THE PUBLIC ADMINSTRATION OF ORGAN ALLOCATION: MAINTAINING THE PUBLIC – PRIVATE PARTNERSHIP

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Abstract

We examine the public administration of the Organ Procurement and Transplantation Network (OPTN), established by Congress to oversee organ rationing. In specific we examine the controversy over who has the final say on organ allocation policy. Generated by increasing demand of organs and apparent geographical inequities in waiting lists, the controversy has pitted the U. S. Department of Health and Human Services (DHHS) against the United Network for Organ Sharing (UNOS), the private contractor operating the OPTN. Based on a case study of DHHS's efforts to promulgate an administrative rule regulating organ allocation, we describe the dynamics of policy making and the political arena. UNOS has claimed that policy making is best left with the private sector. We conclude that the public is well-served by maintaining a strong role for DHHS.

INTRODUCTION

In the United States over 15 people per day die while waiting for a solid organ transplantation. The stark fact is that there are not enough organs to go around and the gap between demand and supply is growing. Through law, we have chosen to explicitly ration the distribution of organs, one of the very few instances where public policy has embraced this method

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of allocation. Regulation (i.e., regulating access to public goods) is our national instrument for allocation. The National Organ Transplant Act of 1984 (NOTA), reflecting the prevailing social norm that organs should not be considered a market good, banned the sale of organs for transplantation and established the Organ Procurement and Transplantation Network (OPTN) to develop policies for and oversee the distribution of this scarce public resource. A private and nonprofit organization, the United Network of Organ Sharing (UNOS), holds the contract from the US Department of Health and Human Services (DHHS) to operate the OPTN.

In this paper we examine the public administration of the national organ transplant system. Public administration encompasses much more than the management activities of government agencies. It recognizes that public administrators are partners with elected officials in public policy making. It also acknowledges the crucial role of the private sector in carrying out public policies. Achieving and maintaining an appropriate balance among these partners within the framework of a democratic society is a continuing challenge. Here we focus on a controversy that has upset the balance in the relationship between DHHS administrators and UNOS. We draw lessons from this controversy and suggest an appropriate role for DHHS in the partnership.

THE CONTROVESY: WHO SHOULD HAVE THE FINAL SAY?

Although the more than 5000 deaths per year of patients awaiting transplant are but a tiny percentage of the nation's mortality, the fact that many of these deaths are preventable and identifiable endows them with political significance and visibility. Americans have accepted the legitimacy of a system that, for over fifteen years, has distributed organs on the basis of what have been considered to be medically justifiable and morally defensible criteria. In specific, we have balanced principles of utility (e.g., who can benefit most from a transplant in terms of length and quality of life) and principles of equity (e.g., who is most in need or who has waited the longest).

Since its inception, our national organ transplantation system has generally been perceived to be fair and accountable. Some have suggested

that the transplantation system be used as a model for national health care reform (*Benjamin et al., 1994*). However, over the past several years the legitimacy of the national organ allocation system has been undermined by a bitter controversy sparked by geographic inequities in access to organs. Congress, the Executive Branch, and some powerful interest groups have been embroiled in an extraordinary rancorous debate on how to distribute scarce livers, hearts, and kidneys among local areas and regions so that patients, regardless of geography, have a fair chance of receiving an organ. In the New York City metropolitan area, a frequently cited example of the apparent injustice of the distribution system has been the median wait for patients with blood type O for a liver transplant: 511 days in New York City versus 56 days in next door cities of New Jersey. Underlying this debate is an intense competition among transplant centers over who "owns" donated organs, the outcome of which is linked not only to extra years of life for desperately ill patients but also to prestige and revenues for transplant surgeons and facilities.

An important dimension of the controversy has been the struggle over the balance of power between government and the private sector partners. During the Clinton Administration, the chief protagonists were the U.S. Department of Health and Human Services (DHHS) and UNOS, the private contractor. In specific, the conflict was brought to a head by DHHS efforts to promulgate an administrative rule giving the Secretary final say over allocation policy.

Former DHHS Secretary Donna Shalala claimed that the National Organ Transplant Act of 1984 gave DHHS the authority to oversee the organ network and have the final say on allocation policy. On the other hand, leaders of UNOS have argued that Congress originally intended that organ allocation and sensitive medical and ethical decision making be made privately by the transplant community organized through UNOS, shielded from direct government involvement. Congress has been divided on this issue. Ironically, the current DHHS Secretary, Tommy Thompson, while Governor of Wisconsin, vigorously and publicly supported the arguments of UNOS.

BACKGROUND: THE OPTN PROGRAM

The blueprint for the OPTN, adopted by DHHS, came directly from a 1986 report (*Organ Transplantation: Issues and Recommendations*) written by the Task Force on Organ Transplantation. This 25 member blue-ribbon commission was established by NOTA to help implement the law and deal with unresolved operational and policy issues. At the request of DHHS and its Office of Organ Transplantation, the Task Force designed the prototype for the organ procurement and transplantation network detailing goals, composition of the board of directors with slots allocated to various constituencies and geographic regions, board responsibilities, organizational components, and membership requirements.

In crafting the model OPTN, the Task Force recognized the requirement to make complex tradeoffs between need for an organ (medical urgency) and the probability of success of the transplant. However it did not presume to make recommendations on this issue. Instead, the Task Force recommended a "thoughtful process of development of policies for organ allocation which takes into account both medical utility and good stewardship." (*Task Force, 1986*, *pp.8-9*) The OPTN, a broadly representative body, would be the vehicle for this thoughtful policy making process. In 1986, UNOS was awarded the contract to administer the OPTN. Headquartered in Richmond, Virginia, UNOS had been formed several years earlier as the Southeast Organ Procurement Foundation.

UNOS has a 40-member board of directors composed of transplant surgeons and other professionals, transplant recipients, and donor family members. The board adopts policies with organized input from the public and the general membership that includes transplant programs, organ procurement organizations (OPOs), and tissue typing laboratories. The policies specify in detail how organs are to be procured and allocated.

Central to the harvesting, preservation, and transportation of organs is the OPO, a publicly funded, not-for-profit organization. An important mission of the OPO, in cooperation with the medical community and the general public, is to encourage and facilitate organ donation. There are 62, geographically based OPOs in United States operating in 11 administrative

regions and working closely with 891 organ-specific transplant programs (*Institute of Medicine, 1999*).

UNOS, through its Organ Center, operates a central computer network which links OPOs and transplant centers. Once a patient is accepted onto the waiting list of a transplant hospital he or she is registered with UNOS. Through a complex process, the organ donors are matched to those on the waiting list based on a formula incorporating medical criteria, i.e., the policies that have been adopted by the UNOS board of directors.

In a nutshell, DHHS wanted to change these policies and the policymaking process that produced them. The ensuing controversy has amply illustrated that our allocation system cannot be separated from the politics of "who gets what, when and how." In spite of the centrality of ostensibly objective medical criteria in allocating organs based on need and effectiveness, students of the public policy making process will recognize the forces, relationships, and actors familiar to the American political arena: interest groups, politicians, and bureaucrats (*Strosberg and Gimbel, 2001*).

THE TRANSPLANT POLICY COMMUNITY

The reliance of the private sector to carry out a public law is not at all unusual. Kettl (*1993*) has noted that the implementation of every policy initiative undertaken by the federal government since World War II, from Medicare and Medicaid to environmental clean-up, has been managed through public-private partnerships. Contracting out to the private sector through competitive bid for the provision of goods and services has long been the management prescription of American public administration. In the instance of the OPTN, Congress through DHHS has chosen to contract out the primary responsibility for regulating access to a life and death resource.

The legitimacy of this public-private relationship is buttressed by the esteemed place of professional authority in American society. Decades ago, Don K. Price (*1965*) distinguished four broad functions in government and public affairs --the scientific, the professional, the administrative, and the political -- each with its institutionalized estate and its own internal

logic and motivations. Price arrayed the four estates along a continuum with truth and knowledge at one end, and power and action at the other. The scientific estate, driven by its pursuit of truth and the advancement of scientific theory, appropriately ignores all other purposes as irrelevant; the professional estate places this scientific knowledge to social purposes in the service of its clients; the administrative estate attempts to advance the general purposes of its political superiors; the political estate makes decisions based on value judgments, compromise and power interests (*Price, 1965*). Although the distance on the continuum separating politicians on the one end and scientists on the other has no doubt diminished over the past decades, the relative placement of the four estates on the continuum has not changed.

The decision by Congress and DHHS in the mid-1980s to place major responsibility for organ allocation policy making in the hands of the professional estate follows a long-established pattern in health politics of ceding public policy making authority to private sector professional associations (*Morone, 1993*). Of course, professional associations, well-served by their lobbyists, are active and effective in the political arena. However, the dominance of physicians over medical policy making and subsequent administrative arrangements is also supported by the widely-shared belief that the medical professionals are indeed the scientifically trained experts in the service of their patients, far removed from the power, politics, and action of the political and administrative estates (*Strosberg and Gimbel, 2001*). According to Price, the further toward the truth side of this ideal-type continuum an estate lies, the more it can be trusted, the less need for oversight. Is this trust warranted? This question will be discussed and addressed later.

In terms of public policy formulation and implementation, the four estates have come together as a "policy community," a group of political actors, both governmental and non-governmental, that focus on a particular policy area (*Longest, 1998*). Sometimes called policy subsystems, policy communities are a common feature on the federal governmental landscape and provide leadership and cohesion in the face of governmental fragmentation and the lack of strong, well-disciplined political parties. When they dominate policy formulation, implementation, and policy modification, they are referred to as "iron triangles," composed of: (1) House and Senate Congressional committees and subcommittees that have

jurisdiction over a particular policy area, (2) public administrators who manage programs carrying out policies, and (3) non-governmental organizations and interest groups focusing on a particular policy area.

Accordingly, the organ transplantation policy community is composed of: (1) members of various Congressional committees and subcommittees including the House Energy and Commerce Committee and its Subcommittee on Health, the Senate Labor and Human Resources Committee; (2) officials of various administrative sub-units of the Public Health Service and HCFA (Health Care Financing Administration), the two main components of DHHS; (3) interest group members and associated lobbyists. Examples of interest groups are transplant surgeons and other health professional groups, medical centers and transplant facilities, single disease associations such as the National Kidney Foundation and the American Liver Foundation, consumer groups, and last but not least, UNOS, the private contractor that operates the OPTN and whose members include transplant professionals, recipients, and donor families (*Strosberg and Gimbel, 2001*).

The policy community described above has long dominated the making of organ transplantation policy. Rettig (*1989*) divides transplantation policy into three different areas: (1) Status (whether the procedure is experimental or non-experimental), insurance coverage, and reimbursement; (2) Organ acquisition and allocation; (3) Facility certification (based on procedure volume and qualifications of providers). The programs associated with these three areas have histories predating NOTA. To a large extent they are constructed from the elements of the federal ESRD (end stage renal disease) program whose provisions provided ample precedent for managing organ procurement and allocation and concomitant problems (*Rettig, 1989*). One reason for the parallel between organ transplantation and the ESRD program, which of course includes transplantation as well as dialysis, is that the alternatives that were considered in policy formulation were generated by basically the same policy community.

RULE MAKING AND THE FINAL RULE

The relationship between the political estate and the administrative estates is said to be one of master and servant, i.e., the administration faithfully implements and administers the laws (policies) passed by Congress. However it is not uncommon for Congress to pass laws with imprecise or ambiguous objectives. It falls to the experts --the bureaucrats of the administrative agencies -- to fill in the gaps with the details so that the law can be implemented. In implementing the law, bureaucrats, or public administrators, make public policy.

The federal Administrative Procedures Act of 1946 recognizes that much of bureaucratic policy making is in fact a quasi-legislative function. Accordingly, it stipulates the formal procedures for making rules, sometimes called regulations. The process of administrative rule-making -- public policymaking -- generally requires publication of a draft of the proposed rule in the *Federal Register* as a "Notice of Proposed Rule-Making (NPRM)" and invites public comment from parties interested in the law's implementation. Administrative agencies may hold hearings and modify the rule in response to comments and testimony. The draft rule may be used to guide implementation of the law until the "final " rule is promulgated. Needless to say, Congress may intervene at any point. If it wants, it can choose to amend the original law, especially during reauthorization. Some of the same interest groups that are active in the legislative process are also active in the rulemaking process. It is the so-called "Final Rule" that ignited a storm of controversy within the organ transplantation transplant community ultimately involving President Clinton, Secretary Shalala, top Congressional leaders, the courts, and even state governors.

To address geographical inequities and other issues of fairness, DHHS, on April 2, 1998, proposed a Final Rule for the OPTN. The Final Rule was scheduled to become effective on July 1, 1998, after a brief period of public comment. As will be explained, this schedule was not even close to being met.

Rather than write a detailed set of regulations on organ allocation, DHHS decided to promulgate performance goals to guide OPTN policy

making. In adopting the performance goal model, used also in many initiatives stemming from the Government Performance and Results Act, DHHS granted the OPTN considerable discretion in making allocation policies as long as they met the following three performance goals:

> 1. standardized listing of criteria for placing patients on waiting lists, using objective and measurable medical criteria;
> 2. standardized criteria for determining medical status, also based on objective and measurable medical criteria, sufficient to differentiate patients from least to most medically urgent.
> 3. organ allocation policies that give priority to those whose needs are most urgent, with the result that differences in waiting times for patients of like medical status will be reduced (*U.S. DHHS 1998, p.3*).

DHHS's proposal to modify OPTN policies and practices with regard to geographic variability in waiting time attempted to resolve the question of which "community" should have first claim on organs, our scarce national resource. During the life of the program, interest groups have argued on behalf of various claimants including: the transplant facility, the local OPO service area where the organ was harvested, the region which encompasses the OPO, the state, and the nation. Unfortunately, as acknowledged in a 1989 article by Task Force Vice Chair, James Childress, the 1986 Task Force Report provided little definitive guidance practically guaranteeing future debate in UNOS over procedural and substantive policies as they concern the relations among local, regional, and national communities (*Childress, 1989*). Nine years later, Childress (*1998*), in testimony before the Joint Congressional Hearing on the DHHS Final Rule for Organ Allocation, conceded that the interpretation of community has been excessively narrow and urged a more national scope, subject to the logistics of organ transport. A 1999 Institute of Medicine Report concluded that, in general, OPTN policies have favored a local area-first approach to prioritization:

> Although potential transplant patients may select from among most transplant hospitals in the United States (subject to insurance coverage), under current OPTN policies the number of organs available to a hospital does not rise or fall as the number of patients on its waiting list increase or decreases. Rather, it is largely

> dependent on the number of donors in that hospital's OPO area. As a consequence of a "local-first" allocation policy, most organs leave the local OPO area only if
> there are no local patients who could use them. (*Institute of Medicine, 1999.p.*31)

In 2001, members of the organ transplantation policy community are still searching for clarity. However the search has become politicized, popularized, and polarized (*Strosberg and Gimbel, 2001*).

The Final Rule did some other important things. Most importantly it gave the Secretary the authority to review and ultimately approve OPTN policies. Also, in an attempt to change the OPTN policy making process, it modified the composition of the OPTN Board of Directors allowing no more than 50% of the members to be transplant surgeons or transplant physicians. This action was taken to moderate the domination of the policy process by transplant professionals. As will be explained later, their perspective, according to Robert Veatch, "skews the allocation principles in ways that are not fully supported by the general public" (*Veatch, 2000, p. 278*). Finally, to improve accountability, the Final Rule required that the OPTN provide greater public access to data detailing characteristics of individual transplant programs as well as waiting times and rates of non-acceptance of organs.

TAKING SIDES IN THE DEBATE OVER THE FINAL RULE: SMALL VS. LARGE, NATIONAL VS. LOCAL, BUREAUCRAT VS. PROFESSIONAL

Ordinarily, policy communities tend to operate in ways that are mutually reinforcing to its members. With interests converging, there is little conflict or media attention. Their insularity diminishes the ability of outsiders to influence policy. Ripley and Franklin describe conditions that weaken the walls of iron triangles. Two conditions in particular that have directly applied to the public administration of organ transplantation are: 1) disagreements arising among normally friendly members of the policy community that become publicized and stimulate attention and intrusion from non-members, and (2) high-level attention from the President or a senior administration official showing particular interest in the functioning

of a program and bringing the overwhelming resources of the Executive Office of the President to bear on the issues (*Ripley and Franklin, 1991*). Both of these conditions were present in the controversy over the Final Rule on organ allocation.

To the consternation of program managers and senior DHHS officials, Congress repeatedly delayed the promulgation of the Final Rule (DHHS had been attempting to promulgate a rule since the early 1990s). It was not until March 16, 2000 that the Final Rule, as amended on October 20, 1999 (*U.S. DHHS, 2000*), became effective. As will be explained, its fate is still not certain.

What were the reasons for the controversy and subsequent delay? To begin with, critics and their Congressional allies claimed that the performance goals spelled out in the Final Rule were inimical to the network and ultimately to patients. They also claimed that DHHS had neither the legal nor moral authority to have the final say over policy making in the OPTN. In essence they argued that the professional estate should not be subservient to the administrative estate. Organ allocation decisions lie in the realm of the “practice of medicine” best left to the transplant community.

UNOS and many others in the transplant community have taken the position that the performance regulations of the Final Rule, no matter how broad the delegation of policy making responsibility, would ultimately lead to the outflow of organs to distant locations containing the sickest patients and would reduce the local donation rate, increase cost and travel time, jeopardize the financial viability of the smaller transplant centers, and increase organ waste when sick patients fail to realize the benefits of transplantation. To investigate these claims, Congress turned to the Institute of Medicine of the National Academy of Sciences. In its 1999 report, the IOM found minimal or inconclusive evidence to support the claims of the critics of the Final Rule (*Institute of Medicine, 1999*). Nevertheless these concerns have remained salient in the political arena.

Although UNOS sees itself as the representative of the transplant community, not all members of UNOS have opposed the Final Rule. Ubel and Caplan (*1998*) have characterized the controversy over the Final Rule as a struggle "between the have and have-nots" and a "battle for supremacy

among transplantation centers." In particular, some of the larger and more well-established transplant centers with longer waiting lists of sicker patients, most notably the University of Pittsburgh Medical Center, have strongly supported the Final Rule. As the number of transplant programs increases and the supply of organs remains relatively flat, the conflict will worsen. The number of liver transplantation programs has increased to 125 in 1998 from 70 in 1988. Ironically, many of the new transplant programs are headed up by transplant surgeons who trained with Dr. Thomas Starzl of the University of Pittsburgh, the founding father of liver transplantation.

Both UNOS and its supporters and the University of Pittsburgh which is leading the battle for the larger centers, have been active lobbying Congress to intervene in DHHS rulemaking. Members of Congress have been taking sides not on the basis of party affiliation but on how the Final Rule might impact the transplant programs of their states or Congressional districts. In general the states with the larger transplant centers have favored the rule, e.g., Pennsylvania, New York, California, Illinois. The following headline from the *Wall Street Journal* (*1998*) captures the flavor of the contest. "With Livingston Adding Power as Speaker, Fight Gets Tougher for Organ-Allocation Reform," describes the fate of the Final Rule in terms of the waxing and waning of the power of various Congressional leaders, such as former Louisiana Congressman and Speaker Robert Livingston, whose state contained eight profitable transplant centers. Another opponent of the Final Rule had been former Congressman Thomas Bliley, chair of the House Commerce Committee with jurisdiction over the OPTN and whose district is home to UNOS headquarters in Richmond, Virginia. Needless to say, Congressmen in powerful positions have many tools at their disposal to delay and thwart implementation of the rule.

The opposing factions have put together broad-based coalitions containing professional associations, single-disease associations, grass-roots consumer organizations, and even governors. For example, the University of Pittsburgh leads a coalition composed of the American Liver Foundation, National Transplant Action Committee, Minority Organ and Tissue Transplant Education Program, and Transplant Recipients International Organization. UNOS is supported by the American Transplant Surgeons Society and the Patient Access to Transplantation Coalition. State governors and legislatures (e.g., Louisiana, Oklahoma, Wisconsin) also joined the fray by passing or threatening to pass legislation barring

transport of organs across state lines. Former Wisconsin Governor Tommy Thompson unsuccessfully sued DHHS claiming that Secretary Shalala overstepped the authority granted to her by NOTA by implementing the Final Rule. Thompson feared that Wisconsin, which operates one of the nation's most effective organ donation programs, would see a drop in its donation rate when its citizens realize that organs are to be transported to states with less effective donation programs.

Both Secretary Shalala and President Clinton took an active interest on behalf of the Final Rule. The level of interest is somewhat unusual. President Clinton's involvement has been attributed to the pro-rule lobbying efforts of David Matter on behalf of the University of Pittsburgh. In 1996, Matter, a long-time friend of Bill Clinton, a major campaign contributor, and the president of a real estate firm with major connections to the University of Pittsburgh Medical Center wrote to Mr. Clinton at the behest of the president of the medical center (*Washington Post, 1996*). Although denied by the Secretary, critics claim that DHHS has doubled its efforts to promulgate the Final Rule in response to presidential interest.

Not surprisingly, the very public consequences of organ allocation have generated widespread media attention focusing on local interest stories as well as the political maneuvering in Washington. On display, for the entire nation to see, is a bitterly divided transplant community.

While political activity in opposition or in support of a rule is certainly not unusual, one cannot help but be struck by the unusually high level of antagonism between UNOS and DHHS. Secretary Shalala, in testimony before the Joint Congressional Hearing on the DHHS Final Rule for Organ Allocation, "Putting Patients First: Resolving Allocation of Transplant Organs," made this extraordinary statement:

> Unfortunately, to this point, UNOS has failed to seize the opportunity by the rule to develop consensus about policy improvements. In fact, UNOS has gone to great lengths to preserve the current unfair system. It has launched a cynical political lobbying campaign against the April 2 rule. This campaign has been characterized by misinformation and outright falsehoods. The essence of the UNOS campaign has been to create phantom policies and use scare tactics that have hospital administrators and patients

> around the country up in arms. UNOS has sent form letters, part of a self-described "legislative action kit," to surgeons and patients across the country. UNOS has been loud and vociferous in its lobbying and is working with some of the highest priced public relations and lobbying firms in town. As a result of their slick lobbying campaign, you are hearing protests about the April 2 rule (*Shalala, 1998, p.77*).

Although the Final Rule giving the Secretary the final say on OPTN policies took effect in March 2000, the war over the control of organ allocation may not be over. Congressional reauthorization of NOTA provides new battlefronts. For example, on April 4, 2000, the House passed the Organ Procurement and Transplant Network Amendments of 1999 (H.R. 2418) by a vote of 275 to 147. This act, if it were to become law, would neutralize many of the key provisions in Final Rule and greatly diminish the DHHS Secretary's control over the OPTN. Needless to say, President Clinton threatened to veto it. The Senate, which failed to act, had been working on a compromise during the final months of the Clinton Administration.

Whether or not the provisions of H.R. 2418 ever become law under a new President and Congress, the positions taken by the opponents in its debate represent two very different prescriptions for the oversight role of the Secretary of DHHS with regard to the OPTN.

In claiming the authority to oversee the network and, if necessary, to overrule OPTN policy making, Secretary Shalala argued, "The primary reason the Act was passed in the first place was because the unregulated network was rife with abuses... To say we have no basis to issue regulations when our authority is clear is a disservice to Congress, which created the network, and to the patients, whose transplant bills are paid by the taxpayers" (*Shalala, 1998, p.78*).

Opponents of the Final Rule and proponents of H.R. 2418 maintain that NOTA of 1984 made no such delegation of power to the Secretary. They argue that NOTA did not authorize the Secretary, through rulemaking, to establish medical criteria, or policies for the Network; such authority was expressly left to the private sector. Rather NOTA gave the Secretary the much more limited role of providing funding by contract for the

establishment and operation of the Network in the private sector. Contracts, as explained by Kettl limit departmental oversight:

> In public-private partnerships, contracts replace hierarchy. Instead of a chain of authority from policy to product, there is a negotiated document that separates policy maker from policy output. Top officials cannot give orders to contractors. They can threaten, cajole, or persuade, but in the end, they can only shape the incentives to which contractors respond *(Kettl, 1993, p.22*).

Paradoxically, the net result of H.R. 2418 proponent's intended insulation of UNOS from DHHS orders would be to increase reliance on Congressional action as the vehicle to modify Network policy. However, the expectation was that Congressional action would reinforce UNOS prerogatives.

Interestingly, the Final Rule forges stronger linkages directly between the administrative estate and the scientific estate. As amended on October 20, 1999, the Final Rule follows a recommendation from the IOM Report calling for the creation of an independent federal advisory committee. Appointed by the Secretary, the scientists and experts of the Advisory Committee of Organ Transplantation will provide comments on proposed OPTN policies and other matters related to transplantation. Thus DHHS could appeal to members of the scientific estate for "impartial scientific advice." Advice and support from this quarter is particularly valuable to DHHS because the scientific estate trumps the professional estate on the truth-to power continuum.

Another major argument against the final rule is that organ allocation is best left to local control. In the words of Congressman (and physician) Tom Coburn, "... Big Brother should not have the right to tell Oklahomans that they can't direct an organ for their own State brothers and sisters" (*Coburn, 1999, p.5)*. The federal bureaucracy is inefficient, unresponsive, overly centralized, too far removed from the people, and too political. This view was also shared by Tommy Thompson while Governor of Wisconsin (*Washington Post, 2000*).

On the other hand, dissenting Congressmen argued in the House Commerce Committee Report:

> Were H.R. 2418 to become law and somehow survive constitutional challenge, it would fail to accomplish what its sponsors claim they desire -- insulate the organ allocation system from politics and bureaucrats. By eliminating Secretarial oversight, H.R. 2418 simply invests private bureaucrats with absolute life-and-death authority and the freedom to exercise it in settling their institutional disputes or professional rivalries (*House Commerce Committee, 1999, p. 39*).

CONCLUSIONS: STRIKING A BALANCE IN THE PUBLIC-PRIVATE PARTNERSHIP

Robert Veatch, prominent bioethicist and former chair of the Organ Allocation Subcommittee of the UNOS Ethics Committee, believes that transplant professionals have no particular expertise on deciding on the tradeoffs between utility and equity. These tradeoffs and associated policies are better made by politicians than transplant professionals (*Veatch, 2000).* We believe that between the political and the professional, there must be room for DHHS to play an essential role as senior partner to the OPTN.

Is DHHS too inefficient, unresponsive, centralized, and political to be the senior partner in policy making for organ allocation? Is the OPTN incapable of moving beyond parochialism on behalf of certain interests to represent the broader public interest? The answer to both questions is of course no. Both entities have an important role to play in governing a decentralized organ and procurement and transplantation network. But a constructive public-private partnership cannot be maintained if DHHS is limited to the role of contract administrator for the OPTN, no matter how representative, well intentioned, expert, or trustworthy the contractor.

DHHS administrators can give voice to interests that may be only faintly heard by either Congress or UNOS. According to Fritschler and Hoefler (*1996*), a federal bureaucracy with policy-making powers, in concert with Congress, assures Americans of a more broadly representative decision-making process. Unlike members of Congress, who frequently have to answer to a narrow constituency, often well-financed and well

organized, administrators can take a broader view of an issue if they wish. "America's rather unique combination of bureaucratic and congressional policy making powers can make important contributions to a system of government based on checks and balances in which expanded participation in democratic policy making is the goal" (*Fritschler and Hoefler, 1996, p.150).*

Checks and balances will serve to constrain "big brother" in Washington from arbitrarily and capriciously telling Oklahomans how to allocate their organs. However, DHHS is certainly not a monolithic department. With responsibility for managing over 300 programs, DHHS is highly decentralized, frustrating efforts by the Secretary to lead the Department though command and control management. Without question, the complex and controversial programs cannot be insulated from external policy, management, and political pressures (*Radin, 1999*). But these pressures, exerted through legislative, judicial, and executive branch channels, act as external checks on bureaucratic power. More often than not, public administrators responsible for managing programs respond to Congress and its budget appropriations and authorization processes, legislative oversight, and casework. Administrative actions are subject to judicial review on procedural or substantive grounds.

There are also important internal checks on bureaucratic power and policy making. The making of rules -- policies -- must be done according to the Administrative Procedures Act. During the long gestation of the Final Rule, there were plenty of opportunities for public participation in the rule-making process. The Final Rule of April 2, 1998, as amended on October 20, 1999 (*U.S. DHHS, 2000*), reflects a responsiveness to public comment and pressure. Finally, as was mentioned previously, administrators, as opposed to Congressmen, can take a broader view of an issue if they wish. It is certainly plausible that public administrators, professionals in their own right, are internally motivated to seek out the public interest.

Of course the system of external and internal checks and balances will not guarantee responsive bureaucracy. Certainly checks and balances can lead to bureaucratic inaction and paralysis. Special interests can still overwhelm and capture the bureaucratic policy making process. And the exercise of arbitrary and capricious behavior is always a danger. However, it would be a mistake to remove the bureaucracy from the decision making

loop. On balance, the maintenance of DHHS as a strong partner in the public administration of our national organ transplantation program will encourage openness in the public policy making process and enhance public support for the OPTN and its resource allocation role.

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