Federal Organ Transplantation Policy: A Time for Reassessment?

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INTRODUCTION

Developing a neutral framework for analyzing organ transplantation policy is difficult. No matter how one shapes the issues, a bias seems to drive the analysis. Indeed, the policy analyst being initiated into the complex world of organ transplantation policy comes away from an initial immersion struck by the overwhelming overlay of ideology — sometimes express, but often implicit — that permeates the field. Given the high stakes involved — for payors, for providers, and most especially for patients — it is unsurprising that ideology seems to have played and continues to play such a fundamental role in the evolution of public policy. Despite the very real, even dramatic progress that has characterized the field of organ transplantation, significant problems continue to beset this enterprise, particularly (although not exclusively) in the area of transplantable organ supply.[1] Ideological dogma may have had an excessive and premature influence in seeking consensus and in shaping public policy.

In what follows, I consider the broader health policy context within which organ transplantation policy issues must be analyzed. Part I demonstrates how different theoretical perspectives influence debate about governmental financing of organ transplantation. Part II then examines the development of federal organ transplantation policy and places it within the broader context of health policy evolution. The analysis indicates that government's role as payor for kidney transplantations has explained much of government's initial regulatory thrust but that government's regulatory role — and its rationale for intervention — have considerably changed in recent years.

In the last half decade, the development of organ transplantation policy has been driven by a philosophical or ideological perspective that is fundamentally different from the perspective that has driven other facets of health policy. This development has been influenced by the 1986 Report of the National Task Force on Organ Transplantation[2] (*DHHS Task Force Report*) and facilitated by a privately operated transplantation network that, with acquiescence and tacit approval from the United States Department of Health and Human Services (DHHS), has embraced the Task Force's ideology. It is interesting to speculate

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[1] *See* REPORT OF THE TASK FORCE ON ORGAN TRANSPLANTATION, U.S. DEP'T OF HEALTH AND HUMAN SERVICES (DHHS), ORGAN TRANSPLANTATION: ISSUES AND RECOMMENDATIONS (1986) [hereafter DHHS TASK FORCE REPORT].

[2] *See id.*

whether this difference reflects a principled departure from the procompetitive approach that has recently gained pre-eminence in other facets of the health policy arena[3] or whether it reflects a confrontation with and rejection of the modish, procompetitive, ideological mainstream.

In any event, as Section III briefly discusses, constraints external to organ transplantation policy may exist that delimit the noncompetitive or even anticompetitive aspects of organ transplantation policy independently developed by the transplantation network. To the extent that the transplantation network's autonomy is observed, so its federally mandated decisions reflect private concerted action potentially anticompetitive in character, the network's policies may likely be subjected to serious antitrust scrutiny and potential challenge. The antitrust laws, therefore, may be invoked to contest the anticompetitive threat that evolving organ transplantation policy poses to competitive norms.

I. The Policy Context: Ways of Thinking About Government's Role in Paying for Organ Transplantation

A. Organ Transplantation as a Catastrophic Disease

At the most basic level, organ transplantation policy is a subset of a broader, generic health policy issue — the problem of coping with the costs of catastrophic disease. For years, health policy analysts have debated about how best to conceptualize the very special problems catastrophic disease poses.[4] Should the nature and effect of an illness (*e.g.*, whether it is life-threatening) guide our thinking? Or should the financial consequences of an illness (*e.g.*, whether it is an acute, life-threatening episode or a long-term, chronic problem) be determinative?[5]

The recently enacted catastrophic disease legislation, although far from comprehensive since it exclusively focuses on the costs of acute care for the Medicare population, reflects adherence to the financial

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[3] *See* Blumstein & Sloan, *Redefining Government's Role in Health: Is a Dose of Competition What the Doctor Should Order?*, 34 Vand. L. Rev. 849, 854-67 (1981); Greenberg, *Introduction*, 13 J. Health Pol., Pol'y & L. 223 (1988).

[4] For an interesting statement on this issue, see the Senate speech of Senator Quayle concerning a proposed block grant program for immunosuppressive drugs. 134 Cong. Rec. S8095-96 (daily ed. June 17, 1988). Senator Quayle objected to 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." *Id.* at S8096.

[5] *See* Havighurst, Blumstein & Bovbjerg, *Strategies in Underwriting the Costs of Catastrophic Disease*, Law & Contemp. Probs., Autumn 1976, at 122, 129-30.

definition.[6] It addresses a portion of the broader problem of financial disruption or potential bankruptcy resulting from extremely expensive episodes of acute illness. The drug benefit, although not limited to organ transplantation, will clearly influence the organ transplantation arena. By reimbursing (after a substantial deductible) for prescription drugs, the new legislation will ease the financial impact on patients of the high cost of post-operative immunosuppressive drugs such as cyclosporine. These antirejection drugs are an essential component of organ transplantation treatment and an important ingredient in recently-improved success rates. Under current Medicare legislation, government will pay for eligible transplant patients' immunosuppressive drugs for only one year after the transplant procedure date.[7] The financial consequences of subsequent out-of-pocket expenses for immunosuppressive drugs can be substantial, *i.e.*, "catastrophic."

Although many analysts have favored the financially-oriented conception of catastrophic illness, until the recent catastrophic disease amendments to Medicare the disease-specific approach had been the path federal public policy pursued. Examples include legislation directed to improve care for heart disease, cancer, and strokes[8] and legislation designed to assist miners suffering from "black lung" disease (pneumoconiosis).[9] Of course, the 1972 inclusion within Medicare of most victims of end-stage renal disease (ESRD) is a dramatic and most germane illustration of this disease-by-disease approach.[10] The 1972 ESRD legislation included Medicare coverage for kidney dialysis and kidney transplantation. As evidence that transplantation was more successful and cost effective than other procedures became available, transplantation became the preferred mode of treatment for ESRD under the ESRD Medicare program.[11] Thus, in the current policy context,

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[6] Medicare Catastrophic Coverage Act of 1988, Pub. L. No. 100-360, 102 Stat. 683, 683-817 (1988) (codified at 42 U.S.C. § 1305 (1988)).

[7] Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, § 9335(c), 100 Stat. 1874, 2030 (1986) (codified at 42 U.S.C. § 1395x (Supp. IV 1986)).

[8] *See* Heart Disease, Cancer, and Stroke Amendments of 1965, Pub. L. No. 89-239, 79 Stat. 926, 926-31 (1965), *repealed by* Pub. L. No. 99-117, § 12(d), 99 Stat. 495 (1985).

[9] *See* Federal Coal Mine Health & Safety Act of 1969, Pub. L. No. 91-173, 83 Stat. 742, 742-804 (1969) (codified as amended at 30 U.S.C. § 801-878 (1982)); Black Lung Benefits Act of 1972, Pub. L. No. 92-303, 86 Stat. 150, 150-57 (1972) (codified as amended at 30 U.S.C. 901-941 (1982)).

[10] *See* Social Security Amendments of 1972, Pub. L. No. 92-603, § 299I, 86 Stat. 1329, 1463 (1972) (codified as amended at 42 U.S.C. § 426 (1982)).

[11] *See* Eggers, *Effect of Transplantation on the Medicare End-Stage Renal Disease Program*, 318 NEW. ENG. J. MED. 223, 223-24 (1988).

organ transplantation policy must be understood within the broader health policy debate about the proper approach to catastrophic disease and the nature and scope of government's appropriate role in dealing with that precarious health policy issue.

As a form of treatment for ESRD, kidney dialysis satisfied both definitions of catastrophic disease. Without dialysis (or now, transplantation), ESRD was surely life-threatening. Since no stigma was associated with the onset of ESRD, victims were sympathetically perceived. With dialysis, ESRD patients could look forward to a prognosis for decent sustenance and an acceptable quality of life. Thus, a lifesaving technology was available, but financial constraints limited its accessibility. Absent a source of subsidy, not all who could benefit from kidney dialysis would be able to take advantage of that lifesaving treatment. Advocates for including dialysis within the scope of Medicare were able to exploit society's traditional unwillingness to engage in nice calculations of costs and benefits when a clearly identifiable life is in the balance. The skillful use of "symbolic blackmail"[12] helped to explain the initial legislation that engrafted treatment for ESRD patients onto the Medicare program.[13]

However, not all such potentially worthy treatments have found shelter under the federal financial umbrella, and the current debate about the nature and scope of governmental responsibility for transplantation of extrarenal organs must be understood within this broader health policy framework.

Should federal financial support for organ transplantation be extended beyond the kidney program to cover heart, liver, and other extrarenal organs? The case for federal financial coverage of transplantation for extrarenal organs can be argued either within the context of a generic financially-based catastrophic disease program, or on the basis of a disease-by-disease approach.

The financial approach is straightforward. Once expenses for organ transplantation surpass the "catastrophic" threshold, whether expressed in absolute dollars or as a percentage of income, the procedure would qualify for catastrophic coverage. The nature of the illness would be irrelevant; only the cost would matter. Any special characteristics of organ transplantation would be extraneous.

For extrarenal organ transplantation to secure preferred status under the disease-by-disease approach, advocates must pursue the following

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[12] Blumstein & Sloan, *supra* note 3, at 853.

[13] *See* Rettig, *The Policy Debate on Patient Care Financing for Victims of End-Stage Renal Disease*, LAW & CONTEMP. PROBS., Autumn 1976, at 192, 219-20.

simultaneous arguments: (a) that extrarenal organ transplantation has the same virtuous characteristics that transplantation of (or dialysis of) kidneys has; (b) that the extension of federal financial support to kidney dialysis and kidney transplantation has, on balance, been an effective program worthy of expanding to extrarenal organs; and, finally, (c) that transplantation of extrarenal organs is a higher social priority (including symbolic values) than other catastrophic diseases also competing to enter the coveted inner circle of federal financial support.[14]

Consideration of organ transplantation policy within the framework of catastrophic disease policy implicitly assumes that the catastrophic label has policy implications — that the nature and scope of government's role regarding catastrophic diseases may well differ from its role or obligations in other health policy areas. Thus, advocates for further governmental financial support for extrarenal organ transplantation can seek to assert that government has a special responsibility to deal with catastrophic disease. They would distinguish transplantation from other, more "normal" types of treatment. The extraordinary lifesaving characteristics of transplantation would be the basis for including diseases for which transplantation is necessary within the "catastrophic" category. Those characteristics, when combined with evidence of clinical efficacy, would undergird the argument for assigning extrarenal organ transplantation a high priority within that inner circle of treat-

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[14] Although the foregoing framework for analyzing organ transplantation policy initially seems straightforward, it proceeds under a fundamental (albeit unarticulated) ideological assumption — namely, that organ transplantation potentially deserves special attention because of its claim to status as a treatment for a catastrophic disease (however defined). The framework suggests that society has a special responsibility to provide coverage for catastrophic diseases. It also suggests that public responsibility to pay for medical care might properly be limited. While organ transplantation issues properly fall within the broader category of catastrophic illness, it is not so apparent that the very recognition of a distinct category of illness as "catastrophic" tends to blur a critical ideological assumption. That is,

> [v]iewing catastrophic illness as an independent policy problem calling for independent financing appears to presuppose that government's obligation to assure the provision of medical services is not unlimited. For this reason, proponents of a national cradle-to-grave health care system . . . would not regard particular illnesses or particular levels of expenditure as a separate problem. In their view, equity requires a redistributive allocation of in-kind medical benefits across the board to assure equal access to all types of health care, whatever the health problem. Focusing on catastrophic care may be seen as betraying a fundamental tenet, unacceptably providing only half a loaf.

Havighurst, Blumstein & Bovbjerg, *supra* note 5, at 129-30 (footnotes omitted).

ments for "catastrophic" illnesses.[15]

B. Organ Transplantation as Part of "Adequate" or "Ordinary" Care

If an analyst, following the recommendations of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research,[16] assumes that government has an obligation to provide an adequate level of medical care to citizens without imposing on them an undue financial burden, the nature of the case for covering extrarenal organ transplantation becomes quite different. In that situation the special or extraordinary character of catastrophic disease diminishes in importance. The basic or fundamental nature of extrarenal organ transplantation as an accepted and effective course of treatment for life-threatening illness becomes the centerpiece of the argument. In this scenario the case for covering extrarenal organ transplants is not their extraordinary character. Instead, the argument is that transplantation of organs is now a customary and accepted practice of medicine and should be encompassed within government's obligation to provide an "adequate" level of medical care for those unable to pay for it without incurring an undue burden.[17]

Within existing entitlement programs such as Medicare, the case for coverage is that extrarenal organ transplantation is a reasonable and necessary mode of treatment, and that including this treatment for covered beneficiaries is mandated under existing law (which requires coverage for reasonable and necessary medical care). This argument from "normalcy" was precisely why proponents persuaded the federal gov-

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[15] It is certainly awkward, in determining status within the catastrophic disease category, for the analyst to focus on the mode of treatment — transplantation — rather than on the underlying illness itself. However, extrarenal organ transplantation currently is typically viewed as a last resort regimen for coping with what would otherwise be a life-threatening illness. Thus understood, organ transplantation is a proxy both for catastrophic (*i.e.*, life-threatening) disease and for a financially extensive and expensive course of treatment. Classifying organ transplantation, in which life-threatening indications are not present, within this status would pose other, even more controversial but quite distinct issues.

[16] PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIOR RESEARCH, REPORT: ETHICAL IMPLICATIONS OF DIFFERENCES IN THE AVAILABILITY OF HEALTH SERVICES, SECURING ACCESS TO HEALTH CARE 1 (1983) [hereafter PRESIDENT'S COMMISSION REPORT].

[17] *See* Blumstein, *Thinking About Government's Role in Medical Care*, 32 ST. LOUIS U.L.J. 853 (1988).

ernment to include heart transplantation within Medicare coverage.[18] After commissioning a study and reviewing the data, the DHHS "determined that, for Medicare coverage purposes, heart transplants are medically reasonable and necessary when performed in facilities that meet certain criteria."[19]

C. The Policy Implications of Choosing an Analytical Framework

How one thinks about federal funding for extrarenal organ transplantation substantially depends on broader questions about the scope of governmental responsibility for providing access to medical care. The selection of analytical frameworks involves more than an abstract intellectual nicety. Potentially significant policy consequences exist. For example, if organ transplantation is deemed part of society's obligation to provide an adequate level of care to impecunious individuals, resource scarcity might raise the problem of expenditure priorities. The Oregon debate concerning Medicaid coverage for organ transplantation is illustrative.[20] Should scarce public dollars be expended to provide basic medical care coverage to a group of otherwise uncovered but medically needy persons? Or should those funds be allocated to enhance coverage to the "adequate" level for persons already included within the state's basic medical public assistance program? Simply put, that question involves a value choice between basic (but still not "adequate") medical care coverage for a sizable group of exposed, impecunious individuals versus completing the package of "adequacy" for those already protected by a basic but not quite "adequate" level of medical care coverage. No thumb goes on the scale, in that analysis, for the special role government may have with respect to catastrophic — *i.e.*, in this case, life-threatening — illness.

If government, however, has a special duty to help citizens cope with the consequences of catastrophic, life-threatening disease, then it is inappropriate to engage exclusively in a medically-oriented value comparison between expanding the number of medical public assistance beneficiaries and covering extrarenal organ transplantation for a group

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[18] As organ transplantation proponents seek to secure coverage under private medical insurance policies, they also will assert that transplantation is now an ordinary and accepted mode of treatment. Unless such policies have specific exclusions or other forms of internal limits, the issue typically would be whether organ transplantation is deemed to be ordinary and necessary (and not experimental) medical care.

[19] 52 Fed. Reg. 10935, 10935 (1987); *see* 51 Fed. Reg. 37164 (1986).

[20] *See* Welch & Larson, *Dealing with Limited Resources: The Oregon Decision to Curtail Funding for Organ Transplantation*, 319 NEW. ENG. J. MED. 171 (1988).

of already covered beneficiaries. Like the argument that won the day in 1972 for Medicare coverage of treatment for end-stage renal disease,[21] the case for covering catastrophic illnesses plays to the highly symbolic nature of life-threatening disease. The coverage recognizes that more is at stake than purely a medical calculation of how best to save lives or to improve overall health status. Because they confront government with basic questions of society's humanitarian self-image, medical encounters are likely to elicit public sympathy and to secure public support.

This insight supports an argument that the nature of an illness — *i.e.*, its "catastrophic" status — should trigger a special government duty. This duty would at least help government to protect itself against its own ultimate unwillingness to make tough decisions in the highly symbolic life-and-death situation. By building such expenses into a rational, planned tax-and-expenditure structure, this governmental role could avoid these "free rider" problems.[22] Transplant proponents assert that government's failure to pay for transplants would not, in the intermediate and long run, save money because the lifesaving imperative[23] would result in substantial public support for (and possibly eventual coverage for) the life-threatening illness. No such political push would exist for the less visible claims of uncovered potential beneficiaries to routine, quality-of-life-enhancing medical care.

With the policy debate thus structured, the nature of government's role and responsibility for catastrophic disease would weigh in the balance. Policymakers would consider the values associated with government support of identified citizens in dire straits. Public policy would be driven by a pragmatic recognition that any governmental refusal to pay for catastrophic illness such as organ transplantation would, in the long run, be politically unstable because of the inevitable effects of symbolic blackmail. In the arena of public policy debate, this analysis would reduce reliance on an exclusively medically-oriented, utilitarian balancing of organ transplantation against other medical services that government may be obligated, in principle, to provide.

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[21] *See* Rettig, *supra* note 13, at 223-24.

[22] *See* Havighurst, Blumstein & Bovbjerg, *supra* note 5, at 131.

[23] *See* Havighurst & Blumstein, *Coping with Quality/Cost Trade-Offs in Medical Care: The Role of PSROs*, 70 NW. U.L. REV. 6, 21 (1975).

II. The Federal Government's Role in Organ Transplantation: From Payor to Facilitator to Regulator

This Part turns from considering ways of thinking about governmental financing of organ transplantation to analyzing the federal government's evolving role in the organ transplantation arena.

A. The ESRD Program

By far the largest program of organ transplantation involves kidneys.[24] This is no accident, since Medicare covers nearly all kidney transplants. Costs of these transplants are therefore paid by the federal government. Federal payment for renal transplantation costs emerged from the federal commitment to pay for treating ESRD patients. Kidney transplantation has become an alternative and often more effective method of ESRD treatment than dialysis.[25]

As a major payor for ESRD treatment, the federal government had a distinct role to play in assuring appropriate quality standards when public beneficiaries were undergoing ESRD treatment. Although early programmatic bias for maintaining higher cost treatment methods apparently reflected more the influence of providers than the interest of ESRD patients or federal taxpayers, one cannot deny that government has a special role in monitoring the cost and quality of services it purchases for designated federal beneficiaries. Particularly when it was operating in a health care environment notoriously lacking in incentives for efficiency, government quite legitimately took an interest in the structure of the kidney dialysis, procurement, and transplant systems.

With the evolution of other, extrarenal organ transplantation technology, spurred in part by improved immunosuppressive drugs and more sophisticated tissue matching capabilities, policy analysts naturally used the kidney transplantation experience as a point of reference.

A tradition of organ sharing arose in kidney treatment. Because of the medical desirability of transplanting organs from donors who had certain physiological characteristics in common with recipients, it seemed only reasonable to develop a network for the more efficient use of scarce organs that became available through donation. Similarly, one could understand government's concern about quality standards of entities eligible to receive federal compensation for renal transplants.[26] As a

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[24] *See* DHHS Task Force Report, *supra* note 1, at 18.

[25] *See* Eggers, *supra* note 11, at 223; Rettig, *supra* note 13, at 199.

[26] *See* Rettig, *The Politics of Organ Transplantation: A Parable in Our Time*, 14

prudent purchaser in an industry virtually entirely dominated by federal financing, the federal government legitimately became involved in establishing guidelines of eligibility for provider participation in renal transplant programs.[27] This involvement tracked government's overall approach to providers seeking to participate in the Medicare program.

B. The National Organ Transplant Act of 1984

In 1984 the National Organ Transplant Act[28] began the process of developing a comprehensive framework for considering organ transplantation policy. The statute called for the formation of a task force to deal with specifically enumerated policy issues.[29] It addressed issues of organ procurement and distribution by providing funds for grants to qualified organ procurement organizations and for the establishment of an Organ Procurement and Transplantation Network (OPTN).[30]

As clearly stated in the legislative history,[31] Congress was responding to "major advances" in organ transplantation techniques.[32] Those technological advances had resulted in a one-year survival rate for kidney transplant patients of eighty percent. Introduction of the antirejection drug cyclosporine apparently had doubled the one-year survival rate for liver transplant patients, from thirty-five to seventy percent.[33] Congress thus viewed organ transplantation as providing "new hope" to thousands of patients whose end-stage organ failure would lead "inevitably to total disability and death."[34]

The *Senate Report* noted the shortfall in the number of organs available for transplantation.[35] The number of patients on waiting lists for organ transplantation far exceeded the available supply of transplantable organs — a recurring and ongoing problem.[36] According to then-available estimates, a relatively small percentage (about fifteen percent) of potentially transplantable organs had been harvested.[37] The Senate

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J. HEALTH POL., POL'Y & L. 191 (1989).

[27] *See* 42 C.F.R. § 405.2100 (1987).

[28] Pub. L. No. 98-507, 98 Stat. 2339 (1984) (codified at 42 U.S.C. §§ 201 note, 273, 274a-274e (Supp. IV 1986)).

[29] *See* 42 U.S.C. § 273 (Supp. IV 1986).

[30] *See id.* § 274.

[31] *See* 1984 U.S. CODE CONG. & ADMIN. NEWS 3975.

[32] *Id.* at 3976.

[33] *Id.*

[34] *Id.*

[35] *Id.*

[36] *Id.*

[37] *Id.*

cited an estimate that "20,000 people die annually under circumstances that would make them suitable organ donors."[38] Later, the *DHHS Task Force Report* found that the reliability of estimates about potential organ donors was subject to question because of the wide range of estimates found in different studies.[39] While acknowledging "the crude nature of present estimates," the Task Force concluded that "the potential donor pool for cadaveric organs probably lies between 17,000 and 26,000 donors per year."[40] For kidney transplantation, the overall supply is enhanced by the twenty-five to thirty percent of total transplanted kidneys provided by living kidney donors each year (1704 for 1984).[41]

The *Senate Report* stated that a "limiting factor," particularly for liver and heart transplants, was "the small number of medical centers . . . equipped to carry out organ transplants."[42] Organ transplantation requires highly trained personnel and an extensive commitment of hospital resources.[43] The high cost of organ transplantation was also viewed as a "major hurdle" for many patients in need of a transplant.[44] The *Senate Report* acknowledged that the nationwide publicity attendant to specific organ appeals had placed the organ transplantation issue squarely on the public agenda.[45]

The *Senate Report* recited the nongovernmental efforts that had developed in organ procurement and distribution, yet it concluded that improvements were needed in organ donation, procurement, and distribution.[46] The objective of the 1984 legislation was "to support development of a rational and fair national health policy regarding organ transplantation."[47]

With one exception,[48] the National Organ Transplant Act was not, at least formally, regulatory in character. It provided funds for the OPTN as a vehicle for improving the effectiveness of the organ trans-

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[38] *Id.*

[39] *See* DHHS TASK FORCE REPORT, *supra* note 1, at 35.

[40] *Id.*

[41] *Id.* at 36.

[42] S. REP. NO. 382, 98th Cong., 2d Sess. 4, *reprinted in* 1984 U.S. CODE CONG. & ADMIN. NEWS 3975, 3976.

[43] *Id.* at 3977.

[44] *Id.*

[45] *Id.* at 3979.

[46] *Id.* at 3978.

[47] *Id.*

[48] The statute barred the purchase or sale of organs. *See infra* notes 66-72 and accompanying text.

plantation enterprise.[49] Congress believed that, to the extent a coordinating function needed to be performed, responsibility for it should be "located in the private sector rather than in government."[50] The role of the Network was to establish a registry of patients in need of organs for transplant and to develop a national system for matching donated organs and potential recipients listed on the registry.[51] The OPTN was to assist organ procurement agencies in distributing organs that could not be used in local service areas[52] and to "adopt and use uniform standards of quality for the acquisition and transportation of donated organs."[53] The OPTN was also intended to have an educational mission, providing information to physicians regarding organ donation[54] and collecting, analyzing, and publishing data about organ donation and transplantation.[55] The pre-existing United Network for Organ Sharing (UNOS), a central computer registry of potential kidney recipients, was subsequently designated by the DHHS as the OPTN.

The 1984 Act also provided grants for the planning, establishment, initial operation, and expansion of "qualified organ procurement organizations."[56] To qualify for a grant under the Act, an Organ Procurement Organization (OPO) was required to be a nonprofit entity[57] qualified to receive Medicare reimbursement for kidney procurement and to have established procedures to "obtain payment for non-renal organs provided to transplant centers."[58] The geographic service area for an OPO had to be large enough to include "at least fifty potential organ donors each year,"[59] and each OPO had to have either a board of directors or an advisory board with a statutorily specified array of professional and public representatives. Furthermore, an OPO had to have agreements with a "substantial majority" of institutions in its service area that had facilities for organ donation.[60] The applicant OPO must also participate in the OPTN,[61] adopt standards of organ acquisition,

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[49] *See* 42 U.S.C. § 274 (Supp. IV 1986).
[50] S. REP. NO. 382, *supra* note 42, at 3981.
[51] *See* 42 U.S.C. § 274(b)(2) (Supp. IV 1986).
[52] *Id.* § 274(b)(2)(C).
[53] *Id.* § 274(b)(2)(D).
[54] *See id.* § 274(b)(2)(G).
[55] *See id.* § 274(b)(2)(H).
[56] *Id.* § 273(a)(1)-(2).
[57] *Id.* § 273(b)(1)(A).
[58] *Id.* § 273(b)(1)(D).
[59] *Id.* § 273(b)(1)(E).
[60] *Id.* § 273(b)(2)(A).
[61] *Id.* § 273(b)(2)(H).

preservation, and quality that are consistent with those of the OPTN,[62] arrange for tissue typing of donated organs,[63] have a system for allocating donated organs among transplant centers and patients "according to established medical criteria,"[64] and "arrange for the transportation of donated organs to transplant centers."[65]

Participation in the Network provided for by the Act and the establishment of relationships by transplant centers with the procurement agencies to be funded were not obligatory. The OPTN and OPOs were to be available, but participation by transplant centers was not mandatory. To the extent that the Network was useful and provided a service, transplant centers and their patients could benefit from the system of coordination. To the extent that other avenues of donation and procurement were available and more attractive, transplant centers and their patients were free to utilize those other sources and resources as well.

Interestingly, the one explicitly mandatory regulatory provision of the 1984 Act was its ban on transactions affecting interstate commerce to purchase or to sell human organs.[66] Under the statute, the term "human organ" was defined extremely broadly to cover "the human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin, and any other human organ specified by the Secretary of Health and Human Services by regulation."[67] Remarkably, the legislative history on this provision is extraordinarily sparse. The *Senate Report* states as follows: "It is the sense of the Committee that individuals or organizations should not profit by the sale of human organs for transplantation."[68] The Senate Committee carefully distinguished the sale of blood and blood derivatives, which were not encompassed within the ban: "[B]lood and blood derivatives . . . can be replenished and . . . donation does not compromise the health of the donor. . . . The Senate Committee believes that human body parts should not be viewed as commodities."[69] The *Conference Report* is no more illuminating, merely indicating that the statute "intends to make the buying and selling of human organs unlawful."[70]

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[62] *Id.* § 273(b)(2)(C).
[63] *Id.* § 273(b)(2)(D).
[64] *Id.* § 273(b)(2)(E).
[65] *Id.* § 273(b)(2)(F).
[66] *See id.* § 274e(a).
[67] *Id.* § 274e(c)(1).
[68] S. REP. NO. 382, *supra* note 42, at 3982.
[69] *Id.*
[70] H.R. CONF. REP. NO. 1127, 98th Cong., 2d Sess. 13, 16, *reprinted in* 1984 U.S.

Thus, banning the purchase or sale of organs was one of the first federal regulatory organ transplantation measures (unrelated to the federal government's role as payor) enacted into law. By prohibiting the sale, receipt, or transfer of a human organ "for valuable consideration," the ban restricted the development of any direct financial incentives to enhance the supply of organs, despite Congress' finding that the supply of transplantable organs fell far short of the medical need.[71] The *Senate Report*'s distinction of blood sales is particularly interesting. The Senate Committee's evident concern about compromising the health of organ donors suggests the relevance of donor health concerns to sale of organs by live donors; it would appear unrelated to the question of purchase or sale of cadaver organs, even if the consideration were paid during a person's lifetime. The *Senate Report* does not explain, however, why "individuals or organizations should not profit by the sale of human organs for transplantation" when profit-making from blood sales is apparently acceptable.[72]

A technological question exists about the length of time organs can be preserved for transplantation. Recent evidence suggests advances in organ preservation.[73] To the extent that organ life can be extended, opportunities for transfer increase. If the length of time between organ procurement and organ transplantation can safely be extended, a greater likelihood exists that organs can be transported and distributed more widely, with better chances for improved tissue matching.[74]

Professor Henry Hansmann has recently addressed the ban on purchase and sale of organs and proposed an alternative.[75] For present purposes, it is noteworthy that technical factors allowing some type of market in organs to develop are likely now in place. The issue, however, is intensely ideological — an example of the extraordinary importance of ideology in the evolution of organ transplantation policy. The

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CODE CONG. & ADMIN. NEWS 3989, 3992.

[71] Andrews, *My Body, My Property*, HASTINGS CENTER REP., Oct. 1986, at 28, 32; *see also* Bovbjerg, *Grafting Perspective into Health Law: Organ Transplantation as a Tool for Teaching*, 38 J. LEGAL EDUC. 567, 570 (1988) ("Policy and law on allocation of transplantants . . . should not be accepted as completely settled.").

[72] S. REP. NO. 382, *supra* note 42, at 3982.

[73] *See Test Device Raises Hope of Keeping Organs Alive Longer for Transplant*, N.Y. Times, June 16, 1988, at B10, col. 1.

[74] *See* Opelz, *The Benefit of Exchanging Donor Kidneys Among Transplant Centers*, 318 NEW ENG. J. MED. 1289, 1290-91 (1988); Salvatierra, *Optimal Use of Organs for Transplantation*, 318 NEW ENG. J. MED. 1329, 1329 (1988).

[75] *See* Hansmann, *The Economics and Ethics of Markets for Human Organs*, 14 J. HEALTH POL., POL'Y & L. 57 (1989); *see also* Areen, *A Scarcity of Organs*, 38 J. LEGAL EDUC. 555 (1988) (advocating use of durable power of attorney).

first critical regulatory decision at the federal level, the ban on purchase or sale of organs for transplantation, has shaped further development of transplantation policy and has constrained the options available for its evolution.[76] Certain potential pathways, such as experimenting with various forms of financial inducements for organ "donation," must remain unexplored.[77]

C. The 1986 Budget Reconciliation Act

In May 1986 the Task Force on Organ Transplantation, which was convened under the terms of the National Organ Transplant Act of 1984, transmitted its final report.[78] The Task Force recognized the need to secure more transplantable organs; a shortage in supply of organs constrained further development of this promising method of treatment.[79] The Task Force lamented the relatively small percentage of potentially transplantable organs that were actually harvested for transplantation.[80] It urged an array of public education outreach activities to encourage more individuals and potential donors' next-of-kin to think favorably about donating organs.[81]

The Task Force's approach to increased organ donation placed the value of increasing the supply of organs in the context of broader communitarian values. Thus, the Task Force, quoting a Hastings Center Report, believed in the importance of developing organ transplantation policies that promote "the value of social practices that enhance and strengthen altruism and our sense of community."[82] Specifically, the Task Force enumerated as a core value shaping organ transplantation policy the goal of "[p]romoting a sense of community through acts of generosity,"[83] even if intensive educational and media campaigns would be needed to encourage this kind of altruistic, communitarian act by families of dying patients.

To effectuate this policy — which strictly speaking is unrelated to

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[76] *See* Andrews, *supra* note 71, at 28, 32.

[77] *See* Hansmann, *supra* note 75; Schwindt & Vining, *Proposal for a Future Delivery Market for Transplant Organs*, 11 J. HEALTH POL., POL'Y & L. 483, 489-97 (1986); Vining & Schwindt, *Have a Heart: Increasing the Supply of Transplant Organs for Infants and Children*, 7 J. POL'Y ANALYSIS & MGMT. 706, 706-07 (1988); Note, *Regulating the Sale of Human Organs*, 71 VA. L. REV. 1015 (1985).

[78] *See* DHHS TASK FORCE REPORT, *supra* note 1.

[79] *See id.* at 16, 27.

[80] *See id.* at 34-37.

[81] *See id.* at 39-43.

[82] *Id.* at 28.

[83] *Id.*

organ transplantation but which uses the arena of organ transplantation to make a broader symbolic, political statement — the Task Force recommended that hospitals adopt policies requiring that families of dying patients routinely be asked to consider donating organs of their dead or dying next-of-kin.[84] The ostensible rationale is that families, who have legal authority to donate organs of their next-of-kin,[85] should be given the opportunity to do a good deed for society and to feel good about themselves by donating their dying relative's organs to the common weal. In the Task Force's world view, the organs, once donated, become a national resource, beyond the control of the donor or her family.[86] For the Task Force, the decision to donate should be altruistically motivated. The routine-inquiry policy must be institutionalized because individual professionals typically feel squeamish about raising these sensitive issues with family members in such delicate circumstances. An institutional rule is needed to make the organ donation inquiry an obligation.

The Omnibus Budget Reconciliation Act of 1986[87] implemented this facet of the Task Force's recommendations by adding Section 1138 to the Social Security Act.[88] Using a hospital's eligibility to participate in Medicaid or Medicare as the coercive lever, Section 1138 requires all Medicaid or Medicare hospitals to institutionalize a required request policy.[89] Such hospitals must establish "written protocols" for identifying potential organ donors[90] and for notifying an organ procurement agency of a potential organ donor.[91] These protocols must "assure that

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[84] *Id.* at 31-34.

[85] *See* UNIFORM ANATOMICAL GIFT ACT § 3(a), 8A U.L.A. supp. 8 (Supp. 1988). The Uniform Anatomical Gift Act contains both a 1968 and a 1987 version. This cite is to the 1987 version. The separate Acts will hereafter be distinguished as 1968 UAGA and 1987 UAGA.

[86] *See* DHHS TASK FORCE REPORT, *supra* note 1, at 85-86. This points to a significant tension for those who maintain the need for voluntarism and altruism. The Task Force's desire for communal control of organ distribution on grounds of equity runs counter to the common sense recognition that charitable impulses are encouraged when donors (and their families) can identify (and choose) a potential transplant beneficiary. *See, e.g.*, Areen, *supra* note 75, at 565. This type of identification is difficult under the approach recommended by the Task Force.

[87] Pub. L. No. 99-509, 100 Stat. 1874 (1986) (most relevant sections codified as amended in 42 U.S.C.).

[88] *See id.* § 9318(a), 100 Stat. 1874, 2009-10 (1986). Section 1138 of the Social Security Act is codified at 42 U.S.C. § 1320b-8 (Supp. IV 1986).

[89] *See* 42 U.S.C. § 1320b-8(a)(1)(A) (Supp. IV 1986).

[90] *See id.*

[91] *See id.* § 1138(a)(1)(A)(iii).

families of potential organ donors are made aware of the option of organ or tissue donation and their option to decline."[92]

Thus, the 1986 legislation used a hospital's Medicaid or Medicare participation as the club for imposing on transplant hospitals a set of coercive, federal regulatory requirements concerning organ procurement. The clear goal of this portion of the 1986 legislation was to increase the percentage of actual organ donors from the pool of potential donors. Although the statute was carefully drawn to protect the neutrality of the organ donation inquiry (families have to be informed of their option to donate and of their option to decline donation), the apparent assumption of the proponents was that, given positive societal attitudes toward organ donation, routine inquiries would yield affirmative family responses.[93] Indeed, the implementing regulations published by the DHHS establish as a condition of OPO re-certification that it must meet specific performance standards concerning the number of transplantable kidneys it annually secures (twenty-three cadaveric kidneys per million population of its service area).[94]

The statutorily mandated technique for achieving this goal — others are permitted — relies upon securing approval from families of potential donors at the time of the patient's critical illness or death. In some circumstances, particularly when a dying family member is too young to have considered the possibility of organ donation, the bedside opportunity to help others through organ donation may be psychologically fulfilling to a family — a demonstration of the principle that from a loved one's death may come some silver lining. However, despite the opportunity for this type of fulfillment, bedside confrontation with the issue whether to donate a dying family member's body parts is scarcely an optimal time from a grieving family's perspective. In addition, the mandatory statutory focus on that time and place is of questionable taste or even efficacy.[95] The delicate, potentially ghoulish character of

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[92] *Id.* § 1138(a)(1)(A)(i).

[93] For a discussion of the background of routine inquiry laws, see Andersen & Fox, *The Impact of Routine Inquiry Laws on Organ Donation*, HEALTH AFF., Winter 1988, at 65.

[94] *See* 53 Fed. Reg. 6525, 6551 (1988) (to be codified at 42 C.F.R. § 405.306).

[95] Families may suffer emotional distress when their next-of-kin is not cut off from life support systems promptly upon determining brain death. The request to a family for organ donation can create a painful, stressful dilemma, and it can delay the return of a loved one's body as family members ponder the donation decision. For a case upholding a family's cause of action for emotional distress against a hospital in such a circumstance, see Strachan v. John F. Kennedy Memorial Hosp., 109 N.J. 523, 538 A.2d 346 (1988).

the routine inquiry by hospitals is dictated by the ban in the 1984 legislation on using any "valuable consideration" for inducing potential donors, when they are well, from committing themselves to permitting use of their organs for transplantation.[96]

Although the Uniform Anatomical Gift Act (UAGA) allows potential donors to control disposition of their organs by signing donor cards,[97] very few people apparently sign those cards.[98] The ban on use of financial inducements means that incentives are reduced for salespersons or others actively to seek out potential signees. Furthermore, in the absence of a quid pro quo for signing a donor card and despite the legal authority derived from the UAGA to honor these signed cards, the custom and practice in the organ transplant community is not to rely on a signed donor card but to seek independent approval from a potential donor's family.[99]

That custom would surely change were the signing of the "donor" card viewed as contractual in character — paid for and thereby conferring rights on the contracting party. The entire nature and perception of this transaction would necessarily change, as would the status of a potential donor's earlier decision to commit his cadaveric organs for use in transplantation. If nothing else, such a contractual arrangement would create at least one (and possibly several) interested parties who would aggressively seek enforcement of their contractual rights.

One clear cost of the 1984 legislation's absolutist ideological stance, *i.e.*, the flat-out ban on the purchase or sale of organs for transplantation, is the necessary emphasis on the request to potential organ donors' families at the time of their loved one's fatal illness. Depending on the circumstances, that time may not be the optimal time in terms of humaneness or compassion toward the family. As it turns out, bedside decision making is also probably not an optimal time for the likely efficacy of the request, although the final word on this has not yet been written.[100] Nevertheless, the unwillingness of transplant teams to accept organ donor cards, the low number of donor card signees, and the ban on financial incentives that would shift the locus of decision making away from the hospital room (at the patient's bedside) to the luncheon

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[96] *See* National Organ Transplant Act § 301(a), 42 U.S.C. § 274e (a) (Supp. IV 1986).

[97] *See* 1987 UAGA, *supra* note 85, § 2, at 5-6.

[98] *See* DHHS TASK FORCE REPORT, *supra* note 1, at 29.

[99] *See* Robertson, *Supply and Distribution of Hearts for Transplantation: Legal, Ethical, and Policy Issues*, 75 CIRCULATION 77 (1987).

[100] *See* Andersen & Fox, *supra* note 93, at 75-77.

table, when a person is well and can coolly and rationally consider his or her own future, all lead to the unhappy reliance on requests to families when they are in the greatest emotional pain. This situation is indeed a high price for a somewhat abstract ideological point — the noncommoditization of organs and the zealous commitment to values of communitarian uplift through altruism.[101]

In addition to requiring that Medicaid and Medicare hospitals ask families of potential organ donors to consider organ donation for their dead or dying next-of-kin, the 1986 legislation adopted some other very fundamental, albeit subtle, regulatory policies for organ transplantation.

For example, if organ transplantations are performed in a particular hospital, that hospital, in order to participate in Medicaid or Medicare, must be a member of and abide by the rules and requirements of the OPTN (*i.e.*, UNOS) as established by the National Organ Transplant Act of 1984.[102] On the surface, that condition appears a relatively innocuous requirement — a hospital in which transplants take place should have access to the privately established, publicly funded network for organ procurement and distribution. After all, Congress had funded this network to provide hospitals a measure of private, nongovernmental autonomy in the organ procurement and distribution system. Access to that system would certainly enhance opportunities for patients, hospitals, and organ transplantation programs. It would also provide a better, more complete data base for research and analysis of clinical evidence.[103]

In practice, however, the requirement of membership has become a subtle, indirect means to establish coercive regulation. No hospital seeking to maintain its eligibility for Medicaid or Medicare participation can permit organ transplantation unless the hospital and *all* its transplantation programs meet the network's (UNOS') membership criteria. Instead of having a relatively open membership policy, UNOS took advantage of the statutory requirement for transplant hospital membership[104] by establishing restrictive membership standards. Thus, instead of serving as a publicly funded resource for improving efficiency of the procurement and distribution system, UNOS saw its role as that of a nongovernmental or quasi-governmental regulatory body. This role was

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[101] *See* Havighurst & King, *Liver Transplantation in Massachusetts: Public Policymaking as Morality Play*, 19 IND. L. REV. 955, 975-76 (1986).

[102] *See infra* note 225 and accompanying text.

[103] *See* Salvatierra, *supra* note 74, at 1330.

[104] *See infra* note 225 and accompanying text.

the vision of the National Task Force on Organ Transplantation — that there be a unified national system for organ procurement and allocation.[105]

To qualify for membership in UNOS, a transplant program must satisfy a detailed set of requirements, which include guidelines regarding staffing patterns, personnel qualifications, survival rates, and facilities.[106] Once a member of UNOS, a hospital must abide by UNOS rules and requirements or face disqualification from Medicaid or Medicare participation.

The rationale for UNOS' criteria is quality control. The DHHS has stated that "the purpose for [UNOS'] membership rules is to serve as a proxy for quality."[107] DHHS acknowledged that some UNOS requirements are "more stringent" than DHHS conditions for transplant center eligibility for Medicare participation.[108] If a transplant program meets DHHS criteria for payment under Medicare, it (and the entire hospital of which it is a part) would nevertheless lose eligibility for Medicare participation if the transplant program failed to comply with UNOS standards. The reason for this loss of eligibility is the statutory requirement that a Medicare hospital doing transplants not only be a member of UNOS but also abide by its rules and regulations.

UNOS requires that all transplant programs of a transplant center come into "full compliance with all UNOS membership criteria."[109] If, after a grace period, UNOS approval of a transplant program is not secured, a transplant center must "not perform any further transplant of the applicable organ until after it has established full compliance to the satisfaction of . . . UNOS. . . ."[110] Thus, a hospital with an organ transplantation program that does not satisfy UNOS membership criteria is for all practical purposes barred from continuing its transplantation program. The hospital does not just forgo access to the UNOS network, or even forgo access to Medicare or Medicaid payment for transplantation (when such financial support would be available). The stakes are much steeper. Unless a hospital entirely drops its non-UNOS-qualifying transplantation programs, the hospital would be obliged to "forgo Medicare and Medicaid payment for *all* services, not

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[105] *See* DHHS TASK FORCE REPORT, *supra* note 1, at 68-69.

[106] *See* UNITED NETWORK FOR ORGAN SHARING (UNOS), BY-LAWS app. B (May 31, 1988) [hereafter 1988 BY-LAWS].

[107] 53 Fed. Reg. 6525, 6528 (1988) (to be codified in scattered sections of 42 C.F.R.).

[108] *Id.* at 6529.

[109] UNOS, BY-LAWS §§ 1.2, 2 (November 4, 1987) [hereafter 1987 BY-LAWS].

[110] *Id.*

just transplant services."[111]

Consequently, the statutory requirement that hospitals with transplant programs participate in and abide by the rules and requirements of the Network allows vesting of an enormous amount of coercive regulatory power in UNOS, which can act unconstrained by the limitations placed on governmental power established under the Administrative Procedures Act.[112] From comments disclosed by DHHS, "there is a wide perception that UNOS requirements are unfair" and that, as with proposed governmental regulations, proposed changes in UNOS guidelines should be "open to public comment."[113]

DHHS responded to those comments by negotiating with UNOS to allow provisional membership for transplant centers that do not meet all UNOS requirements for full membership and to require UNOS to establish a satisfactory conflict resolution process.[114] However, the DHHS contract with UNOS permits UNOS to set restrictive membership and program certification policies. These policies have the effect of law because of the requirement that Medicare and Medicaid hospitals with transplantation programs be members of and abide by UNOS policies.

DHHS has readily acknowledged that hospitals wishing to participate in Medicaid and Medicare must "discontinue transplant programs that do not meet UNOS' requirements."[115] Thus, as DHHS expressly acknowledged in response to comments on its proposed regulations, "[i]f a hospital has multiple organ transplant programs, it must meet Network criteria for all programs or immediately terminate any program that does not meet UNOS membership criteria in order for the hospital to continue participation in the Medicare and Medicaid programs."[116] DHHS expressed its belief that such an outcome "represents a significant barrier to market entry" and could have a "significant adverse effect on competition."[117] The Department concluded that those anticompetitive effects were not the result of the proposed rule but instead stemmed from the 1986 statute, since the statute dictated that Medicaid

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[111] 53 Fed. Reg. 6525, 6529, 6530 (1988) (emphasis in original) (to be codified in scattered sections of 42 C.F.R.).

[112] *See generally* Administrative Procedure Act ch. 324, §§ 1 to 12, 60 Stat. 237 (codified as amended in scattered sections of 5 U.S.C.).

[113] 53 Fed. Reg. 6525, 6529 (1988) (to be codified in scattered sections of 42 C.F.R.).

[114] *Id.*

[115] *Id.* at 6546.

[116] *Id.* at 6530.

[117] *Id.* at 6546.

and Medicare participation for a transplant hospital depend on meeting Network transplant requirements.[118] DHHS also concluded that the regulations would have only a "slight impact on hospitals" because "all transplant centers are accredited by the JCAHO, which already requires hospitals to participate in the Network."[119] However, these statements by DHHS are only partly correct.[120]

That the 1986 legislation requires transplant hospitals to satisfy OPTN requirements if they wish to participate in Medicare and Medicaid is true. Similarly, JCAHO accreditation standards may compel hospitals seeking accreditation to participate in the OPTN. While these observations are correct, they are also largely beside the point. Membership in the OPTN need not be anticompetitive. The effect of membership on competition turns entirely on the nature of the membership requirements UNOS establishes and enforces. The substance of the rules governing membership, not the membership requirements themselves, determines whether competition will suffer a significant adverse effect. The substance of Network rules will likely govern any potential antitrust analysis of anticompetitive impact from exclusionary Network guidelines.

The nature of UNOS membership rules, in turn, derives from the conceptualization (*i.e.*, the ideology) that UNOS and DHHS adopt as the role of the OPTN. There is, in this regard, an essential similarity to the conceptualization of health planning and its relation to competition. One view suggests that health planning is fundamentally at odds with competition. Needs and goals are centrally determined in a political and technocratic fashion; planners seek to influence or even control resource allocation decisions (*e.g.*, through "rationing"). That vision of health planning "manifestly is designed to substitute for the market in the allocation of resources . . . . Resource allocation decisions are centralized and politicized. Attention to developing appropriate institutions for democratic decision making substitutes for attention to the proper functioning of an economic marketplace."[121]

While the market-substitution vision of health planning may be incompatible with a more decentralized, pluralistic, market-oriented sys-

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[118] *Id.*

[119] *Id.*

[120] The potential antitrust implications of these restrictions on competition are briefly discussed *infra* Part III.

[121] Blumstein, *Effective Health Planning in a Competitive Environment*, in COST, QUALITY, AND ACCESS IN HEALTH CARE: NEW ROLES FOR HEALTH PLANNING IN A COMPETITIVE ENVIRONMENT 21, 28-29 (F. Sloan, J. Blumstein & J. Perrin eds. 1988) [hereafter COST, QUALITY, AND ACCESS IN HEALTH CARE].

tem, the central-planning approach is not the only available option. Market-enhancing roles for planning are possible:

> For example, planners can collect and disseminate information . . . . Planners can also gather and evaluate . . . data and . . . contribute to the measurement and disclosure of assessments of indicia of quality . . . . [P]lanners could maintain a vigil against restraints of trade, and they could identify and recommend the elimination of public or private barriers to . . . efficient medical care delivery . . . .[122]

Thus, in the health planning context, "a great deal turns on one's vision" of what health planning is and what its proper role should be:

> Is it to be viewed as a comprehensive, top-down method of resource allocation designed to substitute a politically driven command-and-control bureaucratic system, which blends technocratic expertise and interest-group negotiation, for the resource allocation decisions of decentralized decisionmakers in a functioning market? Or is it to be viewed as a means of facilitating competition by providing technical assistance and independent analysis to participants in the market process?[123]

The analogy from health planning to UNOS is quite close. If UNOS is to resemble a comprehensive, top-down system for determining the best way to do transplants and to procure and distribute organs, then a tight regulatory approach might well follow as a logical strategy. If, however, one desires to maintain a flexible, decentralized system of transplantation and organ procurement and distribution, a very different, much less command-and-control-oriented approach would be appropriate. The top-down regulatory approach, obviously, would have a much more substantial impact on competition — and possibly on other values such as breadth of access.[124] The approach also would trench on values associated with and protected by the antitrust laws.

The next question to be addressed, then, is whether DHHS could have chosen the more flexible, decentralized, pluralistic system for the OPTN, or whether it was constrained by controlling legislation, as it claimed, to select the regulatory approach. This inquiry is important for two critical reasons. First, it addresses the question whether DHHS has flexibility through exercise of administrative oversight to alter the existing vision of the OPTN. Second, the inquiry influences the antitrust analysis, which asks whether Congress intended to nullify the application of the antitrust laws to this arena.

Careful analysis of the governing legislation reveals that DHHS had

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[122] *Id.* at 38.

[123] *Id.* at 39.

[124] *See* Bovbjerg, *Human Organ Transplantation: Societal, Medical-Legal, Regulatory, and Reimbursement Issues*, 9 J. LEGAL MED. 467 (1988).

and still has a great deal of freedom to choose among competing visions of the OPTN. Either DHHS failed to understand properly the competing visions for the OPTN, or it misread the requirements of existing law. That misreading, in turn, could have been a handy mechanism through which proponents of one viewpoint effectively and conveniently shut off serious consideration of clearly expressed concerns. These concerns were about the impact of the UNOS regulations on competition and about other values associated with pluralism and decentralization (and protected by the antitrust laws).

The National Organ Transplant Act of 1984 required DHHS to contract with a private, nonprofit entity to establish and to operate a network,[125] which would establish both a registry of patients in need of organs and a national system for matching organs and individuals "in accordance with established medical criteria."[126] The network was to "assist organ procurement organizations in the distribution of organs which cannot be placed" locally.[127] The network was to develop "standards of quality" for organs used in the network[128] and to coordinate transportation of organs from procurement organizations to transplant centers.[129] Nothing in the 1984 statute or its legislative history mandates the kind of restrictive, exclusionary authority that UNOS now has and that its contract with DHHS apparently sanctions. The 1984 statute also did not suggest that the system developed by the network must be exclusive. On the contrary, the rationale for the network seemed to be that of a facilitator, a useful tool for improving transplantation center efficiency and effectiveness.

The *Conference Report* on the 1984 legislation matter-of-factly described the provision concerning the OPTN as providing grants to establish and to operate a network "to match donor organs to individuals in need of transplantation."[130] The statute itself does not intimate the potential for exclusivity or restrictiveness. Indeed, the 1984 Act has distinct elements of a market-perfecting orientation — a network to match organs more efficiently, to reduce the number of wasted organs, to facilitate transportation, and to educate physicians by making available information and analyses of data regarding organ transplantation. That is a function compatible with a pluralistic, decentralized, voluntary sys-

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[125] *See* 42 U.S.C. § 274(a)-(b) (Supp. IV 1986).

[126] *Id.* § 274(b)(2)(A)(ii).

[127] *Id.* § 274(b)(2)(C).

[128] *Id.* § 274(b)(2)(D).

[129] *Id.* § 274 (b)(2)(F).

[130] H.R. CONF. REP. NO. 1127, *supra* note 70, at 3990.

tem. It is a far different role than the nongovernmental or quasi-governmental regulatory role UNOS now has in virtually every facet of organ transplantation — organ procurement, organ distribution, and the actual details of the transplantation procedure itself.

In sum, the 1984 legislation does not require DHHS to choose a highly regulatory model for the OPTN. The selection of models is a matter of DHHS discretion. DHHS's exercise of discretion, in turn, must be gauged by the substantive policies adopted and implemented by the OPTN. DHHS cannot distance itself from the policies of the OPTN but must take responsibility for those policies. Once membership in the OPTN became mandatory, the case for autonomy of the OPTN became much less compelling, since the federal government was effectively regulating by delegating authority to UNOS, the OPTN contractor. Oversight of UNOS through the OPTN contract is possible and, given the coercive effect of OPTN rules and regulations, clearly necessary. Such oversight may even be constitutionally required under cases limiting the ability of the federal government to delegate lawmaking or rulemaking authority to private, self-interested persons or groups.[131] In any event, as Part III will discuss, the fact that neither the 1984 nor the 1986 legislation mandates a particular vision for the OPTN leaves open the substantial likelihood that UNOS' restrictive or otherwise anticompetitive conduct will be subject to antitrust scrutiny.

D. The UNOS Policies

UNOS has established an elaborate set of rules and regulations guiding standards for membership. Institutional members, as defined in UNOS' Articles of Incorporation, must be "active in the field of human organ transplantation" and be either (a) a transplant center; (b) an independent organ procurement agency (IOPA) which serves two or more transplant centers within its service area; or (c) an independent tissue typing laboratory (ITTL) which serves two or more centers within its service area.[132] The By-Laws further provide for nonvoting institutional memberships for IOPAs and ITTLs serving only one

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[131] *See* A.L.A. Schechter Poultry Corp. v. United States, 295 U.S. 495 (1935); Eubank v. Richmond, 226 U.S. 137 (1912); *see also* United Chiropractors of Washington, Inc. v. State, 90 Wash. 2d 1, 578 P.2d 38 (1978). For further elaboration of a possible change in position by DHHS, see Letter of Robert Windom, M.D., *infra* note 245.

[132] UNOS, ARTICLES OF INCORPORATION, art. III (August 10, 1987) [hereafter ARTICLES].

UNOS member transplant center within their service area.[133] Although the term for institutional members of UNOS is indefinite, failure by institutional members to conform with UNOS standards or performance levels can result in termination of membership.

The core of UNOS is its policies and standards for membership. No distinctions are drawn between membership and participation in UNOS and in the OPTN, which UNOS operates under contract with DHHS. Although this relationship is not a requirement of federal statutory law, or even of DHHS regulatory policy, under current practice UNOS and the OPTN are for all practical purposes functionally identical.[134]

The organizational culture behind UNOS policies and guidelines clearly reflects an intellectual debt to the recommendations of the National Task Force on Organ Transplantation. In a relatively recent Statement of Policy, published on February 3, 1988, UNOS clearly regarded the Task Force's recommendations as the basis upon which its own policies have been based.[135] For example, UNOS noted the Task Force recommendation "that a single national system for organ sharing be established; that its participants agree on and adopt uniform policies and standards by which all will abide."[136] Adhering to the Task Force Report, UNOS has stated that "the effectiveness of the national network would depend on the development of uniform standards and policies that all participants agree to follow."[137] The role of UNOS, as envisioned by its leadership, seems to be establishing and enforcing uniform standards of organ allocation that should be adhered to by all procurement agencies and transplant centers.[138] UNOS is charged, in that view, with developing the standards that will control all facets of the organ transplantation process. UNOS' structure will appropriately be representative of a variety of constituencies. Within that political

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[133] *See* 1988 BY-LAWS, *supra* note 106, at 1.

[134] Whether the identity of UNOS and the OPTN should be retained is questionable. UNOS, as an organization, can have membership rules and regulations appropriate to its voluntary purposes. Membership in the OPTN is mandatory for Medicare/Medicaid hospitals. Because of this coercive, regulatory status, and because of antitrust policy concerns, the OPTN should be governed by less restrictive membership rules and regulations than UNOS.

[135] *See* UNOS, STATEMENT OF POLICY REGARDING TRANSPLANTATION OF FOREIGN NATIONALS AND EXPORTATION AND IMPORTATION OF ORGANS 5-6, 10, 21-22 (Feb. 3, 1988).

[136] *Id.* at 6 (quoting DHHS TASK FORCE REPORT, *supra* note 1, at 69).

[137] *Id.*

[138] *Id.* at 10.

framework, however, UNOS will settle on the tune and its members will dance to the music or pay the price — discontinuance of organ transplantation or excommunication from all participation in Medicaid or Medicare.

Quite clearly, UNOS has embraced the top-down, command-and-control regulatory vision of its role. This role is compatible with the suspicion of pluralism and decentralization underlying the *DHHS Task Force Report.* Under the applicable statutes, DHHS has the ability to alter this conception of UNOS' role — to bring UNOS policies into conformity with a very different approach toward the proper role of the OPTN. Indeed, the contract with UNOS provided (and continues to provide) DHHS with leverage over UNOS policies, a power DHHS apparently chose to exercise only modestly.[139] As a result, at a time when health policy has been marching increasingly to the tune of pluralism and competition, organ transplantation policy, with DHHS complicity, has been marching to the beat of a very different drummer — centralized, command-and-control, bureaucratic decision making. Despite DHHS' protestations to the contrary, this outcome, which conflicted with the Reagan Administration's professed belief in pluralism and decentralization, is not mandated by federal statutory law. Federal law permitted this result by establishing a private-sector network and then in effect mandating transplant center membership in the network. The private network — UNOS — has embraced the conception of its role embodied in the *DHHS Task Force Report.* By controlling the contracting specifications and rulemaking process, however, DHHS had (and still has) the authority and the power to reshape the Network in accordance with a very different vision of the Network's proper and properly delimited role.

As examples, I will focus on three areas of UNOS regulatory standards and criteria: IOPA membership; transplant program membership; and organ acquisition and distribution.

1. IOPAs

UNOS established detailed guidelines for IOPAs to assure the smooth functioning of the organ procurement process.[140] For example, an IOPA must maintain the potential organ donor, document an array of laboratory results (designed to ensure organ procurement quality),

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[139] There is some evidence that DHHS now sees the issue and is in the process of considering the proper oversight relationship between DHHS and the OPTN. *See infra* note 245.

[140] *See* 1988 BY-LAWS, *supra* note 106, Appendix B, Attachment 2.

and secure and document appropriate consent for organ donation.[141] UNOS requires that an IOPA have agreements with regional transplant centers designating the IOPA as a procurement agency.[142] UNOS also specifies an IOPA's minimum personnel requirements.[143] One interesting criterion, which appears to conflict with subsequently adopted DHHS regulations, is that an IOPA "have a defined exclusive service area."[144] The 1986 legislation specifically states that DHHS "may not designate more than one organ procurement organization for each service area."[145] This was a response to the *DHHS Task Force Report*'s recommendation that competition among organ procurement agencies be discouraged. DHHS has recognized that this requirement will inevitably reduce the number of OPOs qualified to participate in Medicare.[146] In part to alleviate this potential problem, DHHS in its regulations expressly permits transplant hospitals to deal with any designated OPO it wishes.[147] DHHS requires one OPO per service area,[148] but it does not give any OPO a monopoly within its service area. Transplant hospitals are free to work with a number of OPOs from various geographic areas. This freedom is an example of DHHS sensitivity to the anticompetitive consequences of an exclusive, monolithic system that bars entry and otherwise precludes the stimulus to performance that typically results from competition.

Thus, the UNOS requirement that an IOPA have a "defined *exclusive* service area"[149] is troublesome and a bit puzzling. To be qualified for DHHS designation, an OPO must be an UNOS member. DHHS has stated its position that OPOs should not have exclusive territorial rights.[150] If the UNOS requirement should be interpreted to be in conflict with the DHHS regulation, then by enforcing its rule to deny an IOPA membership, UNOS could possibly overturn the directives of the federal agency charged with administering the federal organ transplantation policy. If this overturning is permitted (as DHHS suggests),[151]

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[141] *See id.*

[142] *See id.*

[143] *See id.*

[144] *Id.*

[145] Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, § 9318(b)(2), 100 Stat. 2009, 2010 (1986) (codified at 42 U.S.C. § 1320b-8(b)(2) (Supp. IV (1986)).

[146] 53 Fed. Reg. 6525, 6546 (1988).

[147] *Id.* at 6541.

[148] *See id.*

[149] *See* 1988 BY-LAWS, *supra* note 106, Appendix B, Attachment 6.

[150] *See* 53 Fed. Reg. 6525, 6541 (1988).

[151] *See id.* at 6529-30.

then UNOS, a private organization, could possibly override policies established by the federal government itself — a remarkable outcome that demonstrates UNOS' incredible potential power. In this example, the centralized, bureaucratic, command-and-control ideology of both UNOS and the Task Force Report could supersede the attempted accommodation of competition adopted by DHHS in its regulations.[152]

2. Transplant Programs

To qualify for UNOS membership, a transplant program must meet specific, detailed requirements, particularly concerning personnel. This is apparently a response to the *DHHS Task Force Report*'s recommendation that "transplant centers be designated by an explicit, formal process using well-defined, published criteria."[153]

In some details, the UNOS personnel criteria differ from DHHS criteria for approving Medicare transplant programs, especially for kidney transplants, which Medicare covers. The tougher UNOS standards effectively bar federal payment to transplant centers not meeting UNOS standards, even if they meet DHHS standards. Moreover, a transplant center's failure to comply with the Medicare designation standards bars only federal payment for otherwise eligible transplants in the non-complying centers. Hospitals are allowed to develop transplant protocols at odds with Medicare regulations and either to seek payment from other sources or to subsidize them internally through other available funds. The cost of noncompliance is transplant-specific and would allow noncomplying hospitals to experiment on their own without adversely affecting their other operations.

On the other hand, a transplant center's nonadherence to UNOS policies has much more wide-sweeping consequences. Failure of any transplant program to comply with UNOS policies means debarment of an entire hospital from Medicare or Medicaid participation. In substance, this means that no hospital will be able to strike out on its own

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[152] Senator Hatch, an original sponsor of the 1984 organ transplantation legislation, has voiced concern about this potential for vesting of excessive power in private hands. *See* 134 CONG. REC. S8094 (1988). Senator Hatch has expressed the view, on the Senate floor, that the delegation of regulatory authority to UNOS is unconstitutional. *Id.* Relying on A.L.A. Schechter Poultry Corp. v. United States, 295 U.S. 495 (1935), Senator Hatch argued that Congress cannot delegate regulatory authority to a private entity. *Id.* The delegation to UNOS is particularly troublesome, according to Senator Hatch, because the UNOS "guidelines take effect without any affirmative action by the executive." *Id.*

[153] DHHS TASK FORCE REPORT, *supra* note 1, at 113.

in organ transplantation unless it secures UNOS authorization. Even if DHHS guidelines are satisfied or if DHHS might otherwise approve (or not disapprove) a transplant program, no such non-UNOS-conforming venture can be undertaken without jeopardizing an entire hospital's Medicare and Medicaid participation. This situation poses a staggering potential problem regarding entry barriers and resistance to innovation — especially when the existing transplant establishment is entrusted with such enormous control to impose clinical orthodoxy on the potential heretic.

DHHS has acknowledged the implicit supremacy of UNOS in circumstances in which UNOS guidelines conflict with DHHS policies: federal law "does not require the Network's [*i.e.*, UNOS'] rules to be identical to those under Medicare."[154] As a result, when there are differences, the practical consequence is that UNOS criteria prevail, thus potentially reducing the number of eligible transplant centers.

The *DHHS Task Force Report* asserted that "authority . . . for [transplant] center designation should reside within DHHS."[155] Subsequent to the *DHHS Task Force Report*, DHHS adopted a designated center approach for Medicare payment for heart transplantation, reflecting an extrapolation of its authority to designate kidney transplant centers.[156] The question is whether DHHS designation or non-designation decisions should be permitted, under the DHHS contract with UNOS, to be superseded by potentially conflicting UNOS designation standards. Although federal law may not require that UNOS and Medicare rules be identical, as DHHS asserts, surely DHHS has ample authority to require UNOS, under its contract with DHHS, to defer to Medicare rules when conflicts exist.

An example of UNOS policies' potential for restrictiveness is the limited opportunity for new transplant programs to begin operation.[157] Only an "established transplant program in one organ" may start a transplant program in another organ and be granted two years to comply with all UNOS standards.[158] Transplant programs being started without this background in transplantation of another organ must meet all UNOS criteria from the outset. UNOS defines an "established transplant program" as one that has performed fifty or more trans-

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[154] 53 Fed. Reg. 6525, 6530 (1988) (to be codified in scattered sections of 42 C.F.R.).

[155] DHHS TASK FORCE REPORT, *supra* note 1, at 115.

[156] *See* 52 Fed. Reg. 10935 (April 6, 1987); *supra* note 27 and accompanying text.

[157] *See* 1988 BY-LAWS, *supra* note 106, Appendix B, at III.C.(2).

[158] *See id.*

plants in a specific organ and has been in operation for at least two years.[159] That type of entry barrier clearly tends to preserve new transplant opportunities for pre-existing (*i.e.*, "established") transplant programs. The requirement should prima facie make any marketeer apprehensive, particularly since such restrictiveness is being imposed on potential entrants by entrenched interests that could be threatened by the development of new, competitive programs. In other contexts, the antitrust laws have been invoked to scrutinize such arrangements carefully.

The historical evolution of this policy, moreover, should provide little comfort. In the November 4, 1987, By-Laws, UNOS allowed new transplant programs not started by an "established transplant program" to come into existence if UNOS criteria were satisfied at the outset "except for survival criteria which will be evaluated for compliance two years after the start of the program."[160] Under the May 31, 1988, By-Laws, UNOS requires such new programs to "meet all UNOS membership criteria from the outset."[161] This presumably would include satisfying survival criteria, which the By-Laws do not specify. Given that a hospital can only have a transplant program that satisfies UNOS requirements, it is not at all clear how such a new program can even be commenced outside an "established transplant program," *i.e.*, how it can immediately demonstrate compliance with UNOS survival rate requirements. This requirement seems extraordinarily restrictive — a virtual Catch 22 — and a significant (if not insuperable) barrier to entry by programs set up by any program other than an "established transplant program." The basis for the more restrictive policy adopted between November 1987 and May 1988 is not clear and, given its self-evident anti-competitive character, seems highly suspicious on its face.[162]

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[159] *See id.*

[160] 1987 BY-LAWS, *supra* note 109, Appendix B, at III.C.(2).

[161] 1988 BY-LAWS, *supra* note 106, Appendix B, at III.C.(2).

[162] The May 31, 1988, provisions for new programs are more restrictive for an "established transplant program" as well. Under the November 1987 policies, an established program could start a new program in another organ type on an unrestricted basis, provided it complied with all UNOS criteria within two years. No regulations restricted the new start-up operation for that interim two-year period. *See* 1987 BY-LAWS, *supra* note 109, Appendix B, at III.C.(2). The May 1988 policies are much more restrictive, calling for "conditional approval" for a two-year period but only if the new program satisfies specific "criteria for conditional approval." 1988 BY-LAWS, *supra* note 106, Appendix B, at III.C.(2). These criteria concern staffing and compliance with open-ended, potentially *ad hoc* policies of UNOS' Membership and Professional Standards Committee (MPSC). *Id.* Thus, a new program, for conditional ap-

Although the rhetoric tends to emphasize quality and access concerns, one need not probe too deeply to discover that payors as well as entrenched providers have a potential interest in restricting the number of designated centers to keep overall costs down. Limited availability of facilities (and of organs) may reduce the number of transplants and help limit costs.[163] This reasoning is quite a different agenda than the one used to justify establishment of and support for the OPTN. Given the differences between UNOS and DHHS standards, and given the nature and composition of UNOS, a healthy skepticism of the UNOS regulatory provisions and their impact on competition is entirely justified.[164]

3. Organ Acquisition and Distribution

Of the various proposals that the Task Force on Organ Transplantation was asked by Congress to study,[165] a proposed list of prospective organ donors was the major idea the *DHHS Task Force Report* rejected. The Report did recommend a centralized list of potential recipients but concluded that a list of potential donors was not useful.[166] UNOS has followed the Task Force's recommendations by establishing and maintaining a computerized list of potential recipients and by declining to establish a potential donor list.

The donor list issue is very revealing for several reasons. Advocates for formulating and maintaining such a list would argue that it might serve as a stimulus for recruiting potential donors, thus encouraging solicitation of signees who, left on their own, might not sign a donor card. A potential donor list might therefore increase organ supply. It could help shift the locus of organ solicitation away from the potential donor's family to the donor herself. The list could also shift the timing of organ solicitation away from the time when a beloved family member is at death's door to a time when the potential donor herself could more rationally and relaxedly decide whether to allow her name to be placed on a potential donor list.

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proval, must comply with "such interim operating policies and procedures as shall be required by" the MPSC. *Id.* This standard is an entirely discretionary standard subject to the potential for abuse, arbitrary application, and anti-competitiveness.

[163] *See* Bovbjerg, *supra* note 124.

[164] *See* Sloan, Shayne & Doyle, *Organ Transplantation Services: Is There a Rationale for Regionalization*, 14 J. HEALTH POL., POL'Y & LAW 115 (1989).

[165] *See* Pub. L. No. 98-507, 98 Stat. 2339, 2340 (1984) (at 42 U.S.C. § 273 note (Supp. IV 1986)).

[166] *See* DHHS TASK FORCE REPORT, *supra* note 1, at 49-51.

Moreover, and one may conjecture that this is the real rub, the existence of a potential donor list would provide a handy vehicle to introduce incentives. Financial or other incentives might be used to induce potential "donors" to make binding commitments for fixed periods of time to allow their organs to be used for transplantation upon their death.

The resistance to establishing a list of potential organ donors is another example of the policy-inhibiting aspects of a set of hard ideological rules — no valuable consideration for allowing one's organs to be used after death for transplantation; exclusive reliance on altruistic motivation for transplantable organ supply; and total commitment to the purported benefits of communitarian expressions of solidarity through families' choosing to donate the organs of their next-of-kin at the time of death. The existence of a list of potential donors might cause analysts concerned about transplantable organ supply to consider legalizing inducements for signing up. Whether or not such inducements would be effective in increasing transplantable organ supply is an empirical question. Some states apparently have such ideas (*e.g.*, through tax credits) under consideration, although the 1987 revision to the UAGA proposes, on the basis of the most abstract and skimpy reasoning, that all states should ban the purchase or sale of cadaver organs.[167] Until flexibility exists and until financial inducements are allowed, no one will know how effective or costly they might be.

Opponents' conventional wisdom is that financial inducements will not enhance organ supply;[168] however, in the absence of evidence it is clear that the opposition stems from ideology not empiricism. For example, the cursory commentary on section 10 of the 1987 revised UAGA, which proposes the ban on purchase or sale of cadaveric organs, quotes the recommendation of the *DHHS Task Force Report* that each state should enact laws prohibiting "the sale of organs from cadavers or living donors within their boundaries."[169] It further quotes a 1985 *Hastings Center Report*, which emphasizes "[a]ltruism and a desire to benefit other members of the community" and expresses concern that transplantation "undertaken primarily with an eye toward profit rather than therapy will severely imperil the moral foundations, and thus the efficacy of the system."[170]

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[167] *See* 1987 UAGA § 10 & comments, 8A U.L.A. supp. 18-19 (Supp. 1988).

[168] *See* Robertson, *supra* note 99, at 80.

[169] DHHS TASK FORCE REPORT, *supra* note 1, at 99.

[170] *See* 1987 UAGA § 10 & comments, 8A U.L.A. 18-19 (Supp. 1988) (quoting HASTINGS CENTER, *Ethical, Legal and Policy Issues Pertaining to Solid Organ Pro-*

UNOS could contribute modestly by creating a list of potential organ donors and by concurrently allowing nonpecuniary inducements (such as active appeals to good citizenship) to be tried. This plan would shift the timing and locus of decision making and perhaps provide some basis and impetus for legalizing experiments with solicitation or sign-up inducements. In addition, with greater evidence of a donor's public commitment to organ donation, the culture of transplantation centers might change to allow sign-ups to be deemed sufficient to allow organ harvesting without further involvement of or imposition on next-of-kin at the bedside. After all, under existing law,[171] any person of sound mind and 18 years of age or more can donate his organs for transplantation. Moreover, anyone who acts in good faith in accord with the UAGA is immune from civil liability or criminal prosecution.[172] The 1987 revised UAGA goes even further in this direction, expressly stating that "[a]n anatomical gift that is not revoked by the donor . . . does not require the consent or concurrence of any person after the donor's death."[173]

However, on ideological grounds opponents of a donor registry seem to object even to the shift of decision making locus and timing to what surely is a more rational, compassionate setting — prior to any life-threatening episode. Transplant orthodoxy seems to reject this shift because it deemphasizes "next-of-kin consent," thereby depriving the family of an opportunity for "[p]romoting a sense of community through acts of generosity."[174] This strong ideological stance, which is implicitly embodied in the UNOS requirement of consent by the next of kin,[175] is out of sync with the legal position of the UAGA, as reinforced by the 1987 revisions. In short, as the *DHHS Task Force Report* candidly acknowledged, efficiency and lifesaving values need to be balanced against other social values, such as the rather abstract and ethereally romantic "value of social practices that enhance and strengthen altruism and our sense of community."[176] Given the precarious — and sometimes even ghoulish — dimensions to next-of-kin donation at the time of death, and given the questionable efficacy of that approach for organ supply, rigid adherence to this communitarian value seems to be

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curement: A Report of the Project on Organ Transplantation 2 (Oct. 1985)).

[171] 1968 UAGA §§ 2(a), 4(b), 8A U.L.A. 34, 43 (1983); 1987 UAGA § 2(a), 8A U.L.A. supp. 5 (Supp. 1988).

[172] *See* 1968 UAGA § 7(c), 8A U.L.A. 59, 59-60 (1983).

[173] 1987 UAGA § 2(h), 8A U.L.A. supp. 6 (Supp. 1988).

[174] DHHS TASK FORCE REPORT, *supra* note 1, at 28.

[175] UNOS, POLICIES § 2.5 (May 31, 1988).

[176] DHHS TASK FORCE REPORT, *supra* note 1, at 28.

achieved at a very high price indeed.

UNOS policies require that all potential recipients of organ transplants be listed on the UNOS computerized waiting list.[177] UNOS does not establish a monolithic nationwide system. It does not, for example, require that all locally harvested organs be regionally or nationally shared. An individual transplant center may retain organs it harvests with two important constraints. First, UNOS requires mandatory regional sharing for all kidneys having a "six antigen match."[178] This type of tissue typing and matching can improve the likelihood of long-term graft success,[179] adding to and enhancing the effects of immunosuppressive drugs such as cyclosporine.[180]

Second, UNOS has established a detailed point system for allocating cadaveric kidneys[181] and extrarenal organs.[182] While transplant centers can retain organs they harvest (other than six antigen match kidneys), each center must abide by UNOS allocative criteria in distributing organs within its own institution. Thus, UNOS' explicit criteria control distribution of organs within all member institutions and when organs are regionally or nationally shared.

The requirement for mandatory sharing of six antigen match kidneys and the mandatory allocative point systems both demonstrate the lack of control, under UNOS policies, by organ donors of the identity of potential recipients. The UAGA allows the organ donor to designate a donee, who can be a specific individual.[183] The 1987 UAGA revision continues to allow donors to designate a specific individual as a donee.[184] The 1986 *DHHS Task Force Report* in contrast, recommended that "donated organs be considered a national resource to be used for the public good."[185] Organs would become socialized, with individual donors stripped of power to control the destiny of their donated organs or to designate specific beneficiaries.

Because every jurisdiction has enacted the UAGA, the Task Force's recommendation would substantially change the law. The UNOS policies, which reflect general agreement with the Task Force's approach, would indicate that, despite legal authority conferred on donors by

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[177] UNOS, POLICIES § 3.1 (May 31, 1988).
[178] *See id.* § 3.3.
[179] DHHS TASK FORCE REPORT, *supra* note 1, at 67.
[180] *Id.* at 70.
[181] *See* UNOS, POLICIES § 3.5 (May 31, 1988).
[182] *See id.* §§ 3.6-.7.
[183] *See* 1968 UAGA §§ 3(4), 4(c), 8A U.L.A. 41, 44 (1983).
[184] *See* 1987 UAGA §§ 6(a)(3), 6(b), 8A U.L.A. supp. 13 (Supp. 1988).
[185] DHHS TASK FORCE REPORT, *supra* note 1, at 86.

UAGA, a transplant center could not honor a specific bequest to an individual recipient if that recipient did not have the highest point total under the UNOS point system. Thus, a potential conflict exists between the provisions of state law and the ability of transplant centers to comply with state law. Violation of UNOS policies could result in loss of UNOS membership, and that loss would consequently make hospitals ineligible for Medicaid and Medicare participation.[186]

It is interesting to speculate what remedy, if any, a frustrated recipient would have when a donor has designated a specific recipient as donee but the hospital refuses to honor that legally authoritative gift out of fear of violating UNOS policies.[187] Under Section 2(e) of the UAGA, "[t]he rights of the donee created by the gift are paramount to the rights of others . . . ."[188] The 1987 revision retains this provision.[189] Section 2(c) of the UAGA bars a donee with "actual notice of contrary indications by the decedent" from accepting a gift,[190] and Section 2(b) prohibits next-of-kin donation which contradicts the decedent donor's wishes.[191] Thus, UNOS policies potentially require transplant center conduct explicitly at odds with and in violation of state law (as reflected by the UAGA).

Would state courts under these circumstances order transplant centers to follow authoritative state law, against a hospital's defense that adherence to state law would violate UNOS policies and thereby jeopardize that hospital's continued eligibility for Medicaid and Medicare participation? Would a hospital be able to defend successfully an after-the-fact liability claim that its refusal to honor an organ bequest to a specific, designated beneficiary was based on its desire to comply with UNOS policies? Although these issues have not authoritatively been litigated, one might reasonably conjecture that state courts might likely give effect to controlling state law, which empowers donors and recipients. It is even conceivable that state courts would impose liability on UNOS for its coercive role in compelling transplant centers to dishonor state law. In any event, the potential for conflict between UNOS poli-

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[186] Whether or not UNOS would expel a member for a single act in which a hospital acceded to the dictates of state law is not the issue. Given the stakes involved, prudent hospitals will proceed in ways unlikely to challenge the supremacy of UNOS rules.

[187] This could happen because a donee is not the best match, or because the donee is not listed on the waiting list of the hospital in which the prospective donor is a patient.

[188] 1968 UAGA § 2(e), 8A U.L.A. 35 (1983).

[189] 1987 UAGA § 8(a), 8A U.L.A. supp. 14 (Supp. 1988).

[190] 1968 UAGA § 2(c), 8A U.L.A. 34 (1983).

[191] *Id.* § 2(b).

cies and state law has not yet been played out and, unlike the UAGA, which provides immunity for those who act in reliance on it, no such statutory immunity exists for hospitals acting in reliance on UNOS policies.

It was the vision of the Task Force on Organ Transplantation that donated organs should be considered a "national resource," *i.e.*, a "scarce public resource," whose distribution would be governed "by criteria based on need, effectiveness, and fairness that are publicly stated and publicly defended."[192] Medical criteria should dictate organ allocation, with the major factors being urgency of need and probability of success.[193] According to the Task Force, "[i]f two or more patients are equally good candidates for a particular organ according to the medical criteria of need and probability of success, the principle of justice suggests that length of time on the waiting list is the fairest way to make the final selection."[194]

Although the *DHHS Task Force Report* recognized "[p]ractical and technical limitations,"[195] it labeled as "ideal" a system of organ distribution in which geography would be irrelevant.[196] The 1984 National Organ Transplant Act identifies as a Network (OPTN) function assisting organ procurement organizations (OPOs) in the distribution of organs "which cannot be placed within the [OPO's] service areas."[197] The original statute seemed to prefer a regional orientation, but it is unclear whether that reflected a technocratic judgment as of 1984 or a policy preference.[198] The 1988 amendments of the 1984 Act deleted the geographical language to "remove any statutory bias" about the proper role of geographical factors in organ distribution.[199] The OPTN (UNOS) must now resolve issues concerning "fair and effective distribution of organs" with "[p]atient welfare . . . be[ing] the paramount consideration."[200]

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[192] DHHS TASK FORCE REPORT, *supra* note 1, at 86.

[193] *See id.* at 87.

[194] *Id.* at 89.

[195] *Id.* at 91.

[196] *Id.*

[197] 42 U.S.C. § 274(b)(2)(C) (Supp. IV 1986).

[198] Recent evidence suggests the attractive possibilities for wider distribution of transplantable organs from center to center. *See* Opelz, *supra* note 74, at 1289-92.

[199] *See* HOUSE COMM. ON ENERGY AND COMMERCE, H.B. 3097, H.R. REP. NO. 383, 100th Cong., 2d Sess. 7, Oct. 20, 1987 (enacted as Title IV, Organ Transplant Amendments Act of 1988, Pub. L. No. 100-607, 102 Stat. 3114 (1989); SENATE COMM. ON LABOR AND HUMAN RESOURCES, S. REP. NO. 310, 100th Cong., 2d Sess. 14, Mar. 29, 1988 (enacted as Organ Transplant Amendments Act of 1988, *supra*).

[200] *Id.*

The *DHHS Task Force Report* recommended mandatory sharing of organs across transplant centers for perfectly matched donor-recipient pairs.[201] It discussed the advantages of organ sharing in other circumstances but made no other specific recommendation about mandatory sharing. The Task Force also recommended "a single national system for organ sharing" with "uniform policies and standards by which all will abide."[202] The Task Force recognized a "diversity of practices" among transplant centers on a wide array of transplantation issues, including patient selection criteria.[203] It concluded that uniformity across centers was desirable and, in some contexts, necessary for effective organ sharing.[204]

The organ distribution policies adopted by UNOS very closely parallel the *DHHS Task Force Report*'s recommendations, but they also strike new ground in some areas. UNOS requires sharing of perfectly matched kidneys but does not mandate sharing of other perfectly matched organs.[205] Voluntarily shared organs are allocated "first regionally, and then nationally based upon the [UNOS] point system."[206] Thus, UNOS policies restrict required sharing and expressly provide for regional preference of voluntarily shared organs.

While transplant centers may, therefore, retain organs they procure, all local level organ distributions must comply with the UNOS point system. To the objection of some who advocate a nationally integrated allocation system, UNOS policies expressly permit "[l]istings of patients on multiple local waiting lists."[207] To the extent that organs are not regionally or nationally shared, and therefore remain at the transplant center or other local level, such multiple listings improve a patient's likelihood of being successfully matched at the local level. That provision clearly rewards aggressive patient and transplant center initiative and offends purist, access-egalitarian ideologues, who view such patient behavior as unfair — as improper gaming of the system.

Overall, the Task Force on Organ Transplantation and to a larger extent UNOS have not pushed the "national resource" concept to the extreme. The medical case for matching seems strong,[208] but the Task Force's recommendations and UNOS policies seem to reflect an accom-

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[201] DHHS TASK FORCE REPORT, *supra* note 1, at 70.
[202] *Id.* at 69.
[203] *See id.* at 68.
[204] *See id.* at 68-69.
[205] UNOS, POLICIES § 3.5 (May 31, 1988).
[206] *Id.* §§ 3.5.7., 3.6.9.
[207] *Id.* § 3.2.
[208] *See* Opelz, *supra* note 74, at 1289-91.

modation with prevailing views of major transplant centers and their surgical teams that the availability of immunosuppressive drugs such as cyclosporine makes sharing less important.[209] Speakers at the recent Vanderbilt Symposium indicated that transplant surgeons historically have felt territorial about organs they harvest.[210] The UNOS policies appear to reflect a compromise with this prevailing attitude among transplant surgeons. In light of the Task Force's strong condemnation of commercializing organs and its advocacy that property rights of donors be eliminated, it is ironic that the ideology of "national resource" for organs confronts and must respond to the territoriality or property rights perspective — not of donors or patients, but of transplant centers and their surgical teams.

III. An Antitrust Perspective on Organ Transplantation Policy

In earlier Parts, I alluded to the potential for antitrust scrutiny of restrictive, anticompetitive UNOS policies. The antitrust laws provide an important mechanism for enforcing procompetitive policies and for prohibiting excessive restraints on the competitive ideal. In this Part, I will briefly explore application of potentially relevant antitrust principles and consider whether the 1984 and 1986 organ transplantation legislation would shield the conduct of UNOS from antitrust scrutiny under principles of implied repeal of the antitrust laws. My conclusion is that the case for implied repeal is not strong and that the antitrust laws will apply to UNOS' conduct.

The Supreme Court has repeatedly acknowledged that "private standard-setting associations have traditionally been objects of antitrust scrutiny."[211] The reason for concern is that "private standard-setting associations . . . include members having horizontal and vertical business relationships."[212] Thus, such private standard-setting organizations are typically treated as continuing conspiracies of their members,[213] who often have economic incentives to restrain competition. "[P]roduct standards set by such associations have a serious potential for anticom-

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[209] *See* Salvatierra, *supra* note 74, at 1329.

[210] The Vanderbilt Symposium, held in June 1988, was entitled, "Organ Transplantation: Policies, Problems, and Prospects." Papers from the Symposium are published at 14 J. Health Pol., Pol'y & L. 1 (1989).

[211] Allied Tube & Conduit Corp. v. Indian Head, Inc., 108 S. Ct. 1931, 1937 (1988).

[212] *Id.*

[213] *See* P. Areeda, Antitrust Law para. 1477, at 343 (1986).

petitive harm" and are subject to antitrust scrutiny.[214]

The OPTN is potentially subject to antitrust review on at least two bases — as a private standard-setting organization and as an entity in control of an essential facility.

The behavior of private standard-setting organizations is typically not *per se* illegal. The activities of such groups may be justified because they "promulgate safety standards based on the merits of objective expert judgments and through procedures that prevent the standard-setting process from being biased by members with economic interests in stifling product competition."[215] The reason for antitrust deference, however, is that the standards promulgated by these private associations "can have significant procompetitive advantages."[216]

Under antitrust analysis, courts usually cannot consider alternative values to be balanced against the value of competition. The balancing in an antitrust "Rule of Reason" analysis is an investigation into the competing procompetitive virtues of various ostensible restraints. Antitrust inquiry focuses exclusively on the "challenged restraint's impact on competitive conditions."[217] The function of a Rule of Reason analysis "is to form a judgment about the competitive significance of the restraint; it is not to decide whether a policy favoring competition is in the public interest, or in the interest of members of the industry."[218] The policy decision in favor of competition has been made by the antitrust law, which "reflects a legislative judgment that . . . competition is the best method of allocating resources in a free market. . . ."[219] Arguments about the desirability of procompetitive practices in a particular context are not for courts or for private standard-setting bodies to consider because the procompetitive policy underlying the antitrust law "precludes inquiry into the question whether competition is good or bad."[220] Thus, the Supreme Court has rejected arguments that "the special characteristics of a particular industry" justify anticompetitive arrangements on the ground that they "will better promote trade and commerce than competition."[221] If a restraint is to be justified under a

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[214] American Soc'y of Mechanical Eng'rs, Inc. v. Hydrolevel Corp., 456 U.S. 556, 571 (1982); FTC v. Indiana Fed'n of Dentists, 476 U.S. 447 (1986).

[215] *Allied Tube*, 108 S. Ct. at 1937; *see also American Soc'y of Mechanical Eng'rs*, 456 U.S. at 570-73.

[216] *Allied Tube*, 108 S. Ct. at 1937.

[217] National Soc'y of Professional Eng'rs v. United States, 435 U.S. 679, 688 (1978).

[218] *Id.* at 692.

[219] *Id.* at 695.

[220] *Id.*

[221] *Id.* at 689.

Rule of Reason antitrust analysis, those defending the ostensibly anticompetitive conduct must demonstrate an offsetting "countervailing pro-competitive virtue."[222]

Under this aspect of antitrust scrutiny, therefore, the standards promulgated by the OPTN (*i.e.*, UNOS) must be justified through their procompetitive character. To the extent that such standards are set without empirical support,[223] the procompetitive rationale for their existence diminishes and, in the Rule of Reason antitrust balancing process, such restrictive practices may be held invalid. Moreover, to the extent that the OPTN seeks "to *enforce* (rather than just to agree upon) private product standards," it faces "more rigorous antitrust scrutiny."[224]

In pursuing a coercive, command-and-control regulatory approach — in which the OPTN seeks not only to establish but also to enforce standards on all facets of the transplantation enterprise — the OPTN runs the risk of more intensified antitrust scrutiny. In addition, since OPTN rules and regulations must be justified within the framework of the antitrust laws by reference to procompetitive values, UNOS is not legally authorized to determine that competition in the organ transplantation arena is inappropriate.

The second avenue of potential antitrust scrutiny stems from the OPTN's exclusive control over transplantation activities. This status is conferred by Section 1138(c)(1)(B)'s requirement that a hospital with a transplant program be a member of and abide by the rules of the OPTN if it wishes to participate in Medicare or Medicaid.[225] Situations such as this warrant consideration under the "essential facilities" doctrine, which requires close antitrust scrutiny when potential competitors control and exclude others from access to a facility, service, or resource that is necessary to allow competition to flourish.[226]

UNOS rules bar UNOS members from listing patients for a non-

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[222] FTC v. Indiana Fed'n of Dentists, 476 U.S. 447, 459 (1986).

[223] *See* Sloan, Shayne & Doyle, *supra* note 164.

[224] Allied Tube & Conduit Corp. v. Indian Head, Inc., 108 S. Ct. 1931, 1937 n.6 (1988) (emphasis in original); *see* Radiant Burners, Inc. v. Peoples Gas Light & Coke Co., 364 U.S. 656, 659-60 (1961); Fashion Originators Guild of Am., Inc. v. FTC, 312 U.S. 457 (1941).

[225] *See* 42 U.S.C. § 273(a)(2) (Supp. IV 1986).

[226] *See* Blumstein & Calvani, *State Action as a Shield and a Sword in a Medical Services Antitrust Context:* Parker v. Brown *in Constitutional Perspective*, 1978 DUKE L.J. 389 (1978). For a discussion and a critique of the essential facilities doctrine, see Note, *Rethinking the Monopolist's Duty to Deal: A Legal and Economic Critique of the Doctrine of "Essential Facilities"*, 74 VA. L. REV. 1069 (1988).

UNOS transplant program.[227] UNOS does not allow access to its computer system for matching purposes to non-UNOS OPOs.[228] Non-UNOS transplant centers (if any should exist) cannot obtain any organs from UNOS.[229] Moreover, patients in non-UNOS institutions may not be listed on the UNOS computer; only UNOS members may place a patient's name on the waiting list.[230] When combined with the mandatory UNOS membership for hospitals' Medicare/Medicaid participation,[231] these exclusionary policies reinforce the exclusive power of UNOS over all facets of organ transplantation. Under governing antitrust law, a serious issue arises whether this aspect of the UNOS enterprise may constitute an antitrust violation. In this regard, a case may even be made to apply not the balancing Rule of Reason analysis but the draconian rule of *per se* invalidity.[232]

The foregoing assumes that the antitrust laws are applicable, as adapted to the context of organ transplantation policy. It is possible to argue, as UNOS has done, that the antitrust laws should not apply to the conduct of UNOS and the OPTN. Any claim of immunity from coverage under the antitrust laws must come from either an express statutory exemption or an implied or inferred immunity.

The express immunity from the antitrust laws for certain good faith professional peer review activities contained in the Health Care Quality Improvement Act of 1986[233] is an example of an explicit immunity. No organ transplantation legislation contains any such explicit immunity from the antitrust laws. Therefore, any immunity from coverage under the antitrust laws must come from an implied immunity. However, "the Supreme Court has been very reluctant to imply such a waiver, and it is very unlikely that UNOS would qualify."[234]

Implicit repeal of the antitrust laws is not lightly inferred, and it is questionable whether anything in either the 1984 National Organ Transplant Act or the 1986 Omnibus Budget Reconciliation legislation would be construed to immunize UNOS from antitrust scrutiny.[235] As

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[227] *See* UNOS, POLICIES § 3.8.2 (May 31, 1988).

[228] *See id.* at § 3.8.3.

[229] *See id.* at § 3.8.5.

[230] *See id.* at § 3.8.6.

[231] *See supra* note 225 and accompanying text.

[232] *See* Northwest Wholesale Stationers, Inc. v. Pacific Stationery and Printing Co., 472 U.S. 284, 293-99 (1985).

[233] Pub. L. No. 99-660, 100 Stat. 3784 (1986) (codified at 42 U.S.C. § 11101, 11111-11151 (Supp. IV 1986)).

[234] 134 CONG. REC. S8094 (daily ed. June 17, 1988) (statement of Sen. Hatch).

[235] *See* National Gerimedical Hosp. & Gerontology Center v. Blue Cross of Kansas

the Supreme Court has stated, the antitrust laws are impliedly repealed only if a subsequent federal statutory scheme is "clearly repugnant" to the ongoing validity and application of the antitrust laws.[236] Implied repeal is found only when there is an irreconcilable conflict between the antitrust law and other federal statutory policy — when "operation of the one makes impossible operation of the other."[237]

As this Part has demonstrated, no irreconcilable conflict exists between organ transplantation legislation and antitrust law. The OPTN could surely have achieved its task without imposing the coercive, anticompetitive restraints it did. Since adherence to the 1984 and 1986 legislation does not self-evidently "require breaking" antitrust law,[238] that law remains applicable to UNOS activities.

CONCLUSION

To some in the organ transplant community, consideration of antitrust issues may well seem like heresy. It surely does bring into perspective the antitrust value of promoting competition — a value the *DHHS Task Force Report* frowned on. The antitrust philosophy, and its potential application to the organ transplantation context, highlight the fundamental role of a divergent ideology in the evolution of organ transplantation policy.

Evidence already exists that courts are applying traditional doctrines designed to protect commerce to the organ transplant arena. For example, the State of New Jersey barred the Philadelphia regional organ procurement agency from pursuing its activities in New Jersey.[239] The Philadelphia agency brought suit against New Jersey in federal court, claiming that New Jersey's action was economic protectionism.[240] New Jersey was preserving the market in organ procurement for New Jersey procurement organizations, the Agency asserted, and was thus unconstitutionally interfering with and discriminating against interstate commerce.[241]

City, 452 U.S. 378 (1981).

[236] *See* Silver v. New York Stock Exchange, 373 U.S. 341 (1963).

[237] Calvani & Gee, *Resolving the Tension Between Health Planning and the Antitrust Laws* in COST, QUALITY, AND ACCESS IN HEALTH CARE, *supra* note 121, at 191, 198.

[238] *See id.*

[239] *See* Delaware Valley Transplant Program v. Coye, 678 F. Supp. 479 (D.N.J. 1988) (granting preliminary injunction).

[240] *See id.* at 480-81.

[241] *See id.* at 481-82.

Considering antitrust and commerce clause doctrine is useful because it brings into sharp focus the widely disparate ideologies that have developed in organ transplantation compared to both the non-health field and, more recently, the non-transplantation portions of the health industry itself.[242] The federal organ transplantation policy superstructure, as envisioned by the *DHHS Task Force Report*, reflects intense hostility to pluralism, decentralized decision making, profit-making, commercialization, competition, private choice, and even private property (as reflected in one's control of the disposition of one's own organs and one's ability to buy or sell organs). The organ transplantation enterprise may well have peculiar characteristics that warrant some degree of specialized policy prescription. However, the field currently suffers from ideological hardening of the arteries. In other facets of health policy, the emerging consensus has been to require advocates for deviations from competitive norms and decentralized pluralism to bear a burden of justification and to narrowly tailor proposed deviations to cure specific, delimited market failures.[243] The organ transplantation enterprise has indulged in an orgy of romanticism, mandating altruism and communitarianism at the possible expense of saving lives. Ideology has caused hostility towards and non-adherence to the UAGA's private-property-rights approach toward organ donation, legally adopted in all fifty states. In addition, ideology has caused a romantic glorification of the symbolic act of next-of-kin donation of organs from family members' dying relatives. This glorification is at the expense of a more rational (and compassionate) shifting of the timing of decision making to an earlier stage, when potential "donors" in a more relaxed manner (and with the lure of financial inducements) could confront their own mortality, self-interest, and altruistic desire to help others.

Finally, from an institutional perspective, federal law has not implemented the existing transplant community orthodoxy in any mandatory way. The 1984 legislation called for creating a voluntary network to provide an array of facilitative roles. Participation in the network became mandatory as a precondition for hospitals' Medicare and Medicaid participation by legislation enacted in 1986 (but not effective until November 21, 1987).[244] Nothing in the legislation dictated the type of structure the OPTN should adopt. DHHS apparently viewed the 1986

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[242] *See* Greenberg, *supra* note 3, at 224.

[243] *See* Blumstein & Sloan, *Health Planning and Regulation Through Certificate of Need: An Overview*, 1978 UTAH L. REV. 3; Blumstein & Sloan, *supra* note 3, at 853.

[244] 53 Fed. Reg. 6526, 6527 (1988) (to be codified in scattered sections of 42 C.F.R.).

legislation as mandating a certain type of network, but DHHS should have carefully considered the nature of the OPTN, once its nature was shifted from a voluntary to a mandatory body. DHHS apparently never fully aired the policy implications of the regulatory power conferred on the OPTN. Proponents of a comprehensive, top-down exclusive and coercive system used the enhanced regulatory clout as a covert vehicle to impose their regulatory agenda. DHHS apparently did not seriously consider other models for the OPTN, and DHHS made no real re-assessment of the role of the OPTN once the Network received coercive regulatory powers.[245] For advocates of that approach, moreover, private-sector rulemaking had the benefit of removing the substance of the regulatory rules from political control. Private sector autonomy could be used as a battle cry for allowing private regulatory behavior to take place free from political control — and even to supersede conflicting DHHS policies.

At present, the issue of the relationship between the OPTN and DHHS is beginning to receive attention, although the scope of discussion is not altogether clear.[246] What is clear is that the rigid ideological orthodoxy of the *DHHS Task Force Report* reflects the current culture in the organ transplantation community. Advocates of that viewpoint can use the vehicle of the OPTN to establish its hegemony. State law, however, still provides for donor control of organs — not viewing organs as a community resource. State law may also develop to allow some notion of property protection for body parts.[247] Federal law surely allows DHHS ample flexibility to impose a much altered vision of the role of the OPTN. Federal antitrust laws will likely be found applicable as a restraint on UNOS/OPTN conduct. The issue could arise either as a result of a private action by a disappointed or disaffected entity, or through aggressive enforcement oversight by an appropriate federal agency. Constitutional restraints on the ability of government to delegate coercive regulatory authority to private standard-setting enti-

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[245] There is evidence that DHHS has begun to understand these issues and to take them seriously. This has been stimulated, at least in part, by circulation within the Department of earlier versions of this Article. *See, e.g.*, Letter of Robert Windom, M.D., Assistant Secretary for Health, to H. Keith Johnson, M.D., President, United Network for Organ Sharing, Inc., Dec. 14, 1988 (recognizing the significance of the shift in OPTN membership from voluntary to mandatory status).

[246] *See id.*

[247] Moore v. The Regents of the Univ. of California, 202 Cal. App. 3d 1230, 1238, 249 Cal. Rptr. 494, 504 (1988).

ties may even require a much more direct supervisory role for DHHS.[248]

The evolution and development of federal organ transplantation policy has involved and been influenced by a relatively narrow band of professional participants. As a result, the policy seems out of sync with prevailing policy evolution in other health policy areas. The time has arrived to reassess and reappraise the entire nature and direction of federal organ transplantation policy — a re-evaluation of the constraints on policy imposed by a rigid adherence to doctrinaire ideology.

[248] *See* A.L.A. Schechter Poultry Corp. v. United States, 295 U.S. 495 (1935); *see also* Cospito v. Heckler, 742 F.2d 72, 89-91 (3d Cir. 1984) (Becker, J., dissenting).