

NOTE

***E Pluribus* UNOS: The National Organ Transplant Act and Its Postoperative Complications**

Jed Adam Gross*

INTRODUCTION	147
I. SOCIAL AND TECHNICAL ENVIRONMENT	151
A. THE SOCIO-TECHNICAL ORGANIZATION OF ORGAN MATCHING	153
B. ENLISTING "THE PUBLIC," BUT NOT THE PUBLIC AS A WHOLE	157
C. HEARTS, MINDS, AND CORNEAS IN GEOPOLITICAL CONTEXT	160
D. BUILDING ON HOPE AND BUILT-IN DILEMMAS	163
E. MAKING TRAGIC CHOICES: THE DOMESTIC POLITICS AND ECONOMICS OF ORGAN ALLOCATION	170
F. GREEN LIGHTS AND RED TAPE	174
II. LEGISLATIVE RESPONSE	178
A. CONGRESSIONAL INQUIRY	178
B. ORGANS	183
C. DOLLARS	187

* 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.

D. COORDINATION 197

E. LEGISLATIVE PROCESS (AND PRODUCT) 207

III. SUBSEQUENT DEVELOPMENTS..... 222

A. THE PITTSBURGH CONTROVERSY AND THE CRISIS OF PUBLIC CONFIDENCE 222

B. STRUCTURAL IMPACT 227

C. THE REFINING SCALPEL OF LITIGATION 230

IV. CONCLUSION 241

A. RECENT POLICY DEVELOPMENTS 241

B. ASSESSMENT 248

C. FUTURE DIRECTIONS 251

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

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 Immunoabsorption 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

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

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

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

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

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

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 al., *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

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 to 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

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 surgeons' "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/whowere/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 Histocompatibility 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

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 Grier, 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 death¹⁰⁸—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 literature¹¹⁰ 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

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

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

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

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

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 increasingly 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 Environment 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

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 pioneering 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 . . .

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

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]

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 emerged ranged from blood pressure rates of living related kidney donors¹⁹² 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 desert. “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

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 witness²⁰³—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,

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

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,

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 Grier, 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

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 surgeon 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 Carolyn 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

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 Carolyn 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 immunosuppression seemed to be the next logical step. Less optimistically

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 Carolyn 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

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:

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

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 Carolyn 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

286. *Id.* at 228.

287. *Id.* at 152 (statement of Carolyn 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,

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 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

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 immunosuppression, 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, Krakauer 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

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 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

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); Mueller, *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

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 Purchases" 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 enactable consensus 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 Lingered 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

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 African-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

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

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

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 organization 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 justified 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

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 is 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

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 in 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 “interdependen[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 Karneen 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

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. Engelskjerd, *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 discovered 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

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

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

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,

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.

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-referrals⁵⁶⁶ and updating the prohibition on soliciting or accepting remuneration for federally-reimbursable medical purchases⁵⁶⁷ 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.

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.