio seats on the Task Force in a move that strengthened its connections to the relevant agencies. Agency personnel, in turn, were assured reimbursement for assisting the Task Force, and the HHS Secretary was made director to provide it with necessary "administrative and support services." Its charges were broad, including "comprehensive examinations of the medical, legal, ethical, economic, and social issues presented by human organ procurement and transplantation."[406] Lingering unresolved issues such as the economic consequences of funding immunosuppression, reimbursement of transplant surgery, the desirability of registering prospective organ donors, and the coordination of tissue procurement were expressly handed to the Task Force for "assessment" and "analysis."[407] The Task Force was charged with formulating recommendations on other matters such as educating professionals and the general public about organ procurement and "assuring equitable access by patients," perhaps reflecting consensus on these matters at a high enough level of abstraction.[408] The Task Force would report on immunosuppression within seven months and produce its general final report within twelve months, but it would remain commissioned for three months after the final report, leaving a window for expanding its inquiry.[409]

Title II amended the Public Health Service Act to authorize "Assistance for

404. Margaret Jane Radin, *Market-Inalienability*, 100 HARV. L. REV. 1849, 1924 n.261 (1987).

405. *Compromise Organ Transplant Bill Passed, supra* note 231, at 476.

406. H.R. CONF. REP. NO. 98-1127, at 1-4 (1984).

407. *Id.* at 1-2.

408. *Id.* at 2-3.

409. *Id.* at 5.

Organ Procurement Organizations," to create the "Organ Procurement and Transplantation Network" (OPTN) and a "Scientific Registry," and to require a unit of the Public Health Service to administer such support. The bill authorized a total of $25 million in grants for organ procurement organizations' start up and expansion expenses over three years. It employed an abundance of enticements and pressures to increase the efficiency of procurement activities through processes of coordination, consolidation, and selection. Organ procurement organizations were required to coordinate with tissue banks "as may be appropriate to assure that all useable tissues are obtained from potential donors."

At the same time, HHS would wield a degree of power vis-à-vis tissue banks because the bill authorized the Secretary to bring any organs or tissue except eyes and corneas into the organ procurement financing structure. The grant eligibility requirements assured that qualifying organ procurement organizations would be actively involved in professional education, arrangements for tissue typing and organ transport, and self-evaluation, suggesting a means for implementing national objectives on a decentralized basis. By requiring these organizations to include transplant professionals on their board of directors or advisory board, the bill also offered a way to draw on professional expertise while aligning it with a public interest larger than loyalties to individual transplant programs.[410]

NOTA similarly required representation of "procurement organizations, . . . transplant centers, voluntary health organizations, and the general public" on the OPTN's board of directors. Although NOTA did not foreclose the possibility that the OPTN would maintained through multiple, simultaneous contracts, and it allowed the OPTN to operate "through regional centers," the conference committee unequivocally called for OPTN to be operated by a single "private nonprofit entity which is not in any activity unrelated to organ procurement."[411] The OPTN was to match organs "in accordance with established medical criteria."[412] Beyond this requirement, the language of Title II reflected a few specific ethical aims, such as tending to the needs of patients "whose immune system makes it difficult for them to receive organs" by distributing blood sera samples.[413] The provision establishing the OPTN was otherwise silent, however, as to whether the OPTN would properly articulate normative commitments or implement them in its organ distribution practices.

The Scientific Registry required by the conference committee was a registry of "patients and procedures" to aid in "ongoing evaluation of the scientific and clinical status of organ transplantation."[414] By thus distinguishing the registry

410. *Id.*
411. *Id.* at 7.
412. *Id.*
413. *Id.*
414. *Id.*

from the allocation network, the Act achieved greater consistency with established data collection practices in the field of clinical transplantation.

NOTA's Title III, prohibiting purchases or paid transfers of human organs and non-renewable tissues for transplantation, was apparently not a source of tension between the two chambers. Enacted under Congress's authority to regulate interstate commerce, the provision was enforceable with fines up to $50,000 and up to five years imprisonment.[415] The final language tracked the House bill, broadly excluding "reasonable payments" for technical and logistical support and reimbursements for costs incurred by donors from the forbidden "valuable consideration."[416] Although the conference committee report spoke of "prohibiting the sale . . . of human organs," the plain language of the ban focused on buyers and recipients of organs, without explicitly referring to people who would part with their own organs for money. Congress may have been reluctant to impose criminal penalties on the latter class, viewing them as potential victims of organ commerce, who could be suffering ill effects (and could be located overseas). The move to ban organ purchases likely originated in visceral reactions against commodification or at least commercialization without adequate safeguards. The resulting regulatory framework governing anatomical gifts reflected desires to create a fair and functional organ allocation system by structuring incentives and disincentives (including exposure to liability) beneficently.

Title IV of NOTA directed HHS personnel to create the bone marrow registry if a conference convened by the Secretary found the plan "feasible" and "likely to be effective." This provision required the Secretary to report back to specific congressional committees within two years of establishing the registry on issues such as the need for a permanent bone marrow registry and the "implementation of . . . informed consent and confidentiality requirements."[417] Implicit in this arrangement was an expectation of continued congressional oversight of anatomical gifts.

On October 3 and 4, just days before the 98th Congress would adjourn on October 12, the two chambers agreed to the Conference Report.[418] Fifteen days later, President Ronald Reagan signed NOTA into law. Once support for transplantation became identified with the Act, Reagan may have had little choice. As Hatch had remarked at the opening of the Senate hearings, "[i]f anyone were to oppose transplants, they would quickly earn the title of 'Scrooge of the Year.'"[419] In 1984, this title might have been inflated to "Scrooge of the

415. *Id.* at 9.

416. *Id.*

417. *Id.* at 10.

418. *See id.* at 29,475 (recording the House vote); *id.* at 29,982 (recording the Senate vote).

419. *Human Resources Hearing*, *supra* note 185, at 2.

Presidential Election Year." Despite misgivings about federal intervention, the President was not an avowed opponent of transplants. Perhaps attempting to put a small government gloss on the Act, he described it in a signing statement as legislation that would support and enhance the ongoing work of the private sector.[420] When the Reagan Administration failed to follow through with the expected budgetary support after the signing, politicians and patients' advocates kept the hot lights on the Executive Branch.[421] In 1986, HHS would finally award UNOS a $379,200 grant to organize a national Organ Procurement and Transplant Network (OPTN).[422]

III. SUBSEQUENT DEVELOPMENTS

By the time UNOS won the contract to operate the OPTN, subsequent political developments had given NOTA a gloss of their own. In a values conflict engendered by scarcity, policymakers' desire to incorporate private enterprise into the transplant system would collide with a nationalistic moral fervor. The result—a bureaucratic allocation network maintained by centralized governmental power—was not precluded by the letter of the law, but nonetheless might have startled the more conservative of NOTA's framers.

A. The Pittsburgh Controversy and the Crisis of Public Confidence

In a statement to members of Congress in 1983, David Ogden of the Kidney Foundation expressed his desire to discuss briefly an issue not directly addressed in the proposed legislation. "The National Kidney Foundation," Ogden asserted, "believes that . . . organs donated by deceased American citizens or their next of kin are inherently intended by the donor to benefit a fellow American citizen, if a suitable recipient can be identified by the matching program in effect at the time." If such a recipient could not be found, Ogden reasoned, donors would not want usable organs to go to waste, so "transplantation to a foreign national" would be "entirely appropriate."[423] The privileges and obligations of citizenship with respect to transplantation had been a recurring subtext of the NOTA

420. *See* Statement on Signing the National Organ Transplant Act, 2 PUB. PAPERS 1578, 1579 (Oct. 19, 1984).

421. *See, e.g.*, *Backers of Organ Gifts Criticize Reagan Cuts*, N.Y. TIMES, Jan. 13, 1987, at C9.

422. *U.S. Establishes National Organ Donor Network in Virginia*, N.Y. TIMES, Oct. 1, 1986, at A24. The only serious threat to UNOS's responsibility for the OPTN came from the RAND Corporation in 1999 and was short-lived. *See Rand Informs Government It Will Not Bid on Contracts to Administer OPTN, SRTR*, TRANSPLANT NEWS, Nov. 30, 1999, *available at* http://findarticles.com/p/articles/mi_m0YUG/is_22_9/ai_n18609209.

423. *Energy and Commerce Hearing*, *supra* note 147, at 361 (statement of David A. Ogden, M.D., President, National Kidney Foundation).

hearings. As a social, ethical, and pragmatic problem, it fit squarely within the ambit of the Task Force. Now, publicity surrounding foreign nationals' access to donated organs at American transplant centers would galvanize the movement toward an organ allocation system that was not only organized according to revealed public preferences, but also publicly accountable.

In May 1985, the *Pittsburgh Press* revealed the results of "a three month investigation," indicating that Pittsburgh doctors "bypassed hospital policy that set[] transplant priority" in order to expedite foreign patients' operations. "In at least 27 cases, blood samples from Americans and foreigners were examined and while suitable cross-matches for the organs were confirmed among the Americans the kidneys went to foreigners."[424] The chief of surgery at Presbyterian University Hospital, Dr. Henry Bahnson, explained that the usual policy could be waived "for 'compassionate' reasons," such as when a patient was "running short on money to stay in Pittsburgh, or [was] a doctor or the children of doctors or members of the Saudi royal family."[425]

In a series of related articles, the *Press* combined detailed records of blood type and cross-match results with human interest stories juxtaposing the transplant experiences of foreign and American families. A relative of a North Carolina car accident victim traced the victim's kidneys to Pittsburgh, where they were "transplanted into" a Saudi national and an Egyptian doctor's son, "both of whom were told to report to the hospital before the lab work on . . . three Americans had been completed." Reportedly, the latter recipient had only been waiting for twenty-four days "and had not been on dialysis," whereas a suitable American recipient had been on the waitlist for three years and "was running out of . . . sites on her body where doctors [could] connect the dialysis machine."[426] Evidence quickly accumulated that many of the foreign patients obtaining organs at Pittsburgh were wealthy, powerful, or well-connected, included a princess and the wife of a royal financial advisor to Saudi Arabia's King Fahd.[427] The basic contentions of the series resonated beyond Pittsburgh, and the *Washington Post* similarly found that a high percentage of D.C. area transplants benefited foreign nationals.[428] About the same time, news that "some kidneys were being shipped to Japan for transplants" prompted some California donors to write the words

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424. Andrew Schneider & Mary Pat Flaherty, *Favoritism Shrouds Presby Transplants*, PITTSBURGH PRESS, May 12, 1985, at A1.

425. *Id.*

426. Andrew Schneider & Mary Pat Flaherty, *Woman Passed Over After 3-Year Wait*, PITTSBURGH PRESS, May 12, 1985, at A10.

427. *Saudi Received 2 Kidney Operations After Presby Set Its Transplant Ban*, PITTSBURGH PRESS, June 30, 1985, at A1.

428. Margaret Engel, *Foreigners Got High Percentage of Kidney Transplants*, WASH. POST, June 10, 1985, at C1.

"resident only" on their driver's licenses.[429]

The media also implicitly linked transplants to foreign nationals with the high representation of African-Americans on the transplant waitlist, perhaps appealing to a broad societal recognition that the burdens of social inequalities in America often fell especially heavily on blacks. For example, a *Washington Post* article titled "Foreigners Got High Percentage of Kidney Transplants" noted that "[a]bout 150 D.C. residents, mostly blacks, are waiting for kidneys."[430] Thus, international patients' access to transplants in urban centers, including the nation's capital, was perceived as compounding the ongoing challenge of ensuring equitable access for minority patients in American society. Read cynically, such reporting implied that representatives of the (predominantly white) transplant officialdom cared more about foreigners and their money than about minority citizens of their own country, though the situation was more complicated than it superficially appeared. Wealthy foreigners made a convenient scapegoat for a difficult problem, which was tied to African-Americans' reluctance to sign up as organ donors, the high incidence of kidney disease in the African-American community, and the political and economic legacies of racism.[431] The federal government's conscious policy of funding transplants for ESRD patients through public transplantation, while expecting patients and insurers to pick up the steady stream of bills for immunosuppressive drugs further marginalized Americans of limited means.

The Pittsburgh controversy was the direct outgrowth of an allocation logic embedded in a nationalistic political culture based on local enterprise with a global orientation. The inclusion of diplomatic considerations among the grounds for compassionate exceptions to protocol was wholly consistent with a Cold War belief that providing compassionate care to foreign nationals would build international confidence in America, but in a challenging geopolitical climate, diplomatic considerations threatened to swallow the "compassionate" intent of the policy.[432] The *Pittsburgh Press* eventually discovered that the hospital and Pittsburgh surgeons materially benefited from accepting foreign transplant patients, who paid surgical fees four times higher than the average rate charged to American patients. Additionally, the Saudi royal family had donated $650,000 to the university for transplant research.[433] The ideals underpinning organ

429. *Id.*

430. *Id.*

431. *See* Laura A. Siminoff & Robert Arnold, *Increasing Organ Donation in the Africa-American Community: Altruism in the Face of an Untrustworthy* System, 130 ANNALS INTERNAL MED. 607 (1999); Nat'l Kidney Disease Educ. Program, Fact Sheet. African Americans & Kidney Disease (Aug. 2004), http://www.nkdep.nih.gov/news/campaign/african_americans_508.pdf.

432. Schneider & Flaherty, *supra* note 424 (quoting Thomas Starzl).

433. Andrew Schneider & Mary Pat Flaherty, *Foreigners Paid Extra for Kidney Transplants*, PITTSBURGH PRESS, June 30, 1985, at A1.

donation—gift giving and reciprocity—now appeared to be warped into improper kickbacks.[434]

Perks, however, are not necessarily motivations, and reputational considerations almost certainly influenced the Pittsburgh program's stance regarding international patients more than the "four-foot, gold-plated ceremonial sword"[435] that Starzl acknowledged receiving from Saudis. "Presby's position as an international center creat[ed] pressure to accept foreign transplant candidates," not only because transplant expertise was highly concentrated in the United States, but also "because the presence of foreigners enhance[d] the university's prestige."[436] Prestige, in turn, could "draw additional patients, research funding and top-flight medical talent."[437]

Exactly which word in the phrase "Saudi royal" generated more pique was unclear, but the backlash was swift. Previously majoritarian nationalism and free enterprise conspired against egalitarianism, but now egalitarianism and majoritarian nationalism militated against transplant institutions' internationally-oriented enterprise. Some egalitarian critics emphasized that they objected not to the presence of foreign patients on American waitlists, but to an allocation system that favored the wealthy and the well connected. "If people from other countries need a transplant to live, they should have a chance to get it, but their chance shouldn't be any greater than those of us also waiting," stated one U.S. kidney patient.[438] "It's not American organs going to foreign recipients that is unfair," one reader wrote to the *Pittsburgh Press*. "It's donated organs going to the best paying customers, be they foreign or American, that is grossly unjust and scandalous."[439] Other reports, however, suggested that the allegations of preferential treatment for international patients inflamed stridently nationalistic and xenophobic sentiments: an HHS acting director, Dr. Edward Martin, said that donors "are writing that I didn't sign my donor card to give to a foreign kid. I'm going to tear up my card."[440] "There are countless stories of people saying count me out, if you count foreigners in," added Ronald L. Dreffer, the transplant coordinator at the University of Cincinnati Medical Center. "[I]t's that national

434. For a discussion of how the reciprocity instinct can lead to inappropriate favoritism, see Tom Susman, Op-Ed, *Reciprocity Underlies Lobbying Scandals*, HILL, June 28, 2006, *available at* http://thehill.com/op-eds/reciprocity-underlies-lobbying-scandals-2006-06-28.html.

435. Siminoff & Arnold, supra note 431.

436. Schneider & Flaherty, *supra* note 424.

437. *Id.*

438. Andrew Schneider, *Presbyterian To Revise Kidney Transplant Rule*, PITTSBURGH PRESS, May 20, 1985, at A1.

439. Linda Berry, Letter to the Editor, *Capitalism Blamed*, PITTSBURGH PRESS, May 19, 1985, at B4.

440. Lindsey Gruson, *Some Doctors Move To Bar Transplants to Foreign Patients*, N.Y. TIMES, Aug. 10, 1985, at A1.

spirit."[441] In an oft-quoted comment, an immunologist on a federal transplantation task force remarked, "[i]t's not like we're getting a cross section of foreign nationals. [The economic skew in the foreign patient pool is] not especially fair, so I don't see why we have to be. When they start sending over their shepherds with their bankers, come back and we'll talk."[442] As transplant surgeon Clive Callendar pointed out, however, such rhetoric about foreign inequalities conveniently overlooked substantial disparities closer to home.[443] Indeed, to the extent that the country's Cold War political leadership sought to demonstrate America's "generosity" on the stage of world affairs,[444] the needed sacrifice may have been disproportionately extracted from citizens who were less well-off.[445]

Egalitarian principles could cut in another direction, too: Restricting foreigners' access to American transplant institutions would give American citizens privileged access to transplant surgery. But the revelations about foreign patients leaving the United States with Americans' organs tapped into larger patterns of suspicion, indignation, and resentment. Between the early Cold War and the Pittsburgh controversy, a series of events—including Japan's juggernaut economic recovery, America's growing trade deficit, American casualties in Vietnam, a retaliatory oil embargo by the Organization of Arab Petroleum Exporting Countries, American deaths in airline hijackings, terrorist bombings of U.S. embassies in Lebanon and Kuwait, and the hostage crisis in Iran—likely fostered a sense that American society was under siege by foreign nationals who would take advantage of Americans' good will. In 1984, Sherry Clifton, whose fifty-year-old gospel singer husband Hardie Clifton received a Medicaid-financed

441. *Id.*

442. Mary Pat Flaherty, *Organ Network Gives Foreigners Lowest Priority*, PITTSBURGH PRESS, May 23, 1985, at A1.

443. Gayle McCracken, *Transplant Rules for Foreign Patients Debated*, PITTSBURGH PRESS, June 18, 1985, at A1.

444. *See, e.g.*, Kennedy, Inaugural Address, *supra* note 67 (asserting to the world "that we shall pay any price, bear any burden, meet any hardship, support any friend, oppose any foe, in order to assure the survival and the success of liberty"). *See also* Ronald Reagan, Acceptance of the Republican Nomination for President (July 17, 1980) (casually characterizing "the American people" as "the most generous on earth"), *available at* http://www.pbs.org/wgbh/amex/reagan/filmmore/reference/primary/acceptance.html. For a discussion of this theme in Reagan's rhetoric, see Chidester, *supra* note 279 at 179 ("Ronald Reagan . . . spoke of winning through sacrifice. America had won and would continue to win in the struggle for freedom (under the rule of law) only because America's sons and daughters paid the highest price, gave the greatest gift, made the supreme sacrifice.").

445. For an examination of the class demographics and social experiences of enlisted military personnel serving in the Vietnam conflict, see CHRISTIAN G. APPY, WORKING CLASS WAR: AMERICAN COMBAT SOLDIERS AND VIETNAM (1993).

heart transplant after she called the White House and explained her frustration with the reimbursement bureaucracy:

> I'm an American citizen. I see what's going on in America, how the United States takes it upon itself to help everybody—all the postwar things we did for Japan, and the Vietnamese refugees—and I'm calling agency after agency, and everybody's saying, 'We don't do this,' and I'm saying, 'Where am I? Am I still in America or off in the twilight zone?'"[446]

Much as ongoing public financial support for dialysis had given taxpayers a stake in the NOTA hearings, taxpayer support for organ transplants and transplant institutions now provided a plausible jurisdictional nexus for the public's concern about how organs were allocated. The *Pittsburgh Press* argued that "patients suffering from severe kidney disease are included in federal payment programs. Virtually all costs of treatment and replacement surgery are covered. So the public has a direct financial involvement in transplant decisions and policies."[447] By August 1985, numerous medical centers had reportedly instituted quotas limiting the availability of organs to "foreigners."[448] Some activist officials may have anxiously leapt to action on the basis of anecdotal evidence of public offense, or seized on the prospect of an impending backlash to bolster the case for nationalistic policies they already personally supported. The apprehension was that otherwise, members of the public would reduce the overall supply by refusing to donate.

B. Structural Impact

Today, nonresident aliens' access to cadaver transplants at U.S. hospitals is effectively governed by UNOS policies. These policies allow non-resident aliens to obtain up to five percent of donated cadaveric organs at each transplant center "on equal footing with U.S. residents."[449] Historically nationwide transplants to non-residents aliens have not reached this quota. However, if it is exceeded for any type of organ at any given transplant center, UNOS will conduct an investigation.[450] Clearly, the 1985 scandal influenced the policies of UNOS member institutions and influenced how UNOS communicates with the public to

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446. Meyer, *supra* note 282.

447. Editorial, *Transplant Line-Jumping*, PITTSBURGH PRESS, May 19, 1985, at B2.

448. Gruson, *supra* note 440.

449. Katrina A. Bramstedt, *Supporting Organ Transplantation in Non-resident Aliens Within Limits*, ETHICS & MED., Summer 2006, at 39.

450. *See id. See also* Letter from Senate Finance Committee Chairman Charles Grassley to Elizabeth M. Duke, Administrator of Health Resources and Services Administration (Nov. 29, 2005); Shankar Vendantam, *U.S. Citizens Get More Organs Than They Give*, WASH. POST, Mar. 3, 2003, at A03.

maintain confidence in America's organ allocation system. A 2003 *USA Today* article, noting that an undocumented immigrant teenager was included on Duke University's transplant waitlist in contravention of a UNOS rule "requir[ing] that non-resident organ recipients be in the country legally," highlighted the divergence between this story and the earlier scandal. "[UNOS] officials have no plans to reprimand Duke for treating Jesica, 17," reporter Tim Friend noted. "The network says limits on transplants to non-resident aliens are designed mainly to ensure that the USA doesn't become a transplant mecca for rich foreigners."[451]

The privileged international patient controversy undoubtedly shaped how the transplant community built public trust, but it likely also had a deeper effect, shaping the allocation system's very structure—how its rules were made and enforced—in the years following the passage of NOTA. In April 1986, the NOTA Task Force on Organ Transplantation released its comprehensive report, titled *Organ Transplantation: Issues and Recommendations.* Consistent with NOTA, the Task Force, convened by HHS Secretary Margaret Heckler and chaired by Illinois surgeon Olga Jonasson, included medical professionals, social and behavioral scientists, a legal scholar, an ethicist with a background in religious studies, representatives of the public and private insurance sectors, and representatives of the general public.[452]

The Task Force's report, totaling more than 200 pages, evaluated existing organ procurement efforts and made recommendations for increasing public awareness, assuring equitable access to organs, and coordinating the organ matching process.[453] Some of the Task Force's analysis revisited issues already raised by Congress, such as the coordination of organ and tissue procurement and the balance between market forces and government certification. The value of a second look at the political feasibility of renegotiating these issues was debatable. In other cases, the Task Force process allowed procurement and allocation practices to be organized at different levels of government. For example, the Task Force urged HHS to implement a set of certification guidelines developed by the Association of Independent Organ Procurement Agencies, including a requirement that procurement organizations have "a defined exclusive service area."[454] This criterion was subsequently embraced by UNOS, giving it great organizational power even in the absence of HHS adoption.[455]

Quite possibly, the recommendation with the greatest impact was the Task Force's proposal that "transplantation procedures should not be reimbursed under

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451. Tim Friend, *Duke Didn't Follow the Rules in Jesica's Transplant*, USA TODAY, Mar. 4, 2003, at 1D.

452. TASK FORCE ON ORGAN TRANSPLANTATION, *supra* note 128, at xiii-xv.

453. *Id.* at xv.

454. *Id.* at 60, 222.

455. *See* Blumstein, *supra* note 10, at 25.

Medicare, Medicaid, . . . and other public payers, unless the transplant center meets payment, organ sharing, reporting, and other guidelines to be established by the [OPTN] or another agency administratively responsible for the development of such guidelines."[456] In the Sixth Omnibus Budget Reconciliation Act (SOBRA), enacted in 1986, Congress would go even further, threatening to cut off *all* Medicare reimbursements for hospitals that did not comply with UNOS's rules or obtain a valid waiver.[457] Transplant centers already had a strong incentive to comply with the guidelines: They relied on the network for access to matched organs from outside their immediate geographical areas. After SOBRA, the cost of noncompliance became so high that the guidelines would effectively function as binding policies on hospitals that operated transplant programs.

This practically important recommendation was not in the chapter of the report concerning organ sharing, as one might suppose. Tellingly, the recommendation was contained in the section of the report called "Non-Immigrant Aliens." Following the Pittsburgh revelations, the Task Force added the problem of nationality and access to its agenda and heard testimony on the issue from various transplant professionals. The hearing did not lead to a consensus for the allocation policy,[458] nor did a subsequent HHS investigation result in a uniform binding policy.[459] Nonetheless, the Task Force's final report spoke to a widely perceived need for control over allocation practices that was removed from transplant programs' immediate interests. The report detailed how "evidence that giving non-immigrant aliens priority on a waiting list" threatened America's "voluntary, cooperative system of organ procurement."[460] It further noted that money may be "the real reason for assigning priority to non-immigrant aliens," but in any case, favoritism was unjustified.[461] Counterintuitively, the Task Force, composed largely of transplant professionals, adopted a more stridently populist line than even elected legislators had articulated before the Pittsburgh uproar.[462]

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456. TASK FORCE ON ORGAN TRANSPLANTATION, *supra* note 128, at 95.

457. Ian Ayres et al., *Unequal Racial Access to Kidney Transplantation*, 46 VAND. L. REV. 805, 814 (1993) (citing Pub. L. No. 99-509, 100 Stat. 1874 (1986)). For a more detailed account of how the Task Force operated and how Congress responded to its report, see Laurel R. Siegel, Comment, *Re-engineering the Laws of Organ Transplantation*, 49 EMORY L.J. 917, 936 (discussing 42 U.S.C. § 1320b-8(a)(1)(B)(1994)).

458. *Supra* note 440.

459. OFFICE OF THE INSPECTOR GEN., DEP'T OF HEALTH & HUMAN SERVS., THE ACCESS OF FOREIGN NATIONALS TO U.S. CADAVER ORGANS (1986).

460. TASK FORCE ON ORGAN TRANSPLANTATION, *supra* note 128, at 93.

461. *Id.*

462. The *Pittsburgh Press* reported that its articles prompted the Task Force's examination of the intersection of nationality and access to transplantation, which led to several points of consensus about patient recruitment and billing. *See* McCracken, *supra* note 443.

Insofar as NOTA itself was ambiguous or multivalent, the Pittsburgh controversy tipped the law's implementation toward greater direct federal oversight. The concern that privileged access for international patients would undermine the entire system was so prominent that elected and appointed policymakers summoned the power of the public purse to enforce ostensibly voluntary guidelines developed by a private, non-profit agency.[463] This move, though heavy-handed, fit into a policy vision that had been foreshadowed in the congressional hearings leading to NOTA. Under this vision, transplant institutions were not just trustees acting on behalf of individual organ donors (as the UAGA implied), but were also entrusted by a broad voting and taxpaying public to impose uniform, accountable rules on all organ transfers.

C. The Refining Scalpel of Litigation

Remaining details of the NOTA system would be worked out in the network, the Executive Branch, federal and state legislatures, and the courtroom, while legal scholars would wrestle with the system's perplexities and complications. HHS regulations and UNOS rules, which were increasingly intertwined, would govern, coordinate, and regularize the logistics of organ sharing. Moreover, the close nexus between the federal government and the facilities engaged in transplantation spurred the nationalization of transplant policy developments. Thus, as the movement to require health care providers to present the option of organ donation gathered steam, the principle of "routine inquiry" was fixed in a new Medicare requirement, as well as model state legislation.[464] On occasion, Congress directly interceded to alter financing policies or other aspects of the transplant enterprise. The 1986 budget reconciliation legislation, which strengthened UNOS's hand vis-à-vis individual transplant centers, also authorized Medicare to reimburse immunosuppressive drugs for a finite period following transplant surgery.[465] Although this about-face may have reflected the Democratic Party's takeover of the Senate in 1986, it also responded to evidence of the financial pressures hypothesized during the NOTA debate. Republican Senator Orrin G. Hatch, who had become an advocate of financing immunosuppression, and Democratic Senator Edward M. Kennedy "estimated that . . . 2,000 patients per year [became] medically eligible for transplant surgery, but [could not] afford the $5,000 to $7,000 annual cost of Cyclosporine."[466] Proposals by various Senators to finance immunosuppression

463. *Id.*

464. *See* Kathleen S. Anderson & Daniel M. Fox, *The Impact of Routine Inquiry Laws on Organ Donation*, HEALTH AFF., Winter 1998, at 65.

465. *See Major Provisions of the Fiscal 1987 Reconciliation Bill,* CONG. Q. WKLY., Nov. 1, 1986, at 2795.

466. Julie Rovner, *Administration Draws Criticism: Senate Panel Votes Grants for Post-*

with block grants or according to state determinations of need, which differed from the national approach favored by the Task Force, demonstrated that the Task Force was indeed playing an advisory role, with Congress maintaining its legislative authority.[467] In 1988, NOTA was amended to explicitly require that procurement organizations "have a system to allocate donated organs *equitably* among transplant patients according to established medical criteria."[468]

Political actors' attempts to control or steer the sharing of organs within the OPTN—among Organ Procurement Organizations (OPOs) and across state lines—generated especially tense and expansive controversy. The issue arose early in the implementation of NOTA, when New Jersey's Health Commissioner attempted to use the state's Certificate of Need process governing the operation of health care facilities to consolidate the state's OPOs. In 1987, after two of the state's three OPOs merged, "the combined organization . . . received a Certificate of Need . . . conditioned on its filing an application to become the sole statewide OPA."[469] The remaining OPO was soon absorbed and, after limited opportunity for public comment, the Commissioner certified the consolidated organization, dubbed the New Jersey Organ and Tissue Network, to act as an independently organized "statewide organ retrieval agency for the state."[470] To the Delaware Valley Transplant Program (DVTP), a Philadelphia-based organized that for thirteen years had procured organs in eastern Pennsylvania, southern New Jersey, and Delaware, this state-centric consolidation and coordination represented a disruption of longstanding relationships among medical institutions in the tri-state area.[471]

DVTP brought suit, alleging inter alia that New Jersey was trampling on the federal government's exclusive power to regulate interstate commerce merely to ensure that the nationwide process of consolidation would not divide the state into a northern territory tended by a metropolitan New York procurement agency, and a southern territory served by a metropolitan Philadelphia procurement agency.[472] New Jersey justifyied its policy toward in-state OPOs in terms of efficiency, but eventually acknowledged that DVTP was free to continue its activities in the state, and the New Jersey Network's claims of unfair competition

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transplant Drugs, CONG. Q. WKLY., June 28, 1986, at 1482.

467. *Id.*

468. 42 U.S.C. § 273(b)(3)(E) (2000) (emphasis added).

469. Del. Valley Transplant Program v. Coye (*Delaware Valley II*), 722 F. Supp. 1188, 1190 (D.N.J. 1989). In litigation spanning two years, the court first granted DVTP's petition for a Temporary Restraining Order enjoining the Commissioner's decision, Del. Valley Transplant Program v. Coye (*Delaware Valley I*) 678 F. Supp. 479 (D.N.J. 1988), and subsequently granted partial summary judgment in favor of DVTP, *Delaware Valley II*, 722 F.Supp. at 1188.

470. *Id.* at 1190.

471. *Delaware Valley I*, 678 F. Supp. at 480.

472. *Delaware Valley II*, 722 F. Supp. at 1191; *Delaware Valley I*, 678 F. Supp. at 481.

and tortuous interference by DVTP were dismissed.[473]

The reorganization at issue in the Delaware Valley litigation, though apparently driven by the state's health department, was carried out in the context of a NOTA-like process. In 1986, the New Jersey Health Commissioner organized a state Task Force "to assure that retrieved organs are distributed fairly and efficiently, so [as] to avoid the public perception that organ donating unfairly benefits those outside the community."[474] Although many of the points of contention in the Delaware Valley litigation had also arisen—and would continue to arise—on a national scale, the pronounced federalism analysis may have had the immediate effect of strengthening NOTA's conception of transplant policy as a *national* prerogative.

Changes in the structure and technology of organ allocation prompted questions of territoriality, like the NOTA debate itself. During the Delaware Valley litigation, southern New Jersey's only certified transplant program was limited to kidney transplants, whereas Philadelphia institutions were performing single- and multi-organ transplants involving the liver, heart, lungs, and pancreas.[475] By the late 1980s, numerous surgeons trained at the University of Pittsburgh Medical Center were establishing "liver transplant programs in areas of the country that previously did not have them."[476] Dissemination of surgical expertise meant that livers that would have been "exported . . . to major transplant centers were now kept for local use."[477] With financing issues now largely off the table, a new tension developed between transplant centers with established national reputations and those that primarily served local communities with shorter wait times. The centers-of-excellence question was effectively being decided by individual patients who were mobile and resourceful enough to get listed outside their local region and vote with their feet.

At the same time, improvements in liver preservation technology allowed the organs to be shipped over longer distances, leaving professionals affiliated with major centers acutely aware that the substantial disparities in liver wait times were a social artifact, rather than a clinical necessity.[478] Since UNOS data showed that higher-volume transplant facilities obtained lower mortality rates, arguments for greater organ sharing rested on expected clinical outcomes, as well

473. *Delaware Valley II*, 722 F. Supp. at 1200 & n.15; *Id.* at 1203.

474. *Delaware Valley I*, 678 F. Supp. at 480.

475. *Id.* at 480-81.

476. David L. Wiemar, *Public and Private Regulation of Organ Transplantation: Liver Allocation and the Final Rule*, 32 J. HEALTH POL. POL'Y & L. 9, 23 (2007).

477. *Id.*

478. *See id. See also* Rosamond Rhodes, *Justice in Organ Allocation*, *in* A DEATH RETOLD, *supra* note 20, at 158, 168-69.

as equity among patients.[479] Rationales for localism included the therapeutic (the importance of local transplant centers in providing postoperative care), the equitable (ensuring access to patients too sick to travel far) and the pragmatic (procurement efforts were likely to be more than perfunctory if local patients depended on them).[480] UNOS and HHS began tinkering with the liver allocation criteria, seeking to gradually increase inter-regional sharing. During the Bill Clinton Administration, these plans ignited latent conflicts of interest between small and large centers, between patients with chronic and acute conditions, between states with high and low procurement rates, and between enthusiasts of private regulation and advocates of government rulemaking.[481]

Facing prospects of prolonged litigation and congressional arbitration of the showdown,[482] UNOS and HHS hammered out a set of compromises that emphasized reciprocity and enhanced the network's ability to prevent gaming of the system, which depended on trust in anonymous procedures.[483] The conflict between UNOS, which formed policy positions on the basis of one vote per transplant center,[484] and authorities structured along other lines pressured UNOS to more clearly articulate the OPTN's domain of expertise.[485] At times, appeals to authorities outside the OPTN, including an Institute of Medicine panel that did not include any "active liver transplants surgeons,"[486] gave the entire strategy of delegation a confoundingly iterative twist. Nonetheless, the basic questions raised in the liver sharing debate were ultimately negotiated by OPTN stakeholders in a manner consistent with NOTA's commitments to equity and efficacy.

In contrast, persons whose contacts with the OPTN are more sporadic have found the courts to be an accessible forum to adjudicate the interaction between NOTA and external sources of authority, producing a steady trickle of OPTN-related litigation. However, direct legal challenges to NOTA and the system it created have thus far been rare and generally ineffectual. In *Calon v. Apfel*, a 1999 case in the Tenth Circuit, a pro se plaintiff asked for protection from state

479. Wiemar, *supra* note 476, at 23-24.

480. *See id.* at 24.

481. *See id.*

482. *See* Dulcinea A. Grantham, *Transforming Transplantation: The Effect of the Health and Human Services Final Rule on the Organ Allocation System*, 35 U.S.F. L. REV. 751, 759-65 (2001); Wiemar, *supra* note 476, at 32-36.

483. *See* Neal R. Barshes et al., *Justice, Administrative Law, and the Transplant Clinician: The Ethical and Legislative Basis of a National Policy on Donor Liver Allocation*, 23 J. CONTEMP. HEALTH L. & POL'Y 200, 224-25 (2007); Wiemar, *supra* note 476, at 37-41.

484. *See* Rhodes, *supra* note 478, at 169.

485. Wiemar, *supra* note 476, at 44.

486. *Id.* at 34.

or federal interference with his contemplated assisted suicide.[487] By this time, the U.S. Supreme Court had already held in *Vacco v. Quill*[488] and *Washington v. Glucksberg*[489] that state prohibitions on assisted suicide did not violate the Fourteenth Amendment's Equal Protection Clause or the substantive liberty protected by its Due Process Clause, so the Tenth Circuit summarily dismissed almost all of the plaintiff's claims. On appeal, the plaintiff "[f]or the first time" also challenged NOTA, alleging that the Act's prohibition on organ purchases "prevent[ed] him from selling his organs to pay for his euthanasia."[490] The court did not respond to this claim except to note that it "generally will not address issues raised for the first time on appeal."[491]

Thus, the *Calon* plaintiff directly contested the ban on organ sales, but his claim—dismissed as untimely—is best understood as an applied challenge, rather than a facial challenge to the Act. The gravamen of his complaint was that the prohibition impermissibly interfered with his right to kill himself. Somewhat differently, some scholarly literature argues against the ban on selling one's own organs on the ground that it violates a constitutional right of bodily autonomy, reflected in the Supreme Court's due process jurisprudence concerning abortion and heroic measures at the end-of-life.[492] Clearly, the Court does not currently recognize a general right to bodily autonomy. One need merely consider the assisted suicide cases or restrictions on the use of prescription and illicit drugs. In *Lawrence v. Texas*, Justice Kennedy, writing for the Court, suggested that moral repugnance alone may be inadequate to trump the liberty interest contained in the Due Process Clause.[493] However, repugnance about commodifying the body is not the only factor rationale for banning organ sales. Protecting would-be organ sellers against the physical risk of bodily harm or death during surgery, for example, could be asserted as a state interest. While this concern was not explicitly mentioned in the congressional debate over NOTA, it has been prominent in public and scholarly discussion of organ procurement since the Uniform Anatomical Gift Act of 1968.[494]

Another case, *Wheat v. Mass*, arising in the Fifth Circuit, might be regarded as a challenge to the UNOS *system* on antitrust grounds.[495] The decedent in *Wheat* was placed on the liver transplant waitlist after the Louisiana state

487. Calon v. Apfel, 1999 U.S. App. LEXIS 7955, at *2-3, *5 (10th Cir. Apr. 26, 1999).

488. 521 U.S. 793 (1997).

489. 521 U.S. 702 (1997).

490. Calon 1999 U.S. App. LEXIS at *9-10.

491. *Id.* at *10.

492. *See, e.g.*, Lori B. Andrews, *My Body, My Property*, HASTINGS CENTER REP., Oct. 1986, at 28.

493. 539 U.S. 558 (2003).

494. *See* Sanders & Dukeminier, *supra* note 109, at 388-390.

495. Wheat v. Mass, 994 F.2d 273, 275 (5th Cir. 1993).

government confirmed that it might pay for the transplant. However, the woman died before such transplant could be arranged.[496] Her surviving family members alleged that two medical institutions and various doctors had discriminated against their deceased relative "on the basis of age, sex, and poverty." In addition to these claims, which the circuit court rejected for lack of evidentiary support, the relatives reportedly "argue[d] that they [were] entitled to show that UNOS and its members such as Ochsner [Hospital] maintain a monopoly on organ transplants and create market harm by restricting the availability of such services and charging prohibitively high prices in violation of the Sherman Anti-Trust Act."[497] The court called these claims "frivolous," noting:

> Appellants have failed to state a claim under § 1 of the Sherman Act because they have failed to allege any effect on interstate commerce, and have failed to show Ochsner's requisite market power or intent to monopolize the market. Appellants have also failed to state a claim under § 2 of the Sherman Act because they have not shown an agreement between two or more economic entities, a specific intent to monopolize, or any overt act in furtherance of the conspiracy.[498]

Importantly, although the circuit court's account of the antitrust claim mentioned UNOS as well as Ochsner Hospital, UNOS, unlike the hospital, was never named as a defendant in the suit. Presumably for this reason, scholarly articles discussing *Wheat* (including the antitrust claim) have invariably described it as a case about a hospital, rather than about the entire UNOS network.[499] Nonetheless, should a judge find that the network's member hospitals violate the Sherman Act by following its uniform rules, the network as it presently functions would effectively be dismantled.

In contrast, scholarly articles questioning whether UNOS could survive antitrust scrutiny have largely focused on the network itself, rather than on specific member institutions. This focus makes sense under the Sherman Act criteria enumerated by the *Wheat* court. While it questionable whether any individual hospital or organ procurement organization has the market power to dominate a large geographical region, anticompetitive behavior can also consist of an agreement between two or more entities—as in network policies. The antitrust scholarship suggests that liability for illegal restraint of trade could

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496. *Id.*

497. *Id.* at 277.

498. *Id.*

499. *See, e.g.*, Charles K. Hawley, *Antitrust Problems and Solutions To Meet the Demand for Transplantable Organs*, 1991 U. ILL. L. REV. 1101; Benjamin Mintz, *Analyzing the OPTN under the State Action Doctrine—Can UNOS's Organ Allocation Criteria Survive Strict Scrutiny?*, 28 COLUM. J. L. & SOC. PROBS. 339, 367 n.145 (1995).

theoretically arise from either "horizontal" collaboration among the network's member institutions or "vertical" collaboration between member institutions and UNOS.[500] In practice, UNOS member institutions do not make horizontal agreements with each other to restrain trade, but vertical market restraints have been documented. Specifically—and controversially—UNOS developed membership rules that would ensure territorial exclusivity among its constituent regional organ procurement organizations, and UNOS policies favored the expansion of services at "established transplant program[s]" over similar expansion of new or small-scale programs.[501] As a "private standard-setting organization," UNOS would be subject to especially rigorous scrutiny because it actively enforces its rules rather than merely issuing guidelines regarding how member institutions should share organs with other network members.[502] Vertically-enforced rules or regulations will ordinarily escape antitrust liability if they tend to "regulate[]" or "promote[] competition," rather than "suppress[ing] or destroy[ing]" it.[503]

This is a high hurdle for UNOS, given the all-embracing nature of its rules, but it might be overcome by the argument that strict regulation across transplant institutions is necessary to maintain public confidence in organ donation. While member institutions do not directly compete against each other by bidding for organs, they can compete for recipient patients—for example, by advertising their surgical success rates. Moreover, in the context of health care delivery, courts have tended to interpret the competitiveness criterion flexibly, with an eye toward efficiency and clinical outcomes.[504] Conceivably, the limited mode of structured competition allowed by UNOS optimizes the delivery of transplant medicine within the bounds of the OPTN's public service ethos.

Similarly, because under NOTA a single contractor (UNOS) is given managerial control over the OPTN, UNOS could potentially run afoul of antitrust law's "essential facilities" doctrine. Under this doctrine, if a single entity controls a unique resource (such as all the railroad terminals in a major city—or perhaps donated organs), it may have a legal obligation not to "exclude or disadvantage customers arbitrarily or invidiously."[505] The primary concern raised from this standpoint is that UNOS only shares information and organs among transplant

500. *See* Hawley, *supra* note 499, at 1115-18.

501. Blumstein, *supra* note 10, at 26.

502. *See* Hawley, *supra* note 499, at 1112-13.

503. Bd. of Trade of Chi. v. United States, 246 U.S. 231, 238 (1918).

504. *See, e.g.*, Weiss v. York Hosp., 745 F.2d 786, 821 (3d Cir. 1984) ("[W]ithin the scope of a hospital's 'public service' function . . . rule of reason analysis . . . would control . . . . [I]t seems obvious that by restricting staff privileges to doctors who have achieved a predetermined level of medical competence, a hospital will enhance its reputation and the quality of the medical care that it delivers. Thus such action is pro-competitive, and therefore, permissible . . . .").

505. Hawley, *supra* note 499, at 1118-19.

centers that belong to the network (and subscribe to its rules).[506] Under existing law, UNOS could likely justify this policy on practicability grounds—allowing transplant centers to participate in the network without any means for ensuring that they comply with the network's organ allocation policies would undermine a major purpose of the network, more efficient organ sharing. As a practical matter, it is unclear who would file suit, as hospitals are unlikely to establish transplant centers outside the network because they would be ineligible for Medicare reimbursement. Individual patients do not directly transact with UNOS (which is largely a standards-setting and rule-enforcing body), so they are not potential "customers" of the network in the ordinary sense of the word.

A case can be made, however, that none of these doctrinal tests apply to UNOS because Congress implicitly exempted the contract from antitrust legislation when it enacted legislation governing the OPTN. As a critic of the monopolistic aspect of the OPTN, Charles Hawley, acknowledged, "by setting up a pervasive legislative scheme such as the NOTA, Congress arguably agrees that 'competition is [sic] an inadequate means of vindicating the public interest.'"[507] For this reason, scholarly assessments of the Sherman Antitrust Act's applicability to the OPTN have queried just how tightly NOTA limited UNOS's choices regarding how to organize the network.[508] The history of the OPTN suggests that this attention to NOTA reflects a sort of tunnel vision in which federal transplant policy is reduced to the 1984 Act. The stronger argument for an implicit antitrust exemption may derive from the 1986 Medicare amendments, which required transplant institutions to participate in the OPTN as a condition of reimbursement. Before the amendments, NOTA contemplated that a single contractor would operate a national "Organ Procurement and Transplant Network," but the legislation was silent as to whether the contractor would allow transplant centers to set their own policies (e.g., regarding who gets priority on internal waitlists) while taking advantage of UNOS's services, such as computerized organ matching. In contrast, the Medicare amendments, by effectively requiring transplant centers to abide by UNOS rules, clearly envisioned that the contractor would exercise monopolistic power over organ allocation. If UNOS were subject to antitrust law, this requirement would be virtually meaningless, because the very UNOS rules that Congress sought to make binding in 1986 would be judicially invalidated as illegal restraints on trade.

In addition to substantive due process and antitrust questions, NOTA and the

506. *See id.* at 1113-15.

507. *Id.* (quoting United States v. AT&T, 461 F. Supp. 1314, 1323 (D.D.C. 1978) (citing numerous other cases)). *AT&T* actually reads "competition to be an inadequate means." *AT&T*, 461 F. Supp. at 1323.

508. *See* Hawley, *supra* note 499, at 1112-14. *See also* Blumstein, *supra* note 10.

1986 amendments raised questions about the extent to which policy decisions enforced by federal power could be delegated to a private, independent agency. The underlying concern was not delegation per se, but rather the perception that UNOS was free to make policy behind closed doors, without giving the public notice and an opportunity to comment on proposed rules, as is required of federal agencies under the Administrative Procedure Act.[509] To preempt this objection, Congress in 1988 passed an "Organ Transplant Amendments Act" clarifying that the OPTN's policies would not be considered legally binding unless the HHS had subjected them to the formal notice-and-comment process.[510] Despite this development, transplant centers still operate under substantial pressure to comply with UNOS policies that have not gone through the notice-and-comment process. For example, violating the UNOS guideline stipulating that no more than five percent of a transplant center's kidney transplants should be to nonresident aliens will "trigger[] an audit of all activities pertaining to transplantation of non-resident aliens." If a center repeatedly exceeds the guideline "without justification or explanation, the matter will be referred to the Membership and Professional Standards Committee."[511] Presumably, hospitals will try to avoid such investigations of their admission policies and allocation practices, because they run the risk of being expelled from the network, thereby losing federal funding, if improprieties are discovered in the course of the investigation. Indeed, a UNOS investigation itself may be a source of negative publicity in the local media.[512]

The increased involvement of HHS in UNOS policymaking increases the likelihood that UNOS would be regarded as a state actor for the purposes of anti-discrimination law, namely the Fourteenth Amendment's Equal Protection Clause. One basis for finding state action—if the entity is engaged is an activity traditionally reserved for the state—has questionable applicability to the OPTN because transplantation, and hence organ allocation, is such a recent innovation. A second basis—a "sufficiently" tight nexus between the action and the state—would likely apply to UNOS's activities. While simply operating as a government-sanctioned monopoly does not necessarily make a private entity a

509. 5 U.S.C. § 551 *et seq.* (2000).

510. *See* U.S. GEN. ACCOUNTING OFFICE, ORGAN TRANSPLANTS: INCREASED EFFORT NEEDED TO BOOST SUPPLY AND ENSURE EQUITABLE DISTRIBUTION OF ORGANS 30 (1993) (referring to Title IV of the Health Omnibus Programs Extension of 1988, Pub. L. No. 100-607). In at least one case, a UNOS performance standard, considered as a matter of administrative law, was invalidated as "arbitrary and capricious." Ark. Reg'l Organ Recovery Agency, Inc. v. Shalala, 104 F. Supp. 2d 1084 (E.D. Ark. 2000)).

511. United Network for Organ Sharing, OPTN Evaluation Plan, http://www.optn.org/content cocuments/eval_plan_VII_6.0.pdf (last visited Nov. 30, 2007).

512. *See, e.g.*, Cheryl Clark, *Transplant Program Chief Steps Down*, SIGN ON SAN DIEGO, Feb. 2, 2006, http://www.signonsandiego.com/news/education/20060202-9999-7m2liver.html.

state actor, specific criteria for finding a "sufficient nexus" include the degree of public financing, the extent to which the private action is influenced by regulatory inducements, and whether the state and the private entity function as "interdepeden[t] . . . joint participant[s]" in the activity. UNOS and HHS are tightly intertwined through financial links, agency oversight of UNOS's rulemaking process, and an annual reporting requirement. Finally, specific actions taken by UNOS could be deemed state action if they are compelled by the government.[513]

While the appellate court in *Wheat* found that a UNOS member hospital was not a state actor, "[n]o court has considered the question of whether the OPTN is a state actor."[514] UNOS deserves some of the credit for this situation. The state actor question would be important if UNOS were accused of illicit discrimination in allocating organs because the Equal Protection Clause is limited in its applicability to state action and the OPTN falls outside other anti-discrimination laws.[515] In practice, UNOS, which now includes a "Minority Affairs Committee" as part of its internal governance structure, has been responsive to concerns that its allocation criteria may have a disparate impact on people of color, and it seems highly unlikely that the organization would engage in the sort of invidious intentional discrimination—whether on the basis of race, disability, age, or some other classification—that is prohibited under current equal protection jurisprudence.[516]

Although courts have not had to confront the state actor problem with respect to UNOS, it is academically interesting because it plays on an ambiguity that has persisted since NOTA's enactment: how to characterize the mix of "private" and "governmental" features constituting the OPTN. Another ambiguity of the OPTN—to what extent its member institutions engage in interstate activity by participating in the network, and to what extent they remain discrete local actors—does have implications in the courtroom. Due process requires that a court have personal jurisdiction over the defendant; in modern American civil procedure, an out-of-state defendant must have had "minimum contacts" with the state "such that the maintenance of the suit does not offend 'traditional notions of fair play and substantial justice.'"[517] Thus, in suits brought

513. *See* Mintz, *supra* note 499.

514. *Id.* at 367 n.145.

515. Title VI of the Civil Right Act of 1964 covers federally subsidized programs, but government contractors are not included in this category, and 42 U.S.C. § 1983 applies to actions taken under color of *state* law. *See* 42 U.S.C. 1983 (2000).

516. *See* Ayres et al., *supra* note 457; Press Release, United Network for Organ Sharing, OPTN/UNOS Continues to Improve Accuracy in Donor/Recipient Matching (Feb. 6, 2004), http://www.unos.org/news/newsDetail.asp?id=308.

517. Int'l Shoe Co. v. Washington, 326 U.S. 310 (1945) (quoting Milliken v. Meyer, 311 U.S. 457, 463 (1940)).

against UNOS members outside their home state, courts have assessed whether the defendant's participation in the network constituted sufficient contact with the forum to create personal jurisdiction. These inquiries tend to be highly fact-specific and difficult to generalize. In a breach of contract suit by a Pennsylvania energy consulting firm against a New Jersey medical center, a Pennsylvania court found insufficient contact between the medical center and Pennsylvania, despite the center's participation in UNOS. Even though the center was part of a three-state regional organ sharing arrangement encompassing New Jersey, Pennsylvania, and West Virginia, the court noted that within the UNOS system, the medical center "decides neither the origin of the organs they receive nor the destination of the organs they donate."[518]

Whereas the lack of discretion accorded to UNOS members under network rules seemed to count against a finding of sufficient contact in the New Jersey-Pennsylvania case, in other cases the *predictable* dynamics of organ sharing within a UNOS region have counted in favor of finding sufficient contact. "Due to the nature of [the] organ sharing network and the inherent necessity for regulated serological testing established by UNOS, [an Alabama trial] court [found] . . . sufficient minimum contacts with the State of Alabama to support in personam jurisdiction over . . ." an out-of-state laboratory accused of failing to detect a hepatitis-infected kidney that was sent to Alabama for transplantation.[519] An appellate court subsequently overturned this ruling, rejecting the trial court's argument that human kidneys were inherently dangerous, lessening the "showing" necessary to find sufficient contact.[520] In another case, however, a federal district court found that an organ procurement organization that sent approximately one kidney per year to North Carolina had sufficient contact with the state to establish personal jurisdiction where this activity was "methodical."[521] The procurement organization "contend[ed] that its involvement with North Carolina was simply a matter of chance. Because there was a six-antigen match, it had no choice but to comply with UNOS's distribution requirements and had no control whatsoever where the kidney was to be sent." The federal court countered that the procurement organization had assumed this chance by maintaining membership in UNOS and participating in its electronic database over an extended period of time.[522]

Organ allocation is fraught with ethical, psychological, and medical concerns. Given the short timeframe before organs deteriorate outside the body,

518. UtiliTech, Inc. v. Somerset Med. Ctr., No. 06-1232, 2006 U.S. Dist. LEXIS 40126, at *10 (E.D. Penn., June 15, 2006).

519. *Ex parte* Hosp. Espanol de Auxilio Mutuo de P.R., Inc., 945 So. 2d 437, 441 (Ala. 2006).

520. *Id.* at 445.

521. Slaughter v. Life Connection of Ohio, 907 F. Supp. 929 (N.D.N.C.1995).

522. *Id.* at 933.

the number of actors involved in organ transfer, competing notions of distributive justice, and the risk of infection to transplant recipients, the OPTN was all but certain to be implicated in litigation. The relative paucity of cases naming UNOS as a defendant suggests that the contractor is by-and-large fulfilling its expected role within the NOTA system. Amid a persistent scarcity of transplantable organs, however, members of the transplant community and outside critics are increasingly questioning the premises of that system. Paradoxically, one of the main factors that provided the impetus for NOTA—the need for more transplantable organs—gave ammunition to the Act's critics following its passage.

IV. CONCLUSION

A. Recent Policy Developments

The demand for transplant surgery can be measured in a number of ways, but it is clearly growing. In 1996, about 18,000 people were waiting for a kidney transplant and roughly 8000 were waiting for a liver transplant. These two organs had the largest waitlists and the longest wait times. In 2006, the kidney waitlist had increased to more than 29,000 people, and roughly 11,000 were waiting for a liver. For kidneys (where transplant candidates can survive on dialysis for an extended period of time), median time to transplant varied from year to year, but the general trend was upward.[523] Explanations for such statistics are multifold, and the trend is likely to continue. In 1985, 2.7% of the American population had been diagnosed with diabetes, a leading cause of kidney failure; by 2005, the national diabetes diagnosis rate had increased to 5.5%.[524] Factors contributing to this increase include increased obesity, the aging of the population, and changing ethnic demographics.[525] Certain social changes, such as the "graying" of the population and fewer undiagnosed ailments, probably increase the number of people placed on the waitlist for virtually every organ. Additionally, as kidney transplantation in particular has become a routine procedure, patients are being listed as transplant candidates who in the past would have been given less

523. U.S. ORGAN PROCUREMENT & TRANSPLANT NETWORK & SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS, 2006 OPTN/SRTR ANNUAL REPORT: TRANSPLANT DATA 1996-2005 (2006), *available at* http://www.optn.org/AR2006/default.htm (follow the "Select Download Option" hyperlink).

524. Ctrs. for Disease Control & Prevention, Dep't of Health & Human Servs, Detailed Data for Prevention of Diabetes, http://www.cdc.gov/diabetes/statistics/prev/national/tprevage.htm (last visited Nov. 30, 2007).

525. *See* Karmeen D. Kulkarni, *Food, Culture, and Diabetes in the United States*, 22 CLINICAL DIABETES 190 (2004).

aggressive treatment.[526]

To say that the supply of organs is not keeping up with this increased demand would be an understatement. Between 1986 and 1996, the "potential [cadaveric] donor pool" and the number of "ideal" donors (aged sixteen to twenty) decreased—not just relative to the donee population, but also in absolute terms. Medical literature has attributed this decrease to "improved safety measures such as helmet laws, air bags, and more stringent drunk-driving laws," as well as greater detection of infectious diseases such as HIV and hepatitis C in potential organ donors.[527]

Given the inadequacy of the supply of cadaveric organs, transplant surgeons and patients are increasingly turning to living donors. Although some of the earliest solid organ transplants involved close relatives going under the knife to donate a "spare" kidney, the medical profession has historically been reluctant to use living donors. Removing an organ from a healthy donor can arguably be reconciled with the Hippocratic duty to "do no harm," because the donor may derive psychological benefits from seeing the recipient survive in improved health. However, when volunteer donors present themselves, transplant professionals recognize that these individuals may feel coerced to donate by family pressures or by dire financial circumstances (since there may be an illicit payment). Potential living donors must undergo psychological screening, but given the desperate need for organs and changing cultural norms, one critic of living donation has suggested that the traditional anxieties it provoked among transplant professionals seem to be attenuating.[528] A particularly disturbing trend involves American residents traveling overseas to obtain organ transplants from dubious sources (including countries with poor human rights records) and then returning to the United States for follow-up care.[529] Such "back alley" transplantation not only threatens the health of the organ providers, but also puts recipients' health at risk.

Meanwhile, greater donor awareness (specifically, awareness of individually-directed living donations and familiarity with individuals on the transplant waitlist) may be heightening expectations of donor control over cadaveric organs. In a case heard by the Second Circuit in 2005, Robert Colavito sued Good Samaritan Hospital Medical Center and the New York Organ Donor

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526. *See* Nancy Scheper-Hughes, *Consuming Differences: Post-human Ethics, Global (In)Justice, and the Transplant Trade in Organs*, *in* A DEATH RETOLD, *supra* note 20, at 205.

527. R.J. Taylor & J.S. Engelsgjerd, *Contemporary Criteria for Cadaveric Organ Donation in Renal Transplantation: The Need for Better Selection Parameters*, 14 WORLD J. UROLOGY 225, 225-29 (1996).

528. Scheper-Hughes, *supra* note 526, at 209.

529. *Id. See also* Thomas Diflo, *The Transplant Surgeon's Perspective on the Bungled Transplant*, *in* A DEATH RETOLD, *supra* note 20, at 70, 77.

Network (NYODN) over the "misdeliver[y]" of a kidney intended for him.[530] After Colavito's friend Peter Lucia died, Lucia's widow testified that she had directed the regional network to give *both* of Lucia's kidneys to Colavito if necessary to restore the friend's renal function. She also signed a form stating that "[i]f it is not feasible for medical or logistical reasons for the donated organs . . . to be used by the person to whom I direct it, the NYODN may allocate the organs . . . as if I had not made a directed donation."[531] While Colavito was being prepared for surgery in Miami, the transplant surgeon there discovery that the kidney he had received was damaged. When the surgeon called NYODN to track down Lucia's other kidney, he was apparently led to believe that it had been allocated to another patient—who underwent the actual transplant days later.[532]

In a further wrinkle, histocompatibility tests, which can be performed even as the patient is being prepped for surgery, purportedly indicated that the kidneys were a devastating mismatch for Colavito's antigen makeup—a position clearly stated in the affidavit of Dr. Robert Gaston, who had previously drawn critical attention to the ethnic implications of antigen matching.[533] The circuit court, in the words of Judge Sack, found it "difficult to ignore the fact that by diverting a kidney that was in all likelihood of no use to [the plaintiff], another life was apparently spared."[534] The court found that the NYODN official on the other end of the line lacked the requisite knowledge about the whereabouts of the other kidney to sustain a fraud charge.[535] The case also presented novel questions of state law; a New York state appellate court denied any basis for granting Colavito relief on either a conversion theory (denying a property right to "an incompatible kidney") or a negligence theory under the state's anatomical gift act (because the plaintiff could not actually "benefit from either kidney").[536] While the case's unusual facts left the rights of donors and donees unsettled, the interplay between UAGA's expectation of fiduciary responsibility and NOTA's assumptions about the public good remains as a zone of friction.

Since the inception of NOTA, with its ban on organ sales, assorted critics have advocated amending or overruling the law. For example, in 1989, Prof. Henry Hansmann suggested the ethical concerns raised by transplantation did not neatly reduce to side effects of organ sales. Weighing the moral hazards associated with different policies (such as the health risks associated with living donation, which is to some extent a substitute for cadaveric organ procurement),

530. Colavito v. N.Y. Organ Donor Network, Inc., 438 F.3d 214, 221 (2d Cir. 2006).

531. *Id.* at 217.

532. *Id.* at 218.

533. *Id.* at 219-20.

534. *Id.* at 223 n.11.

535. *Id.* at 222.

536. Colavito v. N.Y. Organ Donor Network, Inc., 860 N.E. 2d 713, 722 (N.Y. Ct. App. 2006).

Hansmann advocated allowing a futures market for cadaveric organs.[537] Public interest in alternatives to NOTA has increased. According to one sociologist, "media evidence shows that discussion of cash incentives for organs has consistently increased since the late 1980s."[538] Further, more recent media coverage has contained more "policy-oriented discussions of financial incentives as a potential solution to the organ shortage, rather than news stories about organ sales"—a remarkable statement given widespread fascination with the "human" aspects of transplantation, as opposed to policy details.[539] Another proposal that does not rely on financial incentives, namely "presumed consent" for cadaveric organ donation, has also received substantial attention, though the total number of potential cadaveric organ donors is now estimated to be fewer than the number of people receiving transplants annually and far fewer than the number on the waitlist.[540] Concerns about this approach range from the practical (political backlash) to the constitutional (Takings Clause implications).[541]

American libertarian intellectuals took a renewed, personal interest in transplant policy after medical writer Sally Satel, a resident scholar at the American Enterprise Institute, obtained a needed kidney from libertarian journalist Virginia Postrel in 2006, exposing both commentators to the frustrations of a highly-regulated allocation system.[542] In a noteworthy recent challenge to NOTA, constitutional scholar Eugene Volokh posited a right to

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537. Hansmann, *supra* note 266.

538. Kieran Healy, *Sacred Markets and Secular Ritual in the Organ Transplant Industry*, *in* THE SOCIOLOGY OF THE ECONOMY 322 (Frank Dobbin ed., 2004).

539. *Id.* at 323. This statement should be read with a healthy measure of caution. For reasons that are unclear, Healey apparently excluded "horror stories . . . concerned with foreign reports of organ sales" from a key graph, and it is not clear whether he likewise ignored them in his discussion in the text of the article. *Id.* at 322 & fig. 12.3.

540. *Hearing Before the Subcomm. on Human Resources of the H. Comm. on Government Reform and Oversight*, 105th Cong. (Apr. 8, 1998) (statement of Claude Earl Fox, M.D., Acting Administrator, Health Resources and Services Administration, U.S. Department of Health and Human Services), *available at* http://www.hhs.gov/asl/testify/t980408a.html (last visited Nov. 30, 2007).

541. *See* Erik S. Jaffe, *She's Got Bette Davis['s] Eyes: Assessing the Nonconsensual Removal of Cadaver Organs Under the Takings and Due Process Clauses*, 90 COLUM. L. REV. 528, (1990) (discussing when the Takings Clause would apply to the appropriation of body parts). *See also* Dukeminier, *supra* note 43, at 833 (rejecting Takings Clause objection to presumed consent by analogy to precedent involving the abolition of dower). The sources of frustration motivating such proposals are relatively transparent. *See, e.g.*, Christian Williams, Note, *Combatting* [sic] *the Problems of Human Rights Abuses and Inadequate Organ Supply Through Presumed Donative Consent*, 26 CASE W. RES. J. INT'L L. 315 (1994).

542. *See, e.g.*, Virginia Postrel, Op-Ed, *The Surgery Was Simple: The Process Is Another Story*, USA TODAY, Oct. 25, 2006, at A13; Sally Satel, Op-Ed, *A Living Donor Let Me Live On*, USA TODAY, Oct. 25, 2006, at A13.

"medical self-defense," grounded in the common law right to self-defense and a recent case recognizing a terminally ill patient's right to "hir[e] a doctor to administer" an experimental therapy, once it is proven safe, outside the context of a clinical trial.[543] The novel aspect of Volokh's theory is that it leads to a dying person's right to buy a lifesaving organ (rather than a healthy person's right to sell non-vital organs). As currently formulated, however, it is difficult to distinguish Volokh's "medical self-defense" concept from a legal defense of necessity. He apparently does not mean to authorize poor patients to steal medicine from drugstores, but he does not flesh out the legal or moral basis for this distinction. A point in favor of some such right is its resonance with broader principles in American legal culture. In societies that recognize a right to health care, this right is often closely associated with state protection against dangerous or invasive pathogens.[544] While state and municipal governments have historically performed a similar public health function in the United States,[545] they never monopolized the police power: Traditions of personal self-defense and widespread firearms ownership are deeply rooted. A right to self-preservation by medical means could empower similarly situated individuals whose lives are threatened by deteriorating health conditions. In a legal regime that has long recognized self-help and is skeptical of purported social or economic rights, a right to actively pursue better health may be the logical parallel of the right to health care in a full-fledged welfare state.

Volokh's intellectually audacious, direct challenge to NOTA seems to be an exception amid the current generation of policy literature. More common are less sweeping proposals to generate additional organ donations by innovating within the NOTA framework or interpreting the statute with a new gloss.[546] The most noteworthy attempt to boost donation rates by altering the organ allocation dynamic within the NOTA system is probably LifeSharers, a nonprofit network of individuals who "promise to donate upon death, and they give fellow members first access to their organs."[547] The arrangement takes advantage of UNOS's

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543. Volokh, *supra* note 5, at 1814-15.

544. *See, e.g.*, Eleanor D. Kenney & Brian Alexander Clark, *Provisions for Health and Health Care in the Constitutions of the Countries of the World*, 37 CORNELL INT'L L.J. 285, 305 (2004) at 305 (quoting CONSTITUTION DE LA RÉPUBLIQUE ALGÉRIENNE DÉMOCRATIQUE ET POPULAIRE [Constitution] ch 4, art. 54 (Alg.): "All citizens have the right to health protection. The state assures the prevention and the right against epidemic and endemic illnesses.").

545. *See* Jacobson v. Massachusetts, 197 U.S. 11 (1904).

546. Gradual change is a theme of Healy's scholarship on organ procurement. *See* KIERAN HEALY, LAST BEST GIFTS: ALTRUISM AND THE MARKET FOR HUMAN BLOOD AND ORGANS (2006). This scholarship draws on sociologist Viviana Zelizer's earlier work about the acceptance of life insurance in American culture. *See* VIVIANA ZELIZER, MORALS AND MARKETS: THE DEVELOPMENT OF LIFE INSURANCE IN THE UNITED STATES (1976).

547. LifeSharers: Organs for Organ Donors, http://www.lifesharers.org/ (last visited Nov. 30,

policy of allowing dying people to donate organs to specific named individuals (directed donation), but it is constrained by the need for minimally acceptable biological matches. In 1994, Pennsylvania developed "a pilot program for reimbursement of funeral expenses to donor families [that] was not implemented because the state's attorney general was cautioned by government officials that such a program would be a violation of NOTA."[548] Because funeral expenses are incurred whenever someone dies and are not a byproduct of organ donation (in contrast to, say, tissue typing expenses), paying for burials seemed tantamount to paying for organs. Although the Pennsylvania initiative was never operationalized, NOTA does allow "special projects designed to increase the number of organ donors," and precisely where this provision bumps up against NOTA's ban on remuneration remains unclear.[549]

Several manipulations of the directed donation exception that arguably contravene NOTA are already uneasily tolerated. In one of these innovative approaches, "a living donor donates a kidney to an unknown, compatible recipient on the list for a deceased donor. The living donor's intended (but incompatible) recipient receives in turn some priority on the deceased-donor waiting list, and this priority may significantly shorten his waiting time."[550] In the other variation, sometimes called Paired Exchange, incompatible pairs of living donors and would-be recipients are matched with each other, so that in each pair, the donor gives up a kidney and the recipient gets one, although the donations occur in a circular fashion to circumvent incompatibilities.[551] In the first arrangement, a person who is unable to donate a kidney to a loved one can give the kidney to stranger in order to give the loved one priority on the waitlist (adding one extra donation to the system). In the second arrangement, a living donor gives the kidney to a stranger so that a loved one can get a kidney from another stranger (creating no immediately tangible benefit for others on the waitlist who do not likewise have a willing living donor, but reducing the size of the list two-by-two). In either case, the motivation underpinning directed donation (helping a loved one) is combined with the matching process underpinning cadaveric donation to strangers. The problem, from the standpoint of NOTA, is that the donors appear to be trading the organs for something

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2007). *See generally* Mark S. Nadel & Carolina A. Nadel, *Using Reciprocity To Motivate Organ Donations*, 5 YALE. J. HEALTH POL'Y L. & ETHICS 293, 316-17 (2005).

548. Robert Arnold et al., *Financial Incentives for Cadaver Organ Donation: An Ethical Reappraisal*, 73 TRANSPLANTATION 1361, 1363 (2002).

549. 42 U.S.C. § 273(a)(3) (2000) (repealed 2004). Although they wrote before this flexible provision was removed, Arnold et al., *supra* note 548, at 1362, assumed that NOTA would have to be revised before a demonstration project utilizing "financial incentives" would be permissible.

550. Legality of Alternative Organ Donation Practices Under 42 U.S.C. § 274e, 31 Op. Off. Legal Counsel 1 (2007), *available at* http://www.usdoj.gov/olc/2007/organtransplant.pdf.

551. *Id.*

substantial: another organ or improved standing on the waitlist. While no written contract is signed, in a Paired Exchange two or more transplants are scheduled simultaneously so that no one can back out.

In March 2007, the Justice Department's Office of Legal Counsel (OLC) sent a memorandum opinion to the General Counsel of HHS clarifying the Justice Department's view that Paired Exchange and Living Donor/Deceased Donor Exchange "do not violate [NOTA's] prohibition on transfers of organs for 'valuable consideration.'"[552] The memorandum cited a number of factors pointing to this conclusion. First, a variety of other state and federal statutory provisions implied that "valuable consideration" was "monetary or at least has a readily measurable pecuniary value."[553] Further, a general canon of statutory construction holds that different provisions of a legislative scheme should be read in a way that minimizes internal conflict, and elsewhere NOTA asserts a goal of "increas[ing] the supply of donated organs."[554] Similarly, NOTA is predicated on Congress's authority under the Constitution's Commerce Clause, and recent jurisprudence has favored an "economic" conception of Congress's power to regulate interstate commerce.[555] Finally, NOTA makes organ purchases a crime, and the principle of lenity requires that ambiguities in criminal law be resolved "in favor of a narrower" definition of the conduct being criminalized.[556] Interpreting the statute in this aggressively pragmatic way inevitably raises questions of the "how far is too far" variety. For example, since NOTA only bans transferring human organs for valuable consideration, would courts tolerate some compensation for living organ donors' time and pain? If so, do courts have the institutional capacity to limit this compensation according to rational principles on the ground that once it reaches a certain level, it becomes tantamount to buying an organ?[557]

The most radical change that one could imagine occurring within the current statutory language would involve re-interpreting NOTA to ban only the involvement of "middlemen" in organ sales, as was apparently the intent of the California statute. The corresponding wording in NOTA—prohibiting people from "knowingly acquir[ing,] receiv[ing], or otherwise transfer[ring] any human organ for valuable consideration"—is, without further gloss, somewhat

552. *Id.* at 1 (emphasis omitted).

553. *Id.* at 4. OLC noted that *Black's Law Dictionary* added the "pecuniarily measurable" criterion to its definition of "valuable consideration" in 1999. *Id.* at 5.

554. 42 U.S.C. § 274(b)(2)(k) (2000).

555. United States v. Lopez, 514 U.S. 549 (1995).

556. Legality of Alternative Organ Donation Practices Under 42 U.S.C. § 274e, *supra* note 550, at 6.

557. For a contemporary consideration of the inferential objectification of pain in legal and administrative contexts, see Adam J. Kolber, *Pain Detection and the Privacy of Subjective Experience*, 33 AM. J.L. & MED. 433 (2007).

ambiguous as to precisely what may not be done "for valuable consideration."[558] Is the prohibited consideration (a) compensation for the organ or (b) compensation for the acquisition? Devoid of any context, a relatively natural reading of the statute's language would allow a person to exchange his or her own kidney for "valuable consideration," but would prohibit a person from acquiring or transferring a kidney if that act would be compensated. Of course, transplant recipients themselves would gladly "receive" organs without "valuable consideration," so it would be illogical to interpret the statute as banning the patients themselves from being compensated for undergoing transplant surgery—this was not a serious concern. However, one set of actors could conceivably "acquire, receive, or otherwise transfer" human organs and demand valuable consideration for doing so: third parties engaged in for-profit organ procurement.[559] Such entities might have existed legally in the United States but for NOTA. If this interpretation seems strained, it is not so as a matter of grammar, but rather because it is inconsistent with certain aspects of the legislative history of NOTA, such as a hostility toward commodification of human organs, not specifically limited to transactions involving brokers. (Indeed, Title III of NOTA was titled "Prohibition of Organ Purchases," not "Prohibition of Compensated Organ Acquisition."[560]) Recall, though, that the kidney purchasing schemes that initially motivated NOTA were envisioned as business-like enterprises. For this reason, it would not be entirely inconceivable for a court to read the language merely to ban third parties from profiting from organ procurement on a per-transaction basis, especially if public sentiment were to shift dramatically in favor of allowing some sales. The fact that organ allocation policy is evolving in the absence of formal amendments to NOTA suggests that many policymakers believe reforms are needed, but Congress is reluctant to revisit the statute. Unless this political environment changes, one can expect further evolution within the NOTA system, loosely interpreted.

B. Assessment

From the legislative history of NOTA, and a historical inquiry into the political culture in which the NOTA Task Force promulgated its recommendations, it is possible to assess the conflicting claims that present-day scholars and public intellectuals have made about the Act's origins and purpose.

Although President Reagan had signed NOTA before the Pittsburgh controversy erupted, the privileged international patient scandal became a foundational event in the transplant community's understanding of UNOS. Thus,

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558. 42 U.S.C. § 274(e) (2000).

559. *Id.*

560. *Id.*

prominent bioethicist Arthur Caplan has written:

> In the early '80s it was not uncommon for wealthy foreigners to pay big bucks to push their way to the head of the line for a transplant. This trade got so out of hand that Congress insisted a national system be created to ensure that Americans got first crack at the organs that became available and that organs be distributed in an equitable manner [UNOS] has had Congress' [sic] mandate to keep an eye on the distribution of organs ever since.[561]

Technically, Caplan put the cart before the horse in this account. Congress's intervention into the organ allocation system—to the extent that a "system" existed in 1983—did represent an effort to regulate international commerce. But the commercial angle was not that "wealthy foreigners" were buying privileged access to transplant surgery.[562] Rather, the concern was that Americans might seek to purchase organs from desperate foreigners (or fellow citizens), harming the country's reputation on the international stage. Allegations that affluent international patients were purchasing privileged access to transplant surgery, on the other hand, did not perceptibly influence public policy until after NOTA authorized the enlistment of a private contractor to support organ allocation and transplantation on a national basis.

Jeffrey Prottas's claim that the legislation was driven by interest-group lobbying for public insurance coverage of immunosuppression goes further than the evidence available in the public record.[563] Transplant surgeons and centers presumably desired reimbursement and certainly sought to leave an imprint on transplant financing policy, but the record does not indicate that providers were controlling the discussion of how to strengthen America's organ transfer system. The question of whether to finance immunosuppression was subject to thoughtful debate, as were other problems of transplant financing, and when cyclosporine financing was put to a final vote in 1984, Congress answered in the negative. Transplant professionals' economic self-interest—as well as their understanding of their patients' health needs—may have stimulated their numerous public appearances, analytic cost-benefit conjectures, detailed policy statements, and voluminous testimony by representatives of provider organizations. Such advocacy, however, could only be projected onto policy prescriptions through the thorough, yet transparent, mediation of political actors speaking in the name of the national interest.

As the arc of transplant policy bent toward ensuring American patients' access to transplant surgery, the rigid, bureaucratic response embodied in the "members only" reimbursement policy for transplant centers was neither

561. CAPLAN, *supra* note 14.

562. *Id.*

563. *See* Prottas, *supra* note 15.

endorsed by NOTA, nor in direct conflict with a literal reading of the Act. James Blumstein is doubtlessly correct that the organ allocation system as a whole became more centralized over time, notwithstanding the counterexamples that Frank Sloan proffers.[564] However, Blumstein's assertion that this evolution represented a betrayal of NOTA's "market perfecting orientation relies on a too-precise interpretation of NOTA's orientation.[565] Aside from President Reagan's signing statement (which carries limited persuasive force), the official history of NOTA, embodied in committee reports and the text of NOTA itself, was ambivalent as to whether the network would ultimately resemble a voluntary association or a command and control structure.

Much of the debate over the federal government's role focused on the potential cost to taxpayers and the hazard of interfering with the professional practice of medicine, rather than the potential homogenization of organ allocation per se. Congress took pains to emphasize the non-governmental nature of the network, for example, by calling it the "Organ Procurement and Transplantation Network" in the final NOTA, rather than the "United States Transplantation Network," as in the earlier House version. Yet, a centerpiece of the legislation was the appointment of a single private contractor to manage the network. Congress clearly envisioned that the network would have a unifying effect, coordinating the behavior of personnel at disparate transplant institutions. Toward this end, it first entered into a binding contract with a voluntary organization, UNOS, that transplant centers effectively ratified through their membership. Congress then conferred quasi-governmental powers on UNOS, arguably equating organized voluntarism with industry self-governance. The question of who was doing the organizing (largely, a non-governmental organization responsive to stakeholders within the transplant community) should not have been conflated with the question of how much organization would be mandated.

Policymakers uniformly expected that both the public and private sectors would play some role in coordinating and financing this new modality of organ transfer. Individual participants in the NOTA debate, including those who were instrumental to the bill's passage and to the creation of the NOTA system, appreciated that both collective action problems and heavy-handed governmental interventions could be inefficient and stultifying. When transplant programs that had been emblems of initiative and innovation did not seem to be serving the public well—or even faring particularly well themselves—under lax oversight, legislators displayed a marked preference for setting some ground rules and giving private ordering a chance. Yet, the implicit logic of this hesitation could just as easily be characterized as incrementalism, rather than market perfection.

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564. *See* Blumstein, *supra* note 10; Sloan, *supra* note 8.

565. Blumstein, *supra* note 10, at 22.

To be sure, many market-oriented legislators may have signed onto NOTA without fully anticipating the course of events that the hearings and legislation would set in motion. Those members of Congress who were initially most inclined to delegate contentious issues to a Task Force tended to be conservative, Republican, and skeptical of large-scale federal projects. Ironically, they had painted themselves into a corner. When the Task Force reported back to Congress two years later, it called for greater centralization and greater bureaucratization. To those who would pass critical judgment on NOTA's subsequent implementation, the ambiguous legislative history of the Act itself commends a gaze outside that history, to broad legal principles such as those of antitrust and administrative due process.

C. Future Directions

The persistent scarcity in the existing allocation system, the cultural and religious diversity of the American public, and patients' mobility across national borders all intensify the pressures on a unified allocation system built on somewhat nationalized forms of public and private confidence. These challenges have occasionally given rise to new modalities of donor recruitment and organ transfer—either within the UNOS framework or alongside of it—rooted in competing or complementary theories of donor and patient confidence. Proposals to favor organ donors when allocating organs, for example, seek to remedy a perceived collective action problem by predicating individuals' donation decisions on a confidence that fellow members of the allocation pool will also donate. More tangible incentives to donate, such as those that arise in Paired Exchange, are currently pressing the limits of the NOTA regime.

The greatest legislative homage paid to the framers of that regime has been a series of subsequent statutes applying principles established through transplant policy to analogous problems in other realms of health policy. A series of laws regulating physician self-referrals[566] and updating the prohibition on soliciting or accepting remuneration for federally-reimbursable medical purchases[567] have implicitly endorsed the logic of protecting people's health and the public fisc by regulating the flow of payments throughout the patient referral process. In 2003, Congress re-drew the line between financing transplant therapy and health care financing generally by enacting a Medicare prescription drug benefit. A provision in that legislation "direct[ed] the Secretary of [HHS] to make available to the public the factors considered in making national coverage determinations

566. *See, e.g.*, 42 U.S.C. § 1395nn (2000) ("Stark" anti-referral statute).

567. *See, e.g.*, 42 U.S.C. § 1320a-7b (2000) (federal "anti-kickback" statute). This legislation originated in 1972, predating NOTA. *See* Office of Inspector Gen. & Office of Pub. Affairs, Dep't of Health & Human Servs., Fact Sheet, Federal Anti-Kickback Law and Regulatory Safe Harbors (Nov. 1999), http://oig.hhs.gov/fraud/docs/safeharborregulations/safefs.htm.

for coverage of Medicare benefits."[568] By attaching this requirement to a bill increasing the availability of outpatient reimbursements, Congress inspired another reckoning in policy circles of the connections among comprehensive coverage, cost control, and administrative transparency.[569] At the same time, the peculiar dilemmas of allocating a scarce, corporeal resource have not disappeared. Where policymakers once looked for a fresh solution, exasperated observers now see a host of problems.

Scholarly literature concentrating on the tragic dimension of organ substitution options, while containing sharp insights, should not be taken to mean that public policy in this realm should or must consist of endless alternation between tragic choices. The high social cost of system instability and the mistrust it engenders all but require that a degree of path dependence be built into the allocation system—if there is to be a system. This lock-in itself might be tragic, but it has been accompanied by another force imparting some direction to organ transfer: the development of technologies for organizing allocation and improving outcomes. While scientific breakthroughs—especially in drug development—are unpredictable, broad choices of what technologies to support and what research to fund are not beyond human direction. In turn, changing social conditions and technological capacities, as distinct from changing values, can prompt renegotiation of the roles of sponsorship and shared security within the system. In light of NOTA's historical entanglement with global geopolitics, the ultimate irony may be that one approach to organ procurement now receiving serious public and professional attention—fixed compensation to organ donors through a government program—was pioneered in Iran and has been dubbed the "Iranian model" of organ procurement.[570] Reconciling transplantation with some widely shared American values has always required a good deal of political, economic, and ideological "work."[571] Contemporary debate surrounding proposals to increase the supply of organs for transplantation reminds us that this work remains unfinished.

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568. Jacqueline Fox, *Medicare Should, But Cannot, Consider Cost: Legal Impediments to Sound Policy*, 53 BUFF. L. REV. 577, 579 (2005) (citing Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 731, 117 Stat. 2066, 2349 (2003)).

569. *See id. See also* Sandra J. Carnahan, *Medicare's Coverage with Study Participation Policy: Clinical Trials or Tribulations?*, 7 YALE J. HEALTH POL'Y L. & ETHICS 229, 243 (2007).

570. *See, e.g.*, *Psst, Wanna Buy a Kidney?*, ECONOMIST, Nov. 16, 2006, at 58. For a critical assessment, see Alireza Bagheri, *Compensated Kidney Donation: An Ethical Review of the Iranian Model*, 16 KENNEDY INST. ETHICS J. 269 (2006).

571. For a discussion of the work needed to sustain the American organ transfer system, see Healy, *supra* note 538, at 316, 326-27.