On March 15, 1989, I received a letter from Barry Kahan soliciting input on the idea of a newsletter for ASTS. I thought it was a great idea and faxed him my scribbled response (Fig. 1). At the time, I was at the University of Texas Health Science Center at San Antonio. President Wes Alexander, Barry Kahan, Rob Corry, and Oscar Salvatierra were the ad hoc committee appointed by Alexander to explore the feasibility of starting a newsletter and to develop the idea into something of benefit to ASTS. Kahan had concerns about the mounting costs of frequent ad hoc mailouts, and suggested that a newsletter might meet these needs with less expense. Ideas poured forth on the pages of his letter. I was flattered that I was chosen to participate in what would be a major step toward bringing ASTS closer together through regular communication between Council and the membership. I was, in fact, quite impressed (and surprised!) to be consulted by this august group of former, current, and future ASTS presidents.

Kahan phoned me in response to my fax. We had a nice chat and what I thought was a brainstorming session. Well, in retrospect, it must have been an interview. Toward the end of the call I asked him who they had in mind for editor. There was a slight pause, and then Kahan cheerily said, we thought you would be the editor! I think all who know Kahan can imagine the fun he must have had, handing me the lol-

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**Figure 1**

Calliope, M.D. March 15, 1989

To President Wes Alexander’s designation of an ad hoc committee to explore the feasibility of a newsletter for the ASTS community, I joined the group in order to give advice, and thought of the important considerations which we still have to discuss in a conference call (which we did) and at our committee meeting Wednesday evening, 15 May 90, at the Fairmont Hotel in Chicago.

In “working group discussions” the rationale for an ASTS newsletter included the need for a formal statement of Society policy for submission of allowable non-commercial articles and potential for the manuscript to be distributed as a newsletter. Additional considerations included the impact of such a publication on ASTS members and potential for the newsletter to be a forum for the exchange of information of interest to members. On the other hand, the production costs are anticipated to include printing, design, and possibly some advertising. An “ad hoc” committee was formed to discuss the contents, format, and pricing, among the members to use the Society’s tax-exempt status to prepare little free mailing.

It does seem that we accept these premises, there are needed issues which are necessary for our discussion: first, what is the appropriate format? Does it have to be sent? Would members’ comments include formal or informal issues, such as the content of the newsletter? What is the appropriate target? Clearly, the audience is for ASTS, but it would really be useful to have a more specific audience, perhaps ASTS Councilors and Fellows, or other ASTS members. Also, should we include periodic ads for commercial interests and other announcements related to organ transplantation? Should it be to other groups such as AAT, or to other clinical specialties such as vascular surgery? What would be the format? What would be the editorial policy for content? Calliope, M.D.

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**Figure 2**

Calliope, M.D. March 15, 1989

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When I thought it was going to someone else. My greatest attribute at the time was my proximity to Houston so that Kahan could keep an eye on me!

From the beginning, the Editorial Board has been appointed by the incoming president and has grown to include the past president, the president-elect, and the current president. Kahan has become a member in perpetuity. Members of the Editorial Board comprise the ad hoc Newsletter Committee. Part of being ad hoc is that there is no set tenure to the appointment. This has permitted flexibility in maintaining an active and diversified board.

So began The Chimera. Kahan was the master and I was the student in getting it off the ground. He recommended we use World Medical Communications Organizations, Inc. (WMCO), since he was working closely with them on a number of other projects. I called the publisher, Evelio Sardiña, and put together some cost estimates. We needed a masthead. The first draft design appalled me—the first real test of my credibility as a surgeon-cum-editor. After some discussion, the design was changed and continued to evolve over the next two issues into its present form (Fig. 2).

In our first year of publication (August 1989—April 1990), we had a circulation of about 500, serving our membership, about 75 selected members of Congress, and other individuals and groups around the country whose business interfaced with ours. By August 1993, our circulation had increased to almost 800, reflecting growth in ASTS membership, additional complimentary copies to transplant fellows in ASTS-approved transplant fellowship programs, and paid subscribers. While the base funding for the newsletter provided by ASTS has remained at its original level, growth in circulation has been accommodated by subscriptions and greater efficiency in the overall operation—an illustration that managed care begins at home.

None of this, however, could be done without Dorothy Shubert. She and her husband own and
New Insights, New Directions

The Message of the Chimera

Barry D. Kahan, Ph.D., M.D.

Reminiscence - Dr. David Milford Hume
As Remembered and Recorded by Dr. H. M. Lee
operate Tri Art Graphics in Cedar Knolls, New Jersey. My greatest fear is that, for some reason, their family-run operation, down the road from WMCO publishing, will come to a halt (as happened in February 1994 when weather born in Minnesota froze New Jersey doors shut for a day). Tri Art is where I send “the stuff.” They receive my diskette and photos and sundry other materials and make them into a newsletter. She has faxed or Fed Exed galleys to me all over the world and chased me down in Aspen. She has deciphered manuscript changes scrawled in a plane. She has saved me from myself on many occasions. The holidays are tough, but somehow she always gets The Chimera to the readers in the month that it is due, listening patiently all the while as I regale her with a litany of excuses (mine and those of con­trite authors) for being late. It’s hard to forget a woman who will do all that for you—so here’s to Dorothy Shubert!

Each volume begins with an August issue highlighting the Annual Meeting. A volume mirrors the tenure of the president for that year as well as the activities of Council, attending to member concerns. An influence throughout is Kahan, whose fertile mind and work ethic drive the diversity and emphases of The Chimera. This comment is not to take away from the individual imprimatur of each president on The Chimera, but is made in recognition of the great ongoing interest and conceptual contributions made by Kahan. For example, the historical series on legendary transplant surgeons that ran during his presidency began with the very first issue of The Chimera. His “President’s Column,” entitled “The Message of the Chimera,” launched the newsletter, explaining the origin of its name and the signi­fication of our logo:

“There are many interpretations of the sym­bolism of the Chimera. One interesting inter­pretation pits Bellerophon, the father of the line of Lycian princes, against a thoroughly non-Greek oriental style monster. Not only does this show racial xenophobia, but also
conquest of the supernatural. In the language of mythology, monsters were beings of unnatural proportion or parts possessing immense strength and ferocity employed for the injury and annoyance of man, particularly as executioners of infernal judges. Freudi­ans claim the swoop of Bellerophon upon the Chimera denotes sexual conquest. The Chimera is the calendar symbol of the tripartite year: lion for spring, goat for summer, and serpent for winter. Probably the best known use of the word Chimera is to denote a figment of the imagination or a fantastic idea. And what is a more fantastic idea than clinical transplantation, particularly in its multiple manifestations of our present armamentarium? Thus, the Chimera as the logo of the American Society of Transplant Surgeons not only embodies the substance (multiple diverse body parts), but also the spirit of our specialty. This newsletter seeks to embody that substance and spirit.”

The Chimera, I (1), August 1989, page 1

The Kahan volume, Vol. I (1989-90), is a potpourri of history (profiles on Hume, Newton, Kountz), didactic information (“USRDS—National Kidney Disease Data Systems”), and the politicization of transplant surgery (“The ASTS Addresses Issues of Medicare Physician Payment”). It also achieved Kahan’s original objective—to reduce the cost of mailouts—by publishing Council minutes, fellowship award applications, regional reports from members, and the calendar of important dates, all in one document only four times a year. We continue to be the beneficiaries of his effort and imagination.

By Vol. II we had begun to establish some regular features such as a President’s Column, an abridged version of Council minutes, an ASTS calendar, and a historical or other thematic series of articles.

The Sutherland volume, Vol. II (1990-91), reflected our deepening involvement in nonscientific efforts to achieve fair reimbursement for transplantation procedures. In his first “Presi-
dent's Column,” Sutherland felt compelled to articulate and emphasize the true mission of ASTS:

“Inevitably, and necessarily, the Society has become more and more involved in nonscientific issues. Important as these issues are, they must be addressed in parallel with our continuous efforts to advance the science of organ transplantation.”

The Chimera, II (1), August 1990, page 2

Yet, in response to the membership’s need for factual and forewarning information, Sutherland announced in the third issue of “his” volume:

“With this issue of The Chimera, we are inaugurating a new column: A Report from Washington. This will consist of information prepared by Dr. Henry Desmarais of Health Policy Alternatives for the Society's attention.”

The Chimera, II (3), January 1991, page 2

And thus was born another regular and well-received feature in The Chimera. By Vol. III, the format and content of The Chimera were well-established. Expectations were now raised in its readers—the “President’s Column” would be on page 2, “A Report from Washington” would begin on page 3, “Minutes” of the last Council meeting would be near the front, and the ASTS calendar would be on the last page. However, well-established does not mean stagnant, as indicated by the addition of an “Announcements” section just before the last page and a new job placement service. By the second issue of Volume III, ASTS had a new “Job Bulletin Board,” featured quarterly in The Chimera and operated through the office of Arthur Matas at the University of Minnesota. At its inception, only 2 jobs were posted. As of February 1994 (Vol. V, No. 3) the number of jobs posted had risen to 16.

The Diethelm volume, Vol. III (1991-92), began with ASTS celebrating the award of the Nobel Prize in Medicine and Physiology to pioneer transplant surgeon and honorary ASTS member Joseph E. Murray, professor of surgery, Brigham and Women’s Hospital, Harvard Medical School. This event coincided with this presidency’s concern with the education of transplant surgeons. In his “President’s Column” in the first issue of Vol. III, president Arnold Diethelm emphasized the responsibility of ASTS “for the definition of a transplant surgeon and... the educational process.”

“It is important to emphasize that the American Society of Transplant Surgeons has maintained a leadership position in the training of fellows beginning with Dr. John Najarian as chairman of the Education Committee. This has avoided conflict with the American Board of Surgery by not requesting certification. I would strongly suggest that we continue Najarian’s direction and in doing so carefully examine criteria for the number of operations required for training a surgeon in kidney, liver, and pancreas transplantation as well as emphasizing the importance of the intellectual and academic aspects of the fellowship program.”

The Chimera, III (1), August 1991, page 2

Mirroring Diethelm’s interest in the quality of transplant surgeon training was a series in Vol. III featuring seminal transplantation programs selected by the Editorial Board,
including the Brigham where Diethelm himself had trained. The overall tenor of the Diethelm volume was relatively calm and measured. But the battle continued, through appropriate ASTS channels, to ensure adequate representation of transplant surgeon needs during the implementation of Medicare physician payment reforms.

Vol. IV (Clyde Barker, president) and Vol. V (Frank Stuart, president) continued the format established by Vol. III, while becoming less a reflection of the presidency and more a reflection of member business. In his “President’s Column” in the first issue of Vol. V, Stuart summarizes some of this business:

“Old issues and many new ones challenge our society this year. Because so many are controversial, it would help us all if members shared their opinions directly, by mail or phone, throughout the year with committee chairs, councillors-at-large, and officers.

“A brief review of the May 1993 issue of The Chimera will identify matters that continue to concern us. See in particular president Barker’s letter to Congressman Henry Waxman, Henry Desmarais’ Report from Washington, and minutes of the Winter Council meeting. All facets of the practice, regulation, and public image of transplantation are being stressed by the disparity between a static supply of cadaver organ donors and the rapidly increasing numbers of patients on waiting lists.”

The Chimera, V(1), August 1993, page 2

The practice of medicine in the U.S. is now being closely scrutinized for change. One could say physicians and surgeons involved in end-stage renal disease and transplantation have been, for years, the experimental cohort for the rest of medicine.

Since the mid-1980s, our federal government has driven transplant medicine down a long and arduous course toward modification of the mechanics of organ distribution, outcomes evaluation, and more extensive participation of patients in determining priorities of care. While we have always looked to the outside for models and examples of alternative ways to bring high-quality medical care to our patients, the need is even greater now to evaluate the merits of other systems of health care delivery. What better way than to review how transplantation is achieved in other countries — heard from the voices of our surgical colleagues whom we know so well, having shared scientific information with them many times in the past. Thus, Vol. V began an ongoing series of articles from our “Foreign Correspondents,” the first by Mehmet Haberal, our colleague in Turkey.

The Chimera hopes to continue serving ASTS members in ways that are supportive of the presidency and responsive to the operational needs of Council. In addition, this unique newsletter can occasionally open new doors to the changing national political and intellectual environment. Proposals on deck include adding a new utility column for the “hackers” in ASTS, those transplant surgeons eager to share their latest computer/data breakthroughs. Data, outcomes, analysis, change—all are becoming a part of our daily practice lives. It is hoped that The Chimera will help all ASTS members get up to speed and weather the storm of changes to come. It has been a pleasure to be a part of this effort.
Introduction

Medicine, philosophy, and ethics have always intertwined. The three embrace life and death, joy and sorrow, hope and fear, the present and the hereafter. Galen and Hippocrates knew this. These early health care providers offered philosophy and hope. The clients seemed quite satisfied. Malpractice was not a problem.

Modern medicine may be too busy, too engrossed with the latest scientific discovery to remember this embrace. Too bad. The patient feels less satisfied. The physician appears confused. The body outlives the spirit. Kevorkian prospers! Why are we anxious about the wonders of modern medicine? What do we think about it? Who wants it? Who needs it? Who deserves it? Our pursuit of hard science introduces more issues and few answers. A better understanding of human values might help fill the void. Could it be that we are rediscovering the ancient philosophers? Are they reappearing as "bioethicists"?

History

Transplantation has warmed to medical ethics. Or has bioethics embraced transplantation? Probably some of each. Why is this? Transplantation deals with life and death, joy and sorrow. Transplantation also deals with somebody else's joy and sorrow, i.e., the organ donor. Like a new genetic probe, this introduction of a third party into the health care equation permits and requires a new look at old problems.

In fact, the possibility of organ substitution was the springboard for the formal introduction of bioethics into the modern health care setting. Hemodialysis, a kidney substitute, was introduced in the 1950s, but initially was in very short supply. Never before had the confrontation of life and death versus cost and access been so explicit. Rationing was required. Hospitals responded to this shortage by forming committees to develop criteria and select candidates for treatment. The membership of these committees often included ethicists, philosophers, and theologians. Life or death truly teetered on the balance of their decisions.

Fortunately, at least in the U.S., access to dialysis rapidly increased. The need for
these "life/death committees" soon faded. About this time our government became concerned about the propriety of the circumstances and decision making surrounding research in human beings. The paternalistic physician was no longer viewed as an adequate sole advisor or decision maker. In 1974 Congress convened a National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. In 1978 this commission was superseded by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. In 1978 the latter commission issued the landmark Belmont Report(1). This report identified the three most important principles that relate to human research: respect for persons (autonomy), beneficence, and justice. Others added maleficence as a fourth major principle. The work of these commissions resulted in federal regulation requiring the establishment of Human Use Committees in hospitals conducting clinical research. Again, ethicists and theologians were often included as members of these committees, and applied bioethics became a recognized activity in the daily routine of many hospitals. The successor to these committees is the Institutional Review Board (IRB) required in hospitals, universities, and other institutions conducting clinical research. Ethicists and clergy are now regularly included on hospital ethics committees to assist patients, families, and physicians with difficult health care decisions and on transplant evaluation committees charged with evaluating and selecting candidates for organ transplantation.

The importance of ethics in matters related to health and other areas of human conduct has been recognized by the private sector, academia, and the business and legal communities. Philanthropy supports the two major ethics centers in the U.S.: the Center for Biology, Ethics and the Life Sciences at Hastings-on-Hudson, New York and the Kennedy Institute of Ethics at Georgetown University. Almost all medical schools and many business and professional schools have added separate courses or a required series of lectures on bioethics to their curricula. Some medical schools and medical centers have established centers for the study of bioethics, such as the Transplantation and Health Policy Center at the University of Michigan and the Center for Clinical Medical Ethics at the University of Chicago Pritzker School of Medicine. An "ethics committee" is regularly included in the list of standing committees of many professional organizations and corporations. Hence, the ASTS Ethics Committee was established in 1984 and the United Network for Organ Sharing (UNOS) Ethics Committee first met in 1985. The Genome Project requires an ethics committee at all centers supported by the project. The Wall Street Journal recently reported that many corporations are appointing an "ethics officer" at a salary of 90 to 200 thousand dollars annually. Ethics is truly a growth industry!

**Ethics and Transplantation**

"Progress in medicine frequently triggers a reexamination of accepted ethical and moral principles."(2) Transplantation is the epitome of a discipline stimulating such a reexamination. Many did not agree that transplantation was a moral undertaking when the first renal transplants were performed in the 1950s, and some continue to
debate its acceptability. The use of living organ donors, changing definitions of death, severe shortages of donor organs, limited access, and very high cost either quantitatively or qualitatively raise new issues in health care that require new value judgments. Tables II to V list major transplantation issues in groups, according to the most pertinent applicable bioethical principle. (3-6) For many of the issues more than one principle has some potential application. No single principle should be carried to the absolute, and frequently a compromise or resolution of seeming conflict between principles is necessary before a practical conclusion can be reached.

**Ethics and ASTS**

ASTS recognized a need for an Ethics Committee in the mid-1980s, (Table 1). Initially this was conceived as an oversight committee that would counsel ASTS members who seemed to be violating accepted standards of practice or professional conduct. A prime concern was that the conduct of a few members might undermine public support for transplantation and especially organ donation.

The dramatic success of life saving heart and liver transplantation coupled with a severe shortage of organs and intense media exposure brought new problems. Neither the public nor the health care professions shared a consensus concerning such basic issues as the propriety of financial incentives for organ donation, presumed consent for organ donation, access to multiple sequential organs, transplantation of foreign
nationals in the U.S., priorities for organ allocation, or contraindications to transplantation (age, substance abuse, high-risk candidates). The need for the Ethics Committee to assist ASTS by studying the normative ethical considerations underlying these issues and making recommendations to the Council soon became the major activity of the committee.

Financial incentives and rewarded gifting for organ donation have occupied much of the committee’s time in recent years. A survey of the ASTS membership concerning these issues was conducted. Neither the membership nor the committee was in favor of significant cash incentives. A limited trial was recommended but the Council did not wish to pursue this at the present time. Other topics reviewed have been the unreimbursed costs of immunosuppression; Good Samaritan laws; xenotransplantation; presumed, advanced, and directed consent; and ethical issues surrounding retrieving organ from non-heart-beating cadavers. The committee has also recommended that papers on ethical issues or invited speakers be included in the annual meeting on a frequent basis.

### Table 1

<table>
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<th>ASTS Ethics Committee Member from 1985 to Present</th>
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<td>James Cerilli, Chairman, 1985-88</td>
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<td>Oscar Salvatierra, 1985-88</td>
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<td>G. Melville Williams, 1985-88</td>
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<td>Folkert Belzer, 1985-88</td>
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<td>Thomas Marchioro, 1985-86</td>
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<td>Alan G. Birtch, 1987-</td>
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<td>Clyde F. Barker, 1987-88</td>
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<td>Stanley Mandel, Chairman, 1988-91</td>
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<td>Felix Rapaport, 1987-88</td>
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<td>Robert J. Corry, 1987-90</td>
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<td>Jeremiah G. Turcotte, 1989-;</td>
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<td>Chairman, 1991-</td>
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<td>David R. Grant, 1991-</td>
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<td>James S. Wolf, 1991-92</td>
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<td>Charles F. Zukoski, 1991-</td>
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<td>Juliet S. Melzer, 1991-</td>
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<td>William H. Marks, 1992-</td>
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Summary

Philosophy and ethics give life and meaning to both the old and the new medicine. A cultural consensus concerning the impact on human values must necessarily precede acceptance of dramatic new health interventions. Organ transplantation stirs many old fears, and has stimulated a new look at old principles.

The embrace of medicine and ethics is both confounding and enlightening, both interesting and essential, both ancient and modern.
References


The First Ten Years

James Cerilli

ASTS was founded with the primary purpose of providing exchange of scientific information on the discipline of transplantation. It filled a void for a forum for disseminating the rapidly expanding body of transplant-related information. However, in the late 1970s, it became increasingly apparent that transplantation would be different from most other medical disciplines. This difference lay in its very close interrelationship with the regulatory process and with the funding mechanisms for the discipline. Federal legislation in 1972 mandated that end-stage renal disease (ESRD) patients be covered under Medicare, which provided an umbrella of insurance through federal funding. This act made transplantation different from all other medical disciplines, because it was the only clinical discipline totally reimbursed by a federal funding program.

A second major difference was that transplantation involved the use of a scarce national resource, namely the limited number of donor organs. The need for transplant services rapidly rose and outstripped organ supply. This widening gap attracted the interest of federal and state legislators—a situation also quite different from any other major medical technology.

A third difference was that transplantation was rapidly developing both as a science and as a clinical technology. Results dramatically improved during the 1970s. However, access for patients to transplantation was often hindered by their inappropriate maintenance on dialysis. There were many incorrect perceptions about transplantation because of the wide diversity of results among transplant centers, leading to the maintenance of patients on dialysis when many of them should have been referred for transplantation.

These three major issues led to the need to develop more effective communication between the regulators and the providers.

The regulators, i.e., federal legislators and Health Care Finance Administration staff, were often poorly informed as to the capability of transplantation and, most
important were poorly informed as to the needs. Those of us in the surgical arena of transplantation in the late 1970s were a small voice fighting a large chorus of opinion provided by those practicing alternative methods of care for end-stage renal disease. For these reasons, I felt it appropriate to enhance communication between ASTS and the legislative and regulatory process in Washington. It was important that this line of communication not be viewed as a lobbying effort, but rather as a mechanism to provide accurate scientific and clinical input and to obtain information about proposed funding or regulatory changes. After a careful search, Health Policy Alternatives in Washington was engaged. We stressed from the outset that this was not to be a lobbying effort for the passage of any specific legislative act. If we provided accurate and consistent information, I felt the facts and motives would speak for themselves, and the cause of transplantation would be appropriately enhanced.

Many issues needed to be clarified and supported. A group of senior transplant surgeons—including Belzer, Marchioro, Najarian, Turcotte, and later Salvatierra, Monaco, and Corry—made many excursions with me to Washington and to Baltimore in an attempt to disseminate and obtain accurate and appropriate information. I testified on three separate occasions before health subcommittees of Congress during 1980-81. I met many times with representatives, senators, and senior administrators of the Health Care Finance Administration and Medicare.

Among the many issues that were addressed were the following:

1. Our discussions made current the clinical results of transplantation, indicating that outcomes were better than the frequently quoted data. Graft outcome results were variable, but better results were coming from the larger, more dedicated institutions and these often were overlooked.

2. The proliferation of dialysis and transplant units was a problem, which sometimes led to the sequestration of patients on dialysis who should have been referred to transplantation. The proliferation of dialysis facilities expanded the number of beds available for this modality and tended to delay the referral of patients into transplantation. Also, smaller transplant units (performing fewer than 15 transplants per year) could not deliver the quality of services that larger units did. Criteria for defining appropriate need for new transplant and dialysis units were defined.

3. During the 1970s and early 1980s, the reimbursement for the surgeon was not consistent with that for procedures of equal complexity. The fees paid by Medicare for the transplant procedure itself and for procurement were woefully inadequate, compared with vascular procedures of similar complexity. This compromised our ability to provide proper staffing for pre- and posttransplant care of patients. I believe our efforts helped to correct, at least in part, this inequity.

4. Those of us who traveled frequently to Washington during this period continued to emphasize that renal transplantation had a clear cost advantage over dialysis. The cost of ESRD services was beginning to become a major issue. It was clear that transplantation had an advantage on this issue that was unrecognized. We provided a continuing flow of data to the Health Care Financing Administration emphasizing that transplantation was more cost-effective.

5. The cost of drugs for transplant patients was, and continues to be, a major
issue. There was a discriminatory policy against transplant patients who were not provided any drug coverage posttransplant. This contrasted with partial coverage for patients on dialysis. Accordingly, financial support was ultimately obtained for immunosuppressive drugs for the first year, significantly decreasing the fiscal liability of transplantation to potential recipients.

6. Transplantation was the black sheep for research funding. No specific National Institutes of Health (NIH) committee existed to refer transplant grants to. Nor was there a spokesperson for enhancing research support for transplantation. ASTS, through Health Policy Alternatives, established communication with NIH and federal legislative staff to improve funding for transplantation and to designate it as a specific funding target. Ultimately, along with the efforts of the Kidney Foundation, this led to the inclusion of “kidney” as one of the designated organs targeted by NIH research programs.

The first ten years of ASTS were productive and improved transplantation services for patients, thanks to a constant interaction between those responsible for funding and those responsible for providing clinical resources and expanded research. I am convinced that our association with Health Policy Alternatives improved the progress of transplantation by keeping ASTS appropriately informed of developments in Washington and by facilitating our interaction with other appropriate government individuals. Our credibility was enhanced because our recognized primary purpose was the dissemination of scientific information. Since these early efforts new organizations, societies, and groups have sprung up, with a widening impact on health care policy. Nevertheless, the political impact of ASTS has remained at the forefront. Our members are those ultimately responsible for the quality of the overwhelming majority of transplant services in this country.
National Organ Transplant Act
Oscar Salvatierra, Jr.

The passage of the National Organ Transplant Act of 1984 occurred at the midpoint of the 20-year history of the American Society of Transplant Surgeons. 1994, therefore, marks the 10th anniversary of the Act, which has had a profound impact on the distribution of organs throughout the U.S. It also formulated a process for making transplant policies through a national Organ Procurement and Transplantation Network (OPTN), provided by contract through UNOS.

In addition, the National Organ Transplant Act provided for a national registry of all transplanted organs, which has made timely statistics available not only to those working in the field but also to patients and public alike. For example, we are now aware of the precise patient and graft survival statistics for not only kidney, but also liver, heart, pancreas, heart-lung, and lung transplants. In 1983, the primary organ transplant being performed was kidney; inappropriately, it was considered by third-party payers to be the primary organ transplant that was nonexperimental. This greatly affected hospital reimbursement for transplant procedures and, therefore, patient access to therapy. With an accurate registry, including centrally maintained data on every organ, the experimental notion of most transplant procedures was quickly dispelled. Additional accomplishments of the National Organ Transplantation Act were the prohibition of organ purchases, the eventual reimbursement of expensive outpatient immunosuppressive therapy (initially at a 1-year level), and the evolution of regional organ procurements organizations (OPOs).

Not that ASTS was looking for federal legislation, but the rapid expansion of the field of organ transplantation in 1983 and the surfacing of a number of clinical and ethical issues brought forth concern from patients, the public, the government, and transplant surgeons and physicians. The medical and political environment that provided the prelude and impetus for action in 1983 is outlined in the preceding article on the first 10 years of ASTS by Cerilli and in the description of his 1982-83 presidential term by Williams. In fact, Williams’ Presidential Address in May 1983 focused on the need for effective organ sharing and distribution to avoid waste. The gravity of the waste problem was accentuated by the advent of cyclosporine, which produced remarkable improvement in the results of all organ transplants, which in turn resulted in the sudden addition of new candidates to transplant waiting lists. The logistics of organ distribution were in some disarray, best exemplified by the lack of an organized system to effectively use organs somewhere else in the U.S. if a suitable recipient could not be found in the geographic region the organ was procured in. It appeared to be much easier to export kidneys to another country than to place them in some other region of the U.S. Data from the organ center at the Southeastern Organ Procurement Foundation (SEOPF) during the fiscal year 1983-84 showed that of 930 kidneys handled by the center, 266 were exported out of the U.S.

Also complicating matters in the mid-1980s were the numerous appeals through the media, even involving the White House, for organs and funds, particularly for liver
transplants for children with biliary atresia. It was important to develop a national system that accommodated size and age specifications of donor organs through regional and national sharing. In addition, media appeals for organs for specific patients had to be replaced with an equitable distribution system that allowed all patients a fair opportunity at a scarce resource.

The solutions to a number of transplant problems embodied in the National Organ Transplant Act may not have been perfect or optimal. But in 1984, they did represent and had the consensus support of ASTS members. Although ASTS had already begun to address the problems described, the transition of these problems into a more public atmosphere in 1983 provided an incredible impetus for everyone to respond in a responsible and definitive manner.

As I assumed the ASTS presidency in May 1983, I thought the most important way to influence evolving legislation was to develop consensus among transplant surgeons. I embarked on a campaign to provide numerous communications to all ASTS members regarding political developments and canvassed them for their opinions on various issues. The most important consideration was to develop a genuine understanding among the Congressional authors of legislation on the outcomes, benefits, and problems of organ transplantation. I am indebted to the assistance and counsel I received from ASTS members and, in particular, to the many who communicated with me personally on a frequent basis.

A consensus did emerge on most issues. It then became my obligation to assure that the sentiment of ASTS members was conveyed to the Congressional authors and to members of the various House and Senate committees holding hearings on the bills. It was also important to establish direct communication with the many staff members of representatives, senators, and Congressional committees. In the legislative process, staff members appeared to have a profound influence in the actual writing of bills. Thus, during my presidential term, I made 14 trips to Washington for the purposes described, including a number of Congressional testimonies. After my presidential term, 1984-85 president H.M. Lee asked me to continue to direct and coordinate our position on the evolving legislation.

The response of the many ASTS members to my requests for intercessions and letters to Congress was perhaps the most instrumental factor resulting in favorable legislation. In addition, a number of individuals participated in Congressional testimony, listed alphabetically: Nancy Ascher, Ben Barnes, Fred Belzer, Thomas Berne, Clive Callender, Nicholas Feduska, Ronald Ferguson, Barry Kahan, Robert Mendez, Anthony Monaco, Norman Shumway, Thomas Starzl, and Mel Williams. Most important, especially at that time, was the continuous interaction of ASTS members with the Council and with all of the previous presidents. In this manner we were always able to provide timely, credible, and responsible feedback to numerous Congressional inquiries and requests, generally reflecting the consensus of ASTS members.

It is important to understand that we were primarily a scientific society. But our scientific orientation was really balanced with important humanitarian considerations for our patients. Thus, as national legislation evolved, it was imperative for ASTS to ensure that the needs of patients were fully understood.
Support for transplant legislation was both strong and broad, and included many professional and patient organizations. The principal exception, however, was the American Medical Association, which was somewhat confrontational with ASTS during Congressional hearings. This was highlighted by John Iglehart in his Health Policy Report in the *New England Journal of Medicine*:

"The physician representatives who appeared before the Ways and Means Subcommittee on Health were divided. . . . The American Medical Association's witness, Dr. James E. Davis, who is vice-speaker of the House of Delegates, delivered testimony that strongly opposed (the legislation). . . . Salvatierra and two other physicians who testified on behalf of the American Society of Transplant Surgeons offered conflicting views (to Dr. Davis). Joining Salvatierra before the Committee were Drs. Norman Shumway, Chairman of the Department of Cardiovascular Surgery at Stanford University, and Tom Starzl, Director of the Division of Transplantation at the University of Pittsburgh." *(New England Journal of Medicine, Vol. 310, pages 864-868, 1984)*

Four separate bills (HR4080, HR5580, S1728, and S2048) were introduced. After extensive testimony and final reconciliation in conference committee, the result was the National Organ Transplant Act, signed on October 19, 1984, as Public Law 98-507. The bills had been introduced by Representative Albert Gore (Tennessee) in the
House of Representatives and by Senators Edward Kennedy (Massachusetts) and Orrin Hatch (Utah) in the Senate. The lead bills were by Gore, who became principally responsible and most instrumental for the ultimate passage of the National Organ Transplant Act.

The final House Bill, which contained most of the provisions of the Act, was passed by a vote of 396 to 6 on June 20, 1984. The Senate version, which primarily contained the provisions for a task force on transplantation, was passed earlier by a similar near-unanimous margin on April 11, 1984. Later, there appeared some reluctance by a very few in strong political positions to convene a conference committee to reconcile differences in the House and Senate versions. This would have resulted in the legislation dying with the adjournment of Congress, despite overwhelming support for it. A letter I wrote to President Ronald Reagan, dated September 6, 1984, and a response from the White House best describe the atmosphere at that time. Reproductions of these letters are included at the end of this chapter.

As can be appreciated from a review of the correspondence with the White House, the conference committee did finally convene before Congress adjourned, allowing time for the passage of the legislation. Provisions for reimbursement of immunosuppressive medication were deferred until further review by a legislatively authorized national task force on transplantation.

The National Organ Transplant Act resulted in these provisions (in italics), followed by my interpretations of the underlying rationale:

1. The establishment of an Organ Procurement and Transplant Network through the provision of support for a private, national entity to coordinate the distribution of organs nationally, and among regions, and to maintain the registry of individuals needing organs. The OPTN would, through a representative board of directors, establish policy regarding organ distribution nationally. This section of the legislation was felt to be necessary to correct the problems of a fragmented organ distribution system that appeared to result in organ waste and a relatively high export rate of organs outside the U.S. Almost immediately after enactment, the number of transplants dramatically increased—not so much from an increase in organ donation, but because of increased efficiency in distribution and use with a marked decrease in waste and export. As we are all aware, the OPTN contract was awarded to UNOS.

2. Grant assistance for the establishment, initial operation, and expansion of qualified regional procurement organizations. The intent of this section was to facilitate regional organ procurement and, hopefully, increase organ donation regionally through a central regional OPO. Previously, there appeared to be varying degrees of confusion at donor hospitals because of competing regional transplant programs for donors at the same hospital. An OPO was also to conduct and participate in systematic efforts, including professional education, to increase organ donation in the region and, in addition, to participate in the national OPTN.

3. Establishment of a scientific registry. This provided for the maintenance of a central scientific registry for recipients of all organ transplants. The transplant
President Ronald Reagan

September 6, 1984

Dear President Reagan:

I am writing this letter as a follow up to my letter of July 30, 1984 and to again request your assistance in assuring that some of our citizens who need organ transplants are not denied an opportunity to improve and save their lives. More specifically, transplantation legislation has been referred to a Congressional Joint Conference Committee approximately two and a half months ago. However, our Society is concerned with reports of a reluctance to allow this Committee to convene.

There is tremendous urgency to our request for you to exert your influence and leadership in obtaining an early meeting of this Committee since Congress will only be in session for approximately four more weeks before the elections. The legislative provisions that would prove most helpful to patients are embodied in HR5580, and in particular, the provision that would provide help to pay for immunosuppressive agents to those patients unable to pay for these drugs. This is without a doubt a very cost effective piece of legislation since it will remove many patients from the ongoing costs of chronic maintenance therapy. In the area of kidney transplantation the number of patients entering into chronic maintenance dialysis is increasing at a much greater proportion than those patients receiving transplants. Dialysis patients are currently increasing at a rate of 20,000 per year, whereas only about 6,000 transplants are being performed.

The failure to pass meaningful transplantation legislation with a provision to help needy patients receive Cyclosporine will prove a distinct disincentive to transplantation at a time when more transplants should be performed, for not only their medical but also their economic and social benefits. There is a real fairness issue when one considers the statement of Ambassador Jeanne Kirkpatrick at the recent Republican Convention. In her address she indicated that this present Administration is spending more on foreign aid than any other previous government. It seems as though there could be a double standard in giving a large amount of aid to non-citizens while some of our own desperate citizens, in comparison, are being placed at a low priority level for consideration. Likewise, as you, yourself, stated in a radio address approximately two weeks ago, one of the goals of your administration was to advance science and technology. This is a laudable goal, but the current position of some members of the Administration and Senator Hatch provides a major contradiction to this goal. While we have become world leaders in the field of transplantation, our Society is having major difficulties in making transplantation under optimum immunosuppressive therapy available to patients, despite the fact that this is the only fair humanitarian approach that can be taken.

Again, our Society sincerely appreciates your past interest and intervention for a number of patients requiring transplantation. However, as I indicated before, many more patients are in need of your help. This is an area where you can once again demonstrate your noted leadership by providing your personal support for a collective group of needy citizens awaiting transplantation.

Sincerely yours,

Oscar Salvatierra, Jr., M.D.
Immediate Past President
Dear Dr. Salvatierra:

This is in response to your letter to President Reagan in which you asked his support of H.R. 5580, a bill to authorize financial assistance for organ procurement organizations. In particular, you expressed an interest in the "immunosuppressive drug" provision of this bill, which would authorize the Federal government to purchase these drugs for distribution, without charge, to transplant recipients.

Transplantation related bills H.R. 5500 and S. 2048 were discussed in a Congressional Joint Conference Committee and led to a compromise bill which was recently passed by Congress and signed by the President on October 19, 1984. The National Organ Transplant Act, Public Law 98-507, omits any Federal government program to purchase drugs for distribution, without charge, to transplant recipients, but does direct a study of questions concerning immunosuppressive drugs. The Act provides for the establishment of a Task Force on Organ Transplantation and organ procurement, authorizes financial assistance for organ procurement organizations, and establishes a national registry of individuals needing organs.

As you well know, the issue of life sustaining drugs and payment for them extends well beyond the needs of transplant patients. The current law requires the Secretary of Health and Human Services to establish a Task Force on Organ Transplantation to assess issues concerning immunosuppressive drugs, including cyclosporine, and other matters involving organ transplants. The Task Force will make its recommendations, doubtlessly, in the larger context of Americans needing a range of life sustaining drugs.

I know that you and your colleagues will assist the work of the Task Force as it develops over the coming months.

Thank you for expressing your opinion. I hope this information is helpful to you.

Sincerely,

Anne Higgins
Special Assistant to the President
and Director of Correspondence

Oscar Salvatierra, Jr., M.D.
Immediate Past President
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community had been without any scientific registry since the previous loss of funding for the NIH-American College of Surgeons Registry of Kidney Transplants. This new registry was to be much more comprehensive, include all organs, and provide an ongoing evaluation of the scientific and clinical status of organ transplantation. Ten years later, this registry is regarded as the best in the world and has proved to be one of the most important provisions of the Transplant Act.

4. **Prohibition of organ purchases.** This section provided for a fine of not more than $50,000 or imprisonment for not more than 5 years, or both, for any person violating this section. This provision was necessary because of proposals from would-be kidney brokers to provide organs from kidney donors willing to sell them to recipients willing to pay for them. The kidney brokers would themselves provide the service for a per-organ fee, such as $5,000. The existence of such schemes underscored the critical shortage of organs. While the sale of organs became unlawful, ASTS was committed to supporting provisions of the Transplant Act to improve the efficiency and effectiveness of organ distribution as well as to promote organ donation.

5. **The establishment of a task force on transplantation.** The task force was to be composed of 25 members who would conduct comprehensive examinations of the medical, legal, ethical, economic, and social issues involved in organ procurement and transplantation, as well as conduct an analysis of the extent and need of insurance reimbursement for expensive long-term immunosuppression. The task force report on the latter subject resulted in the subsequent legislative provision for Medicare reimbursement for immunosuppression for 1 year posttransplant. The Task Force was chaired by ASTS member Olga Jonasson.

6. **Bone marrow registry demonstration and study.** This provision was to evaluate the feasibility of establishing a national registry of voluntary donors of bone marrow. This section ultimately resulted in the establishment of a national bone marrow registry.
The Second Ten Years

Barry D. Kahan

Approval of Transplant Technologies

There has been an uncertain boundary between the experimental and the accepted "therapeutic" status of transplant interventions beginning with the widespread application of renal grafting in the 1960s. The passage of the End-Stage Renal Disease Act as Section 2991 of the Social Security Amendments of 1972, Public Law 92-603, acknowledged the therapeutic benefit of kidney transplantation, in spite of the fact that only half of the cadaver donor grafts survived for one year and the patient mortality rate was 15 percent. Clearly at the present time, there is no doubt of the therapeutic benefit of the procedure: the half-life of cadaver donor renal transplants is 10.5 years and the one-year mortality rate, 3 percent. The introduction of cyclosporine for maintenance immunosuppressive therapy and of the anti-CD3 monoclonal antibody OKT3 for antirejection treatment account for much of this success. These agents also markedly improved the outcome of nonrenal transplants, leading ASTS to spearhead approaches to the Office of Health Technology Assessment (OHTA), a part of the Agency for Health Care Policy and Research with the Department of Health and Human Services (DHHS). Because rigorous methodologies have not been developed to conduct controlled clinical trials that document transplant advances, surveillance of the experimental results has proceeded at varying paces for different organs.

Heart

In 1986 ASTS supported the findings of The Batelle Institute study from 1981 to 1984 that heart transplantation conferred life-saving, life-extending, and life-enriching benefits. The procedure's therapeutic value was shown by patient survival rates greater than 70 percent as well as a return to premorbid lifestyle and vocation. The OHTA approval of the procedure as "therapeutic" culminated over two decades of perseverance by our member Norman Shumway and his legions of students, many of whom are members of ASTS. Because of the demanding nature of the procedure, in October 1986 Medicare proposed volume and outcome criteria for center selection, in order to qualify for reimbursement. The final rules were published in April 1987.

Liver

The implementation of cyclosporine therapy increased the one-year success rate of liver transplants from 26 to 75 percent. A National Institutes of Health Consensus Conference was convened in June 1983, under the leadership of our member Tom Starzl. A multidisciplinary peer group, chosen by the National Institute of Digestive Diseases and the Office of Medical Applications Research, concluded that liver transplantation deserved broader therapeutic application. Although the panel did not explicitly make a recommendation on the issue, the report paved the way for reim-
bursement by federal and state agencies. Beginning in 1984 Medicare provided reimbursement for beneficiaries under the age of 18 with biliary atresia or other rare congenital defects. The April 1986 report of the Task Force on Organ Transplantation included a recommendation urging private and public health benefit programs, including Medicare and Medicaid, to cover liver (and heart) transplantation. Due to the especially complex nature and high cost of the procedure, the OHTA guidelines released in 1989 not only stipulated volume and outcome criteria, but also stringently defined the premorbid diagnostic indications for reimbursement. ASTS opposed this regulatory posture based upon data generated by our members that the procedure frequently benefited some patients afflicted with original diagnoses that were among the excluded conditions. However, the final rules issued in April 1991 stipulated selected indications for reimbursement in Medicare-approved centers for Medicare-eligible adults. Fortunately, private insurers have chosen to ignore these exclusions for reimbursement within their plans. However, the federal decision may have serious implications for future reimbursement in an era of universal health coverage.

Lung

Although initially perceived to be most readily performed as a combined heart-lung procedure, recent applications use technically secure, isolated lung transplant techniques. Furthermore, the need for endomyocardial biopsy has been supplanted by bronchoalveolar lavage to diagnose insidious, but pernicious, lung transplant rejection. A review by OHTA led to the recommendation for reimbursement, a policy adopted by CHAMPUS, which requires review on a case-by-case basis for payment of billed charges from approved centers. However, the Medicare coverage manual says nothing about reimbursement for lung transplantation. Provision of this service to beneficiaries seems to be governed by local Medicare carrier policies.

Pancreas

In late 1992, the OHTA began the process to examine the therapeutic benefit of pancreas transplantation, due to the persistent efforts of our member David Sutherland. While it is generally agreed that the procedure cannot be presently used to reverse the onset of diabetes mellitus, it may produce significant benefit for a subgroup of diabetic patients undergoing renal transplantation for end-stage nephropathy. A recommendation on the therapeutic value of this procedure is expected in 1994.

National Organ Transplant Act

The Department of Health and Human Services (DHHS) created a Division of Transplantation to implement the mandates of the Organ Transplant Act of 1984: to designate and monitor the Organ Procurement and Transplantation Network (OPTN), together with HCFA to assess the performance of Organ Procurement Organizations (OPOs), to augment organ donation by OPO grants, to gather outcome data, and to
assure equitable access to transplantation. Designation of the OPTN was their first task. Members of ASTS played an important role in the successful bid of the United Network for Organ Sharing (UNOS) as the OPTN, and later in the development of policies consistent with good transplant practice. Although Congressional pressures of perceived inequities have led to concerns by the division regarding UNOS policies, the role of the OPTN continues to strengthen. Clearly the complex nature of transplant practice forces the bureaucratic structure of the division to be reactive to public pressures rather than proactively recommend innovative policies. In addition to their ongoing tasks, in 1992 the division issued a Special Report on 1991 Center-Specific Graft and Patient Survival Statistics. Because only raw data were presented, ASTS has requested that future reports include at least random verification of information provided by individual centers. Finally, for the past four years the division has hosted an annual meeting to review federal initiatives and issues in transplantation.

Organ Transplant Act Reauthorization Bill of 1989

ASTS testimony at public hearings of the House Energy and Commerce Committee under the chairmanship of Henry Waxman (California):

- Underscored support for UNOS as the OPTN, a position that was adopted in the Reauthorization Bill.
- Requested that any nonprofit enterprise (not merely an OPO) with an interest in and novel approach to the organ donation problem be allowed to apply for grants under the Act, a position that was adopted in the Reauthorization Bill.
- Documented the need for strong surgeon/physician representation on the UNOS Board and opposed concerns raised by paraprofessionals and putative patient advocates who desired greater leadership roles, a position that was adopted in the Reauthorization Bill.
- Requested that Congress ensure that rigorous performance standards for OPOs are issued by the Health Care Finance Administration (HCFA), an item that was supported in the Reauthorization Bill but has not yet been finalized by HCFA.
- Recommended extension of immunosuppressive drug coverage from 12 to 36 months, a matter which was only addressed five years later.

Extension of Coverage for Immunosuppressive Drugs

In order to marshal evidence that renal transplant patients need financial assistance, ASTS conducted an *Immunosuppressive Therapy Payment Survey* of transplant centers. This study demonstrated that more than 40 percent of recipients had difficulty paying for cyclosporine after the expiration of their Medicare coverage; moreover, this handicap caused innumerable graft losses due to missed or inadequate doses of cyclosporine. Because these patients frequently required hospitalization, return to dialysis, or another transplant, ASTS argued that an additional 24 months of immunosuppressive drug coverage would actually be a “no cost” item. The belated Congressional Office of Technology Assessment (OTA) report entitled “Extending Medicare Coverage of Immunosuppressive Drugs,” which appeared in 1991, did not
American Society of Transplant Surgeons

concur with the findings of our survey. The OTA suggested that federal intervention was not necessary because the majority of patients were covered by alternate payors. In response, ASTS noted that the report proffered overinflated estimates of state reimbursement programs and of the fraction of patients (75% in their estimate, 25% in ours) with coinsurance. It also underestimated the effects of noncompliance on precipitating graft loss due to rejection, and increasing the costs of renal replacement by rehospitalization, return to dialysis or retransplantation. The failure of government action created a crisis in 1992, when various state kidney programs reduced their medication coverages. Indeed ASTS supported two albeit unsuccessful efforts to extend medication coverage: the Mitchell Bill of 1992, which was never approved, and the Medicare Act of 1993, which was approved by Congress but subsequently vetoed by the President. Fortunately the continued pressure from ASTS, which was fueled by the confirmatory results of a second survey conducted by our Scientific Studies Committee in 1992, the report of the End-Stage Renal Disease Review by the National Academy of Sciences, and the support of other groups, including patient advocates, led to approval in 1993 of a 1994 phase-in program, progressively increasing immunosuppressive drug funding to 36 months.

Performance Standards for OPOs

ASTS has repeatedly requested that Congress and DHHS establish performance standards for OPOs, as initially stipulated in the first Reauthorization Bill to be in place by January 1992, a deadline that has been progressively delayed. Issues related to OPO practices were raised in the report of the Office of the Inspector General (OIG) of DHHS to Congress in fall, 1990, as well as by media attention. The OIG report focused on perceived racial inequities in organ distribution. Our response noted that the investigators had ignored the impact of factors jeopardizing the access of black patients to transplants: namely, presensitization toward Caucasian antigens due to the predominance of white donors of pretransplant blood transfusions and transplantable organs; inability to meet transportation and additional household expenses not provided in the federal benefit program; the bias inherent in organ allocation by the Caucasian-based HLA matching system; the automatic cessation of disability payments three years after a successful transplant; and the negative educational cultural perceptions leading black patients to refuse the procedure. We pointed out that policy makers recognize that we can only strive for equity in the transplant process, because existing federal reimbursement programs are not sufficiently comprehensive to guarantee equality. Furthermore, in response to the OIG report, we proposed that review and recertification procedures mandate each OPO:

- To establish strict medical criteria for listing patients as well as review/punishment procedures for violations.
- To follow well-defined guidelines for distribution of organs based upon time on the waiting list, exceptional medical situations (pediatric, preemptive recipients), 6-antigen HLA matches. ASTS favored guidelines rather than rigid rules, in order that innovation not be stifled yet fairness be maintained.
• To assess the quality of retrieved organs by standards of low rates of acute graft dysfunction or primary nonfunction.
• To deliver services at reasonable cost monitored by strict accounting regulations.
• To meet performance goals concerning retrieval of an appropriate number of transplantable organs.

ASTS recommended formal biannual reviews of OPO activities. Organizations that failed to meet the performance or distribution goals would have to correct their deficiencies within well-defined, short time frames. Furthermore, ASTS recommended that DHHS establish procedures to create new OPO structures in regions demonstrating poor function of existing agencies. Regrettably, the publication of proposed OPO rules in *The Federal Register* in 1993 has not been followed by final regulations.

**Organ Transplant Reauthorization Bill of 1994**

The second series of Reauthorization hearings by the Waxman Committee in 1993 focused on the equity of the present system of organ distribution rather than attack the well-documented shortfall in organ donation. There is little doubt that the only reason that the total number of transplantable organs has not declined is the use of "marginal" donors—namely organs from older, diabetic, or mildly hypertensive individuals. However, patient advocates are more concerned about disparities in waiting times among various regions of the country and among minority, female, or socially disadvantaged patients. In spite of presentations by ASTS concerning the hazards of a policy that generally shipped organs long distances, thereby increasing the risk of ischemic damage, a variety of patient advocates as well as a maverick consortium of surgeons sought action to implement regional or indeed national allocation schemes. Although UNOS has reacted by tightening uniform standards for OPO-wide organ sharing, this Reauthorization Bill stipulates a study of the potential utility of national, or at least large regional, lists for organ allocation. Purposeful Congressional action to establish procedures to monitor OPO activity or to improve organ donation rates, the Achilles heel of the transplant enterprise, must await the next Reauthorization Bill.

**Tissue Transplantation**

In response to reports of transplantation of infected tissues from local or foreign sources, two Congressional bills entitled "The Human Tissue for Transplantation Act of 1993" have been introduced by Senator Paul Simon (Illinois) and Representative Ron Wyden (Oregon) stipulating that:

1. The Secretary of Health and Human Services (presumably through the Food and Drug Administration) would develop regulations (within 5 years after the bill is enacted) for tissue banks dealing with the screening and testing of donors, recordkeeping, good tissue banking practices, labeling, advertising, and promotion.
2. Each tissue bank would need to obtain a permit (which would be effective for no more than 3 years), for which the tissue bank would pay a fee.

3. The Secretary would appoint, within one year of enactment, a 13 to 19-member Tissue Advisory Committee to provide advice on appropriate tissue bank standards and regulations, etc. Appointments to the Committee are to be made "from among physicians, other health care practitioners, and representatives of human tissue bank consumers and industry groups whose clinical practice, research specialization, or expertise include a significant focus on tissue transplantation by human tissue banks."

4. Banked human tissue would be added to the list of items (food, drugs, devices) regulated under the federal Food, Drug and Cosmetic Act, including provisions relating to adulteration, misbranding, prohibited acts, penalties, records of interstate shipment, etc. Tissue banks would also be required to register with the Secretary each year.

5. Tissue bank registration fees would take effect within 1 year of enactment. Tissue bank fees for permits would take effect within 4 years of enactment. Fees would be based on "the gross revenue of the human tissue bank . . . which relates to the procurement, processing, storage, and distribution of human tissue."

6. Banked human tissue is defined as tissue (a) derived from a human body that is intended for administration to a human for the diagnosis, cure, mitigation, treatment, or prevention of any condition or disease; (b) procured, processed, stored, or distributed by methods to prevent the transmission of infectious disease and to preserve clinical usefulness; and (c) not intended to change tissue structure or functional characteristics. The term does not include whole organs, blood, blood products, bone marrow, reproductive tissue, human milk, or "autograft human tissue that is not stored or processed during a single surgical procedure."

7. The FDA's current premarket approval requirements for human heart valves would be overturned.

Because of the delay in enacting these bills and in response to increased public concern about the quality of transplanted tissues, on December 14, 1993, the Food and Drug Administration issued "emergency" rules effective immediately requiring:

- infectious disease testing (i.e., HIV-1 antibody, HIV-2 antibody, hepatitis B surface antigen, hepatitis C virus antibody);
- donor screening (i.e., obtaining a relevant medical history, although the questions that need to be asked are not specified);
- development of written procedures for both the infectious disease testing and the donor screening;
- recordkeeping (with records retained for no less than 10 years) relating to donor testing and screening and generally unannounced FDA inspections of entities subject to the rule.

ASTS applauds these efforts, because the erosion of trust in tissues inevitably (although unrealistically) lessens public security concerning the safety of organ transplants. ASTS is in the process of preparing comments on these matters. Among the
issues of concern to our members is the need for Tissue Banks to coordinate their efforts with OPOs, particularly in approaching families and arranging retrievals.

Research

Of all the fields of medical practice, clinical organ transplantation is one of the best examples of the fruits of basic research. Support for experimental efforts by various components of the National Institutes of Health had been awarded without central coordination. The recent development of an Inter-Institute Coordinating Committee for Transplantation seeks to assess, maximize, and focus ongoing extramural efforts. Furthermore, grant support for clinical research efforts has been partially addressed by the National Institute for Allergy and Infectious Diseases, which established a multiinstitutional group of transplant centers cooperating on single clinical protocols in adult renal transplant recipients. A parallel effort for pediatric renal transplant patients was recently announced. However, it is our perception that the administrative personnel of the NIH group, as well as their review/advisory bodies, overestimate the wealth of knowledge concerning basic transplant immunobiology and particularly the success of its application to the clinical sector. It is as if the clinical advances of transplantation have rendered the field less challenging for research, whereas indeed these successes are the foundation for careful hypothesis-testing investigations, particularly in the difficult areas of humoral presensitization and chronic rejection. The transplant enterprise desperately needs the type of cooperative agreement between the federal government and the pharmaceutical industry that seems likely to accelerate the fight against Human Immunodeficiency Virus infection.

Prospectus

ASTS seeks to strengthen the life-saving and life-enhancing benefits of transplantation by promoting public awareness of our mission and developing appropriate federal policies and procedures to support these goals. We face a need for careful assessment of the present status of the enterprise, beginning with organ donation efforts. Special attention to opportunities to refocus cultural mores through federal initiatives would strengthen projected advertising efforts by nonprofit organizations. We must develop objective scientific tools to evaluate equity in organ allocation measuring the needs of both consumers and providers. We must stimulate government participation in specialized rehabilitation programs for transplant recipients, including educational needs for children, job training for adults, and special civil rights for credit and housing. We must maximize the participation of the various players supporting the effort, including Medicare, Medicaid, state governments, private payors, and academic institutions, while streamlining the reimbursement process and eliminating redundancies. Indeed the major issue confronting the transplant enterprise is the impact of health care reform with its inherent pressures for cost-containment. The benefit package has not yet been defined: Will Congress legislate the end of the organ shortage by stipulating the premorbid diagnoses suitable for all transplant interventions? Will Congress...
exclude specific high-risk patients, such as critically ill, presensitized, or retransplant recipients? Will the package differ for various organs? Will the coverage include prescription drugs? In terms of implementation, will a single body serve as the gatekeeper for judging treatments as therapeutic rather than experimental? Finally, will there be incentives for specialized care within academic health centers? As the founders of the field, the members of ASTS carry a special commitment not only to the medical, but also to the rehabilitative, social, and legislative aspects of the transplant enterprise.

The past 20 years have presented challenges that ASTS has generally successfully addressed by carefully defining the issue, collecting relevant data, and repeatedly communicating with policy makers. The coming decades will present new opportunities for ASTS to serve both our patients and public policy makers in extending the benefits of transplant technology.

Acknowledgment

ASTS owes a great debt to our representative in Washington, Henry Desmaris of Health Policy Alternatives, for his assistance in identifying issues, examining alternate approaches, preparing briefing documents, and arranging and monitoring interactions between our members and policy makers. Henry provided invaluable help in preparing this overview. During the decade covered by this article, the author also benefited immeasurably from collaboration with Oscar Salvatierra, as well as with the subsequent presidents Sutherland, Diethelm, Barker, and Stuart.