Approved 3-27-86
Date

MINUTES OF THE HOUSE COMMITTEE ON PUBLIC HEALTH AND WELFARE.

The meeting was called to order by Marvin L. Littlejohn at
Chairperson

1:30 a.m./p.m. on March 18, 1986 in room 423-S of the Capitol.

All members were present except:

Committee staff present:
Emalene Correll, Research
Norman Furse, Revisor
Sue Hill, Secretary to Committee

Conferees appearing before the committee:

Terri Rosselot, Executive Director, Ks. State Nurses Assoc.
Tom Bell, Kansas Hospital Association
Senator Jack Walker
Ron Hein, Johnson and Johnson Company
Everett Willoughby, Executive Director, State Board of Pharmacy
Lyle Eckhart, State Emergency Medical Services Council of Ks. Highway Patrol

Visitor's register, see (ATtachment No.1.)

Chairman called meeting to order and invited conferees on SB 532 who were deferred until this date to present their testimony.

Hearings continued on SB 532.

Terri Rosselot, executive Director, KSNA, gave hand-out to members, (see Attachment 2-A and 2-B), for details. Their Association is a strong advocate of organ transplantation and stated they have held several conferences in which they have tried to educate nurses, and it is the main focus of an annual program this year, their interest in this program continues to be strong. It is not the transplantation they are against, but a public policy issue they disagree with. (Attachment 2-A is her printed testimony, 2-B is information in regard to organ procurement.) She stated the Kansas Uniform Anatomical Act which provides legal authority and a legal vehicle for such donation, and the Kansas drivers license, for citizens to voluntarily participate in this worthy effort is commendable. However, KSNA (Kansas State Nurses Association) has concerns with mandating organ donation requests. she spoke of concerns of their Association, i.e., hospital administrators that are referred to in lines 43-44 are personnel not generally clinically oriented. Section (c) adds a laundry list of medical record documentation requirements, Section (d) defeats the spirit of the Anatomical Gift Act, by requiring an annual accounting and tote board report, Section (f) without a penalty clause, all parties involved are left to good faith for compliance. KSNA supports mandating development of protocols and criteria for organ donation to set the state for all health professionals to become involved in solicitation in the appropriate setting, and believes that cooperative efforts by hospital and medical staff members will alleviate need for mandating organ donation requests by statute. Further, she commented that perhaps Ms. Wolf's suggestion yesterday of a Task Force would be very beneficial. She spoke to the issue of forensic medicine not spoken to in SB 532 or the Anatomical Gift Act. In the case of a suicide or murder, then forensic medicine should have priority over organ donation. Further, she spoke to the wastage level of organs in programs in United States and Europe and how they differ. One out of every 5 organs donated in this country is wasted. She answered a few questions from members.

Hearings continue on SB 532.

Tom Bell, Kansas Hospital Association, gave hand-out, (see Attachment No. 3), for details of balloon copy of SB 532. He stated their Association is in support of the concept that has been spoken to by Ms. Rosselot, and they are willing to do anything they can to help promote an educational and cooperative effort to help create an effective system for organ donations. He suggested amendments, i.e., Section 1, (a), change language to read, "Where, based on hospital policies and procedures accepted for donations of all or part of the body under the uniform", and language continues in lines 26 as shown in bill. Page 2, (d), take this entire section out. With these recommendations, he stated smaller hospitals will be able to develop a policy for their own circumstances, and would remove language that some think has allowed some hospitals to get around the law. Hospitals will need to develop their own policies. All cannot operate under the same policy, because situations differ too much. He stated again their Association is willing to do what they can to make this program work, including working on a Task Force.

Senator Jack Walker spoke to SB 532 at Chairman's invitation, and stated his one vote in the Senate was the only vote in opposition to it. He voted his conscience as a physician. We have no business mandating organ transplants, he said. The current drivers license is a good mechanism to handle this, and there are many viable groups that have well developed programs that speak to the issue of organ donors. He said he is in sympathy with the hospital staff, (nurses mainly). It is an emotional time for everyone when a patient is this critically ill, and many times it would be inappropriate trying to suggest organ donation. Many times it would place staff in a bad situation trying to suggest donation at those critical times. He stated he felt we should not clutter our books with this legislation, yet, on the other hand, how can I be against this, he said. I am for promoting this work, but think it should be done through an education process. In almost every hospital that is capable of being involved in this type of thing, most all situations of impending death where the possiblity of organ donations exist, the matter has already been discussed by the family, physician, and clergy. Except in cases of extreme emergencies you usually know there is impending death, so the matter has been discussed and a decision reached by the family.

Chairman asked Committee to deviate from planned agenda and hear testimony from Senator Jack Walker on SB 501 and SB 542 next so that he can return to the Senate Chamber.

SB 501:

Dr. Walker expressed his view that SB 501 is sensible legislation. It corrects a problem that exists in Kansas today with the Pharmacy Act. In Kansas any new drug or compound Class I has to be approved by the Legislature before it can be used in Kansas. This means that even though the Federal Drug Administration (FDA) may approve the drug on 5/1/this year, which would be helpful to some patients, in Kansas we have to wait then until the next January when the legislature meets to approve this compound. It would mean the drug would not be available for patients for that period of time. Thus, SB 501 would allow emergency sort of action for Board of Pharmacy. Then if the FDA does approve it, we could use it in Kansas on an emergency basis. It also still means that the compound would have to be officially be approved by the Legislature next session. In the Senate Committee we placed it on consent calendar and made it effective in the register, we wouldn't have to wait until 7/1/86. It is good legislation. He answered a few questions from Chair and members, i.e., by Rules & Regs. The State Board of Pharmacy could not change the Schedule of Controlled Substances Bill. There was some discussion at this point in reference to this matter, i.e., Statutes can only be changed by a bill enacted by Kansas Legislature, therefore Controlled Substances could only be changed in Schedule I and II by enactment of the Legislature.

SB 542

Senator Walker spoke to SB 542, saying it is very simple, and very good legislation. Last year a demonstration pilot program was set up to gather information from it to see if it would be feasible to legalize certain types of medical emergency technicians,

Hearing continued on SB 542:

i.e., ambulance drivers, emergency trained technicians, groups that go out on emergency calls and use manual cardiac defibrillation. He explained the process in detail. The response after a trial period of one year of this pilot program determined there had not been enough cases to form a firm program, so SB 542 would extend the program for another year.

Chair then asked Committee to direct attention to SB 179, and a balloon copy of it. (See Attachment No.4), for details. (This is a detailed balloon, and Mr. Furse the Revisor explained section by section the necessary changes, pointing out policy issues and necessary technical changes.

Mr. Furse asked members to note, line 196, page 6, it might be appropriate to change language to make it conform statutes. Rep. Buehler made a motion to amend SB 179 in line 196-197 to read after the phrase approved by the, "president of board or person designated by president". Motion seconded by Rep. O'Neal, motion carried.

Page 6, Sec. (b) Rep. Runnels made a motion to change the term of Advisory Board Members to one year, rather than two, seconded by Rep. Neufeld, motion carried.

Mr. Furse concluded explanation of balloon on SB 179, and at this point, Rep. Buehler moved to pass SB 179 out as amended favorable for passage, seconded by Rep. Hassler,
* to include all technical changes necessary as explained by Revisor. Motion carried.

Chairman asked members to draw attention back to SB 501.

Hearings continued on SB 501.

Chairman noted there is a hand-out from Mr. Ken Schafermeyer of Ks. Pharmacist Association, (see Attachment No.5), for details. Mr. Schafermeyer is out of town, but wished to present the position of his Association for SB 501.

Mr. Ron Hein speaking in behalf of Johnson and Johnson Company gave hand-out, see (Attachment No.6), for details. He stated Janssen Pharmaceutica, a subsidiary of Johnson and Johnson two years ago marketed a new anesthetic (sufentanil), and after extensive testing it was approved by FDA and drug Enforcement Agency at the Federal level. This drug offered significant advantages to patients over previously available drugs. Legislation proposed in SB 501 will permit the earlier use of this drug on an emergency basis during the time period of the rescheduling of Schedule I drugs through normal procedures of the Legislature. He feels criteria set out insures against any abuse, and urged for passage SB 501.

Mr. Everett Willoughby, Executive secretary, Ks. State Board of Pharmacy gave hand-out to members, (see attachment No.7), for details. SB 501, if passed would give the Ks. State Board of Pharmacy the authority to pass rules & regs specifying certain Schedule I controlled substances as a Schedule I designated prescription substance. He stated the word "designated" is a key word, and would allow only for a controlled substance that has been rescheduled federally by the drug Enforcement Administration from a Schedule I to a Schedule II, or newly approved drug which is scheduled federally, but would not be scheduled in Kansas until done so by a vote of the Legislature. He then explained Schedule I and Schedule II drugs. Further, he said, if SB 501 is passed, an important new or rescheduled drug could be made available, possibly within thirty to sixty days of the time it was released federally. He urged for passage. He then answered questions from members.

Hearings closed on SB 501.

* Note - This statement by Rep. Buehler was amended in minutes of March 27, 1986, with a motion to delete the line "to include all technical changesnecessary.

CONTINUATION SHEET

MINUTES OF THE HOUSE COMMITTEE ON PUBLIC HEALTH AND WELFARE,

room 423-S, Statehouse, at 1:30 a.m./p.m. on March 18, 1986

Hearings began again on SB 542:--

Lyle Eckhart, State Emergency Medical Services Council gave hand-out to members, see (Attachment No.8), for details. (Attachment includes his written testimony, plus a Report to the Legislature 6/15/85-12/15/86 detailing a report on the pilot study Dr. Walker explained in his comments.)

Mr. Eckhart stated the report covers results of the first 6 months of the pilot program, showing the target area of study stated there was only 65% of the number anticipated based on 1983 data. Numbers were insufficient to complete the study, so they are asking for an extension of one year in which to complete the study to determine effectiveness of training select basic emergency medical technicians to defibrillate hearts of patients who are victims of sudden unexpected cardiac arrest.

Hearings closed on sB 542.

Chair asked wishes of members in regard to legislation before them. Rep. Friedeman made a motion to pass SB 501 and SB 542 both, favorable for passage and place on the consent calendar, motion seconded by Rep. Green. No discussion, vote taken, motion carried.

Chair noted there would be several Alzheimer's bills go to Interim Study this year, rathen than a Task Force Study. He thanked members again for a Yoeman's job in the hard work they have all done on bill action in this committee.

Meeting adjourned.

GUEST REGISTER

DATE 3/18/86

HOUSE

PUBLIC HEALTH AND WELFARE

DATE 3-18-86

NAME	ORGANIZATION	ADDRESS
Kyle Eckhart	E.M.S.	111 W 6th Topeka
Marsha Hutchison	ICMS	Topeka
Linda McGill	KANA	"
Tom Bell	K.H.A.	Topeka
Anne Moriarty	N.O.W.	"
Lorna Fleming	Clay Center	
Ron Wenig	Johnson & Johnson	Topeka
Sen. Jack Walker		Overland Park
Ruth Hubbard	W.M.U.	Clay Center
Irma H Gray	Clay center - Ks	United Meth. Church
Alta Arndt	United Meth. Church	Clay Center Ks.
Miriam Martin	united Methodist Church	512 Crawford Clay Center Ks.
KEITH R LANDIS	CHRISTIAN SCIENCE COMMITTEE ON PUBLICATION FOR KANSAS	TOPEKA.
L. H. Williams	Methodist Church	Clay Center Ks.
Cecil Paronto	Clay Center, Methodist Men's Club	Clay Center, Ks.
Juanita Peter	Clay Center, K's, United Methodist Church	Clay Center, Ks.
Verna Paronto	United Methodist Church Clay Center, Ks.	Clay Center, Ks.
PAT SCHAFER	DIVISION OF BUDGET	TOPEKA
Jim Snyder	KFDA	Topeka
Pete McGill	KANA	Topeka

Attachment 1
3-18-86
H. PHW

KSNA
the voice of Nursing in Kansas

For Further Information Contact:

TERRI ROSSELOT, R.N.
Executive Director
(913) 233-8638

March 17, 1986

SB 532 ORGAN DONATION

Mr. Chairman, and Committee members, my name is Terri Rosselot and I represent the Kansas State Nurses' Association. KSNA is very supportive of the concept and health policy considerations of organ donation and transplantation. The Kansas Uniform Anatomical Act which provides legal authority and a legal vehicle for such donation, and the Kansas Drivers license, for citizens to voluntarily participate in this worthy effort is commendable. KSNA believes that recent public attention through the press and efforts of the Department of Health and Human Services has greatly enhanced public awareness should situations present themselves where individuals and families could make such decisions about organ donation. Organ donation and transplantation has been refined in medicine and pharmaceutical products dramatically with the drug cyclosporine released by the FDA in Spring of 1983. This product inhibits the bodies response of rejection, which was a real threat to transplant patients. The Federal governments reimbursement policies for end-stage renal disease patients has also contributed to treatment, research and care of individuals that could benefit from transplantation. The dramatic increase in transplantation is a success story for medern medicine.

Attm. 2-A
3-18-86
Hs. PHW

KSNA believes that increased public awareness and education about organ donation is the single most important factor in obtaining consent from individuals and families. KSNA has reservations about mandating organ donation requests.

Section 1 (a) of the bill indicates that a hospital will develop and adopt criteria for organ donation. KSNA supports this provision which calls for action on the part of hospital medical staffs to develop guidlelines/criteria. These are necessary to help health care professionals identify potential donors. This is a very important step, identifying a potential donor. There are many chronically ill patients who pass on, and others with certain disease histories that make them unsuitable organ donors. KSNA believes that if this step alone is mandated there will be a better understanding among health professionals discussing organ donation and family members deciding about such alternatives.

Nurses in many hospitals are the acting authorities 16 out of 24 hours Monday through Friday and 48 hours on weekends, thus (line 0043,0044)

"person in charge of the hospital or designated representative of the person in charge of the hospital . . ."

would probably be a registered nurse, most likely a supervisor. Registered nurses wold be responsible for implementation of such

legislation, particularly in light of the fact that hospial administrators are not generally clinically oriented.

Section (c),
Currently in hospitals where autopsies or other post-mortem activity is granted, consent documentation in the medical record is the responsibility of physicians and nursing, and is standard operating procedure. This section adds a laundry list of medical record documentation requirements.

Section (d) which mandates annual totals by each hospital to Health and Environment on requests, requests not made and rationale. The most significant number, which is the number of requests for anatomical gifts made and organs donated as a result of the requests is not part of this section. This entire section defeats the spirit of the Anatomical Gift Act by requiring an annual accounting and tote board report.

Section (f) provides Kansas hospitals with wide latitude for non-compliance with this legislation should is pass. Inadequate staff would be a viable excuse under this provision, and without a penalty clause all parties involved are left to good faith for compliance.

KSNA commends the bills authors for attention to organ transplantation needs in Kansas. Nurses in Kansas are keenly aware of our chronically ill in need of transplants for sustained life. Nurses are also witness to those tragic accident victims, unexplained suicides and medical tragedies that provide opportunities for organ donation.

KSNA supports mandating the development of protocols and criteria for organ donation--to set the stage for all health professionals to become involved in solicitation in the appropriate setting.

KSNA believes that cooperative efforts by hospital and medical staff members alleviates the need for mandating organ donation requests by statute.

Thank you.

Attm #2-B
3/.../86

Organ procurement: hospitals need improved policies and protocols

By David L. Martin

TRANSPLANTS

Human organ procurement and exchange was the subject of a Health and Welfare Canada sponsored workshop held October 3-4 in Ottawa. More than 70 participants, representing a broad range of professions and interests, addressed the problem of how to obtain adequate donations of organs and tissues for transplants.

Transplants for many organs and tissues are achieving success rates that illustrate that the procedure is no longer experimental: 90 percent one-year graft survival rates for well-matched cadaver-donated kidneys and 70 percent for hearts, livers and heart-lung combinations.

With the advent of new immune system suppresive agents such as cyclosporin, and new techniques, the problem is less that of rejection failures as an insufficient supply of potential organs for transplantation. At the moment, some one thousand patients on dialysis await kidney transplants. As the continued costs of dialysis are much higher than those of transplanted patients, the implications for the health care economy are obvious. Similar waiting lists are starting to build up for heart and liver transplants, although the cost-benefit relationships are not so positive in the short term.

Not all transplants require a donor on cardio-respiratory support; corneas, inner ear parts, skin and bone tissues are also frequently needed for treatment and can be retrieved at autopsy. At the moment, an extensive waiting list exists for corneas — something which could be easily be addressed.

The best source of organs, however, is young patients suffering from cerebro-vascular accidents or motor vehicle accidents. The former are rare and the latter are decreasing with the increasing use of seat belts, lower driving speeds and improved automobile safety. Therefore, it becomes increasingly necessary to improve the effectiveness of the organ procurement systems, something which will involve more hospitals, physicians and hospital employees — even those not directly involved in an organ transplant program.

The workshop participants recommended that the Canadian Hospital Association go on record as being in favor of improved donor procurement programs and that the Canadian Council on Hospital Accreditation give consideration to organ procurement where appropriate in its accreditation guidelines.

Participants also recommended that provincial health insurance authorities improve financial support for organ procurement, especially where this could seriously affect a hospital's global budget, and in particular, in connection with coverage for out-of-province/country donations and professional fees. In no case should a donor's family be faced with extra charges arising out of their generosity.

Policies and protocols

Workshop participants recommended a number of areas where hospital policies and protocols should be established or strengthened:

1. The procurement of donated organs should be recognized as a standard of good medical practice, where appropriate, and subject to audit.

2. Intensive Care Unit nurses should be recognized as being in a position to identify potential donors and should have direction as to how to proceed.

3. The declaration of death, usually by two neurologists or neurosurgeons, or other physicians capable of diagnosing brain death, who will not be involved in the actual procurement or transplantation procedure, should be outlined. The person then is considered to be a "non-living" donor.

4. Obtaining consent from the next of kin should also be clarified: staff should be able to participate in the grieving process and should understand that, religious restrictions excluded (particularly for certain Jewish groups and Jehovah's Witnesses), the donation of organs or tissues which will benefit others can frequently help the family in its grief. Also, the autopsy form should contain an optional clause allowing the next of kin to donate eyes and other non-vital organs and tissues at autopsy. (This does not disfigure the appearance of the deceased.) The chaplain can play a key role in this process.

5. Policies and protocols should address the cardiorespiratory support of the non-living donor. It is usually preferable that a different care team take over after death is declared, as the psychological trauma of maintaining respiration and circulation in the dead patient is difficult for ICU nurses. Also, different skills are needed for nurses preparing the non-living donor for transfer or for the procurement procedure.

6. Where an "itinerant" or "visiting" surgical team must come to the hospital to obtain the organs, policies and protocols should exist regarding the granting of "one-case" privileges, preferably in advance of the actual need.

7. The protocol should also delineate contact procedures and telephone numbers to regional/provincial procurement agencies (where they exist) and/or to transplant centres or teams.

8. Where the non-living donor is to be transferred to the transplant centre for retrieving the organs, the policies/protocols should also outline who and what equipment and documentation are to accompany the donor.

9. Although this responsibility may be assessed by the regional procurement centre or transplant team, the administration should ensure that all concerned, including next of kin and medical and hospital staff involved, are included in the distribution of follow-up information on the outcome of the procedure.

Participants recommended strongly the establishment of public and inservice education programs, including programs specific to medical staff, ICU nurses, donor support, and hospital chaplains.

Hospital administrators and their staffs may tend to shy away from the area of donor procurement — as it may seem complicated, confusing, an invasion of privacy at times of grief and a traumatic experience for medical and hospital staff. It needn't be any of these things. Remember that for many, such as the child suffering from biliary atresia, the highly compromised cardiac patient, or the person relegated to a lifetime of dialysis, it represents the only hope — whose "odds" are acceptable, and superior to many other therapies. □

Attm. #2-B
3-18-86 Hs. PHW

David L. Martin is a consultant in health technology for Health and Welfare Canada, Ottawa.

FOCUS ON SOCIOECONOMICS

The National Organ Transplantation Act

by Leslie Zaontz, ACS Surgical Practice Department

Human organ transplantation became one of the most widely discussed and publicized health issues in 1984. The second session of the 98th Congress witnessed the passage of S. 2048, the National Organ Transplantation Act, which was signed into law (P.L. 98-507) by President Reagan on October 19, 1984.

The organ transplant bill had a complex history before being passed by Congress. Among its precursors were The National Organ Transplant Act introduced as H.R. 4080 by Representative Albert Gore, Jr., (D-TN) and the Organ Procurement and Transplantation Act introduced as S. 2048, by Senator Orrin G. Hatch (R-UT).

Two provisions under Title II of H.R. 4080 became controversial.

One provision would have provided Medicare coverage for immunosuppressive drugs on an outpatient basis. Members of Congress and the Administration claimed not enough was known about the cost and long-term side effects of the drugs to make an exception in the Medicare Reimbursement policy.

A second provision would have authorized the Secretary of Health and Human Services (HHS) to set criteria concerning the eligibility of Medicare beneficiaries for new technologies and procedures and the conditions under which those services could be provided. The American College of Surgeons was concerned that such criteria established by the Secretary could take precedence over medical decisions regarding the patient's treatment.

Eventually the House passed H.R. 5580, which was similar to H.R. 4080. The Senate passed S. 2048, which deleted the controversial provisions that would have paid for outpatient immunosuppressive drugs and given new authority to the Secretary of HHS under the Medicare program. The differences between S. 2048 and H.R. 5580 were worked out in a joint conference.

In its final form, Public Law 98-507, The National Organ Transplantation Act, authorizes the Secretary to make federal grants to qualified regional Organ Procurement Organizations (OPOs) to increase the availability of organs on a local level. A 24-hour telephone line will permit OPOs and the medical community to communicate with an Organ Procurement and Transplantation Network that will develop and maintain a list of patients awaiting organ transplants. When an organ becomes available, information will be entered into a computer that will attempt to match the organ with a potential recipient. If a match is made, the network will transport the organ to the appropriate transplant center.

The Act authorizes a total of $25-million in grants to the OPOs: $5-million in fiscal year (FY) 1985, $8-million in FY 1986, and $12-million in FY 1987. A national computerized registry to match organ donors and recipients will be established for three years with a $2-million annual authorization.

The Act requires the HHS Secretary to establish a Task Force on Organ Transplantation to review the medical, ethical, legal, and economic issues related to organ transplants. The task force is charged with preparing a report to identify the problems that prevent efforts to procure viable organs for transplant. The task force must also provide an analysis of immunosuppressive drugs and review the extent of insurance coverage for these medications. Finally, it must advise the Secretary regarding the development of regulations involved in making grants to the OPOs. In January, 1985, Olga Jonasson, MD, FACS, was nominated by the College and appointed to the task force, and subsequently was named chairman.

The legislation also calls for a scientific registry to evaluate the effectiveness of transplant procedures and to monitor the clinical status of transplant patients. Information gathered by the registry will form the basis of an annual report on transplantation to be published by the Secretary of HHS.

Finally, the legislation prohibits purchase of human organs for use in transplantation procedures; violation of this provision may result in a maximum fine of $50,000 or five years in prison or both.

With the passage of the National Organ Transplantation Act, Congress is now awaiting the final report from the HHS Task Force on Organ Transplantation. Dr. Jonasson told the first meeting of the task force that "access to human organs for transplant operations is the 'monster issue' and it outweighs the issue of reimbursement for transplants."

Organ Procurement in Europe and the United States

JEFFREY M. PROTTAS

Health Policy Center,
Brandeis University

THE PROCUREMENT OF HUMAN ORGANS FOR transplantation purposes is an activity going on in all the advanced industrial nations of the "Atlantic Community." It represents a social and organizational response to shared medical/technical progress. As progress in the field of immunosuppression and surgical techniques is continuing, it is highly likely that the importance and scale of organ procurement activities in these nations will also increase. Until very recently there has been little exchange of information in this area between the United States and Europe. This has had certain advantages in that it has permitted separate experimentation. However, the organizational approaches to organ procurement, both in Europe and the United States, are now sufficiently mature so that the period of experimentation is, or should be, largely over. It is now time to compare and evaluate; and to select those methodologies that are most effective. Despite real differences among nations, the degree of similarity in national attitudes and in the basic tasks facing organ procurement organizations is very great. These similarities make possible international cooperation and education in the field of organ procurement.

This paper is an attempt to further that end. The author has, for the last three years, been engaged in a comprehensive survey and evaluation of the American organ procurement system (Prottas 1982, 1984). With the assistance of the Eurotransplant Foundation, he has gained access to information about the operation of the organ procurement system in the Eurotransplant region (Germany, Austria, Luxembourg, Belgium, the Netherlands), Great Britain, and France. Comparison among these nations' organ procurement programs is the goal of this article.

Such a comparison is made particularly interesting because of the divergent patterns of success exhibited by organ procurement systems on opposite sides of the Atlantic. There are three general ways of measuring the success of organ procurement efforts. The simplest is the number of organs procured per million population served. By this test, the United States operates the most effective large organ procurement effort in the world. However, not all organs retrieved are actually transplanted; a certain number are thrown away—wasted. Organs not used make no social contribution and so, in a larger sense, it is the number of ultimately transplanted organs procured that is the true test of an organ procurement system's success. The difference between the total number of organs procured and the number of transplanted organs procured is called the "wastage rate." European systems have far lower wastage rates than does the American system. This difference severely decreases, although does not eliminate, America's superiority at organ procurement. America is, it appears, better able to locate and obtain cadaveric organs; Europeans are better able to make use of those organs they do obtain.

This article primarily attributes these differences to differences in the organizational practices and structures. The United States' organ procurement system shows great strength at the local level; its organ procurement agencies each grew up out of local conditions (although with financial support from the federal government) and many are unusually successful at enlisting hospitals' help in retrieving cadaveric organs. In contrast, European organ procurement efforts are characterized by very effective interagency cooperation and centralized control of organ sharing among organ procurement agencies. The individual organ procurement agencies, on the other hand, are often not as professionalized or effective as their American counterparts.

The primary aim of this article is to document these intercontinental differences, examine their causes, and suggest lessons regarding improvement and reform.

A few caveats are called for, however. First, this paper is concerned only with the procurement of "viable" organs from cadaveric donors.

Milbank Memorial Fund Quarterly/*Health and Society*, Vol. 63, No. 1, 1985

body parts, such as skin, corneas, bones, etc. can be taken from cadavers whose hearts no longer are pumping blood and who have di- of causes that often render the "viable" organs no longer trans- ble. The procurement of those kinds of organs is both technically and organizationally quite distinct.

Second, all comparisons will be in terms of kidneys procured. In all countries under discussion, the organ procurement system developed as a kidney procurement system but has, in recent years, expanded its effort into other organs. Nevertheless, it is extremely rare that an organ donor is not first a kidney donor. Therefore, the kidney donation figures remain a valid means of comparison for organ procurement efforts. The number of nonrenal organs procured is very small—less than 4 percent of the transplants of cadaveric organs in the United States in 1982 were nonrenal (Evans 1983)—and more sensitive to the time available to transplant teams than reflective of organ procurement success.

The article that follows is divided into three parts. The first describes the organ procurement process and argues that, despite differing legal contexts, this process is essentially the same everywhere in the United States and Western Europe. Therefore, the contrasting outcomes to be documented cannot be attributed to differences in organ procurement tasks but rather are accounted for by organizational differences in organ procurement systems. The second section will describe the organ procurement networks in America and Western Europe in order to provide a background to the final section that evaluates the differing degrees and kinds of successes these systems have enjoyed.

The Organ Procurement Task

The basic tasks of organ procurement revolve around obtaining access, in a timely manner, to potential donors. Only a small percentage of people dying are suitable as donors of viable organs; an organ donor must be young, otherwise in good health, and must be dying from cause that does not damage the needed organs. In general, this

accidents. The potential pool is further limited in that the organ procurement agency (OPA) must learn of the donor before he or she is actually dead, the donor must be declared dead by brain-death criteria, and he or she must be maintained on a respirator until the organs can be removed. Once the heart stops pumping, visceral organs deteriorate rapidly and quickly become unsuitable for transplantation. Brain-death criteria differ slightly from place to place, but the basic test is complete and permanent cessation of brain activity. This means that a donor must die in a hospital with a staff capable of and willing to declare brain-death and one capable of and willing to inform the OPA that such a patient exists in time for arrangements to be made to do an organ retrieval.

This step, obtaining cooperation and information from a hospital, is called a referral and is critical to organ procurement success anywhere in the world.

The second core task in organ procurement is obtaining permission from the donor's family. In theory, this is not necessary in those nations with "presumed consent" laws, but indications are that, in practice, the process is similar in all nations.

Once the donor has been identified and permission obtained, there follows a number of reasonably routine administrative and medical tasks, from arranging an operating room and surgical team to transporting the organs to a typing laboratory. These tasks are essentially technical in nature and, while the details vary from nation to nation, indeed from locale to locale, the basic requirements are everywhere the same.

The last essential step in the organ procurement process is placing the organ with a transplant team so that it may be used. As we shall see, unlike the organ procurement process per se, this task differs significantly across nations.

While the essential tasks of organ procurement are the same in all Atlantic community nations it is possible that they are not everywhere equally difficult. Success at organ procurement depends on obtaining cooperation from key people outside the organ procurement profession, i.e., families of donors and the medical professionals in the hospitals where donors die. It is the primary task of organ procurement agencies to convince these people to cooperate. The difficulty of their task depends on the attitudes of these groups.

We do know that, in the United States, there is a very high level

of support for organ transplantation and donation. Numerous surveys of the general public, including a Gallup poll in 1983, have all demonstrated very favorable attitudes among the public (Gallup Organization 1983; see Prottas 1983 for a summary of earlier surveys). Less work has been done among medical professionals but what has been done also indicates high levels of support (Kaufman et al. 1979). If European levels of support are substantially lower, then European organ-procurement agencies operate in a more hostile environment and this could partially explain their lower level of success.

Unfortunately, our data on European attitudes is not nearly complete enough for this issue to be resolved. We do have the results of a survey in Great Britain (Moore et al. 1976), which does indicate a high level of support by the British public. However, differences in the way the questions were asked makes direct comparison with the United States difficult and, while high, support did appear to be somewhat lower there than here. Beyond this we have only impressionistic data.

In Holland the chairman of the National Committee for Organ Procurement told me that they were considering terminating operations because public support was already so high. On the other hand the French representatives to the European Transplant Coordinators Conference stated that the French public is less supportive of organ transplantation than are the populations of other nations. Indeed, only the French representatives seemed to believe that public attitudes were a major impediment to organ procurement—although most representatives did wish to improve support levels further by public education. Nevertheless, such impressions are highly unreliable and so, in the absence of good data we must admit that social and cultural factors beyond the scope of this paper may be reflected in different public attitudes toward organ procurement. If this is so it may mean that the job of persuading families is more difficult in some places than in others.

Of greater importance, I believe, is the possibility of differences among the medical professionals treating potential donors. Research in the United States (Prottas 1984, 1985) has shown that it is referrals from medical professionals rather than permission rates from families that correlates with success at organ procurement efforts. Persuading these professionals to cooperate is the key task of organ procurement agencies. The predilections of neurosurgeons, neurologists, and intensive care nurses is, therefore, of great practical importance. We simply do not know if important differences exist across nations in this area. If they do, equally effective organizational efforts would result in different levels of organ procurement success.

The working assumption of this article is that these cultural, social, and professional differences are relatively small within the Atlantic community and, in any case, are quite overwhelmed by organizational differences. In support of this one might look at the very large differences in success rates among American organ procurement agencies in the face of reasonably uniform public and professional attitudes (Prottas 1984). Nevertheless, there are clearly some differences across nations on these social factors and so small differences in organ procurement outcomes will not be given much credence. Of course, if it is later discovered that there are large and systematic differences in the attitudes of the public and of medical professionals across nations, especially if it is found that those attitudes are more favorable in the United States than in Western Europe, the conclusions of this article would have to be modified.

In summation then, we can say that there are three core technologies in organ procurement. The first step is obtaining referrals from medical professionals. All OPAs face the same challenge here—getting medical professionals (whose job is to save the living) to inform the agency of dying patients, and help it maintain and finally make use of the dead. The second task is to get the right to remove the cadaver's organs from those with legal control of the body. In theory, the nature of this task depends on the legal framework of the nation with regard to the family's rights over the organs of a relative. As we shall see, in practice this is not so. Finally, if the entire organ procurement process is not to be futile, the OPA must get the retrieved organ transplanted. If the transplant is to be done locally, this may be a simple step. If it is to be done at some other center, it involves an interagency exchange of greater complexity.

The person who manages this overall organ procurement process is generally referred to as a transplant coordinator. His job is critical to OPA success. He has responsibility for contacting hospital and intensive care unit personnel and motivating their cooperation in the identification of donors. He also generally has the responsibility for making administrative arrangements for the organ removal and for placing the donated organ with a transplant team. In many instances, he also requests permission from the family.

The organizational position and professionalism of transplant coordinators differs between Europe and the United States, and, indeed, between sectors of the organ procurement system within the United States. As we shall shortly discuss, organ procurement in the United States is done by two differently organized kinds of OPAs—OPAs separately incorporated and OPAs administratively a part of the hospital. The independent agencies tend to have more full-time transplant coordinators while the hospital-based agencies depend relatively more on part-time coordinators. However, both make greater use of professional transplant coordinators than do European systems. In Europe, the transplant coordinator function is less fully differentiated and professionalized. Its functions are often fulfilled by hospital nurses whose primary responsibilities are those of staff nursing.

The Legal Framework of Organ Procurement: Obtaining Consent

The final step in obtaining access to a potential donor is to get the agreement of whoever has legal control of that cadaver's organs. In most cases, this is the decedent's family. The legal terms under which an OPA must deal with the decedent's family is, therefore, often considered a critical factor in the organ procurement process (Caplan 1983). In fact, however, it is the social similarities among Atlantic community nations, rather than the legal differences among them, that are important.

There are two archetypal approaches to defining, in law, the rights of the deceased and his family with regard to organ procurement. At one extreme is the "pure" presumed-consent approach. In a nation where such a law exists, in France, for example, a physician may remove an organ from a cadaver if the deceased has not previously left instructions forbidding organ donation. The wishes of the decedent's family have no legal force (Farfor 1977). At the opposite extreme would be the United States prior to adoption of the Uniform Anatomical Gift Act. At that time, the only way an organ would be retrieved from a cadaver was by written permission of the next of kin. In more recent years, those nations with "voluntary" systems have altered the legal principle to permit the deceased to authorize an organ donation. In the United States, Great Britain, and the Netherlands, for example, a person may sign a "donor card." This card is a legally binding

document in which a person may authorize organ donation in the event of his death. The presence of such a card may make the attitude of the next of kin legally irrelevant. Finally, there are a number of nations that presume consent but still require that the family's agreement is sought. If the family refuses, then the donation may not occur. The practical difference between this and a "voluntary" system is difficult to see. Table 1 presents a summary of the laws of various nations.

Apparent differences among national approaches to consent further diminish when actual practice is examined. It is not the law that determines consent-getting practices but social and organizational forces. Among Western nations, at least, these forces all but eliminate legal niceties.

In the United States, the practical irrelevancy of organ donor cards is a case in point. Quite aside from the rarity of such cards, their presence in a given instance has no effect on organ procurement practice. No organ procurement agency in the United States will retrieve an organ solely on the basis of a signed donor card. (If the family is aware that the donor has signed a card they are, however, presumably more likely to give permission for organ donation.) Indeed, not only will no agency go ahead against the wishes of the next of

TABLE 1
Basis for Consent to Remove Cadaver Organs

Countries with presumed consent	Family agreement sought		Countries where family consent or donor card are required
	Yes	No	
Austria		X	Australia
Denmark		X	Belgium
Finland	X		Canada
France		X	Germany
Greece	X		Great Britain
Italy	X		Ireland
Norway	X		The Netherlands
Spain	X		New Zealand
Sweden	X		United States
Switzerland		X	

Source: Adapted from Stuart, Zeith, and Cranford 1981.

kin, they will not even proceed if they are unable to locate a next of kin, except in extraordinary circumstances. This despite the fact that a signed donor card gives them a perfect legal right to do so.

Several factors account for this policy. Organ procurement efforts depend wholly on the cooperation of hospital and intensive care unit personnel. If these parties believe that cooperation in organ procurement might involve them in a public conflict with an outraged parent or spouse they have a strong disincentive to report potential donors. In a confrontation with a mother charging that they mutilated her daughter, the legality of their action would provide little protection. Hospitals and physicians, particularly, might consider a public conflict along those lines as very dangerous to their position in a community.

Of perhaps equal importance are the personal feelings of those involved. Organ donations always occur in tragic circumstances; only in the case of the sudden death of a healthy young person can a transplantable organ be obtained. Organ procurement agency employees, nurses, and attending physicians are unwilling to increase the grief of families in these situations. Indeed, most of those are involved in organ procurement in part because they believe that permitting a donation helps a family deal with grief (Prottas 1983). If asked to act against the wishes of the family many, perhaps most, would not act at all.

These same forces are at work in Europe. Organ procurement specialists from Germany, the Netherlands, and Great Britain all expressed the same appreciation of the practical situation, i.e., organ donations do not go ahead without the express permission of next of kin, even in the presence of a donor card. In France, with its relatively "pure" presumed-consent law, the same is true. French law permits a hospital to remove organs without regard to family attitude, if the deceased has not explicitly stated an objection. French practice requires that the family be asked if the deceased has expressed an objection to them. Strictly, the question could be put in a way so that a positive response would be very rare, as only a small percentage of people have discussed this matter within their family. However, French organ procurement specialists report that they and the involved physicians always use this approach to the family to ask for permission to proceed. Without family permission they will not remove organs. The transplant coordinators believe that doctors and hospitals will not cooperate on any other basis. So, while there may be subtle differences between

talking with a family under various legal frameworks, in general there is a convergence in permission-obtaining practice among Atlantic community nations. This further reinforces the validity of international comparisons of organ procurement practices and success rates. However, before we begin a comparison of effectiveness across organ procurement systems, a description of the organizations that will be compared is necessary.

Organ Procurement Systems in America and Europe

Organ Procurement Networks in the United States

The United States operates the largest organ procurement system in the world. Spread across the country there are approximately 90 organ procurement agencies, ranging in size from some that obtained 4 or 5 organs in 1983 to some that exceeded 250. This huge network provided organs for over 6,100 kidney transplants in 1983 and perhaps 200 transplants of other viable human organs in 1982 (Evans 1983). When we consider the number of kidneys harvested in the United States that are never transplanted (about 800) we can see that almost 7,000 kidneys were obtained of which about 4,900 were from cadaveric donors (Health Care Financing Administration 1983). (Unlike other organs, it is possible to use a living donor to obtain a kidney. About 30 percent of renal transplants in the United States are from living donors (always relatives). In Europe, the percentage is much lower.) Finally, the United States transplant system is large as measured by the number of recipients awaiting an organ and the number of transplant centers involved in implanting them. There are between 150 and 160 officially authorized transplant hospitals in the United States (Health Care Financing Administration 1982) and, depending on one's source, between 6,000 and 10,000 people on lists awaiting a transplant (Caplan 1983). As of December 1983, the Health Care Financing Administration (1983) facility survey indicates that 7,137 people are on transplant waiting lists across the nation. In accordance with American traditions its organ procurement system is very decentralized. Each OPA has its own self-defined catchment area and is responsible to its own local constituency.

For analytical purposes America's organ procurement agencies are

conveniently divided into two groups, those that are administratively a part of a hospital and those that are separately incorporated. These are, respectively, Hospital Based (HOPAs) and Independent Organ Procurement Agencies (IOPAs). All are nonprofit organizations, all are funded by the Federal End-Stage Renal Disease Program and all are under the medical direction of transplant surgeons but, in operational matters, they differ significantly. Independent agencies are less numerous, larger, more professionalized, more likely to employ full-time transplant coordinators, and more effective, on average, than are hospital-based agencies. Table 2 presents a summary of these differences in terms of various measures of size and success. Whenever possible, United States data will be presented separately for independent and hospital-based programs, representing respectively the more progressive and less progressive of American practice.

TABLE 2
Hospital and Independent Organ Procurement Agencies
(1982 data)

	Independent agencies (IOPAs)	Hospital-based agencies (HOPAs)
Number of active organizations in category	32	50–60
Population of average service area (in millions)	4.4	2.3
Average number of cadaveric kidneys retrieved locally	92	34
Average number of nontransplant hospitals associated	54	24
Local recipients on waiting list for transplant	132	52
Average number of transplant coordinators employed	3.7	2.1
Average percentage of locally obtained kidneys not transplanted (wastage)	16.3%	20.5%
Average number of kidneys procured per million population*	22.5	15.4

ource: See appendix.
* The 1983 figure for IOPAs is 25.8. No 1983 figures for HOPAs are available.

About 40 percent of cadaveric kidneys transplanted in the United States are not obtained in the locale where they are finally used (Health Care Financing Administration 1983). This reflects the need to match the immunological characteristics of recipient and donor. For this reason, the interagency transfer of organs is of great importance. The centerpiece of this organ sharing system is the United Network for Organ Sharing (UNOS), a computer system listing all recipients awaiting a kidney transplant. Virtually all OPAs use this system. Use of the system is, however, purely voluntary and there are no universally shared criteria for determining just how organs shall be shared. Nor, with a single limited exception, is there interagency sharing of specimens from recipients to permit cross-matching of a procured organ. In the absence of such cross-matching the suitability of a specific organ for a specific recipient cannot be definitely determined. Therefore, sending an organ to a center across any distance in the United States is a calculated risk. The UNOS listing can identify a potential recipient but until the organ arrives at its destination and is tested certainty is impossible. The risk arises because once removed from a body the viability of transplantable organs rapidly diminishes. This aspect of the United States organ sharing system is in strong contrast with European methods.

Organ Procurement in Europe

There are four major organ sharing networks in Europe, three of them international in scope: Eurotransplant Foundation, which serves Germany, Austria, and the Benelux nations; U.K. Transplant, which serves Great Britain and Eire; Scandia Transplant, serving the Scandinavian nations; and the French national system.

In order to provide a sense of scale, table 3 shows the number of cadaveric kidney transplants done in each of these networks. For two of these networks, U.K. and Eurotransplant, we have detailed data on their organ procurement activities. We have a certain amount of information on the organization of the French system but no reliable quantitative data. Unfortunately, we have no systematic data at all on the highly regarded Scandinavian system.

The largest organ procurement system in Europe and the second largest in the world is Eurotransplant Foundation, located in the Netherlands. Eurotransplant serves as the organ sharing and data

TABLE 3
Cadaveric Kidney Transplants by Organ Sharing Network

	Number	Percentage of Western European total
Eurotransplant	1,532	33%
U.K. Transplant	1.023	22
Scandia Transplant	489	11
France	736	17
Total	3,830	83

Source: Davison 1983.

collection agency for Germany, Austria, Luxembourg, Belgium, and the Netherlands. Each member nation operates its own organ procurement effort, although, in practice, the program in the Netherlands is directed by the Foundation.

The population of the Eurotransplant area is approximately 93 million and in 1982, 1,484 kidneys were procured there. Because there is no equivalent in Europe for our separate reimbursement system for organ procurement, almost all organ procurement is done out of transplant hospitals. There are 38 such hospitals in the Eurotransplant region engaged in organ procurement; Eurotransplant's waiting list for transplants contains 3,756 people. Table 4 breaks down these data by member nation and for the U.K. system.

Because of its size, its reputation in Europe, and the quality of its data, Eurotransplant and its members will be the primary focus of our comparisons. Data for the only other system for which we have reasonably comprehensive data, U.K. Transplant, is also included in table 4. U.K. Transplant also serves Eire and so, with a population base of 59.3 million, is the second largest service in Europe.

Two other, large, organ networks serve a combined population of about 77 million—54 million in France and 24 million in Scandinavia. In both cases the scale of their efforts can be estimated from the number of transplants they do and their international reputation but specific organ procurement data could not be obtained. In 1982 there were 786 cadaveric kidney transplants done in France and 489 in the Scandia Transplant Region (Davison 1983). While this provides a general idea of the scale of their organ procurement efforts, the international movement of organs within Europe can cause significant

TABLE 4
Organ Procurement in Eurotransplant Region and U.K. Transplant Region, 1982

	Eurotransplant	Austria	Belgium	Netherlands	Germany	Luxembourg	U.K. Transplant
Population (millions)	93.3	7.5	9.9	14.3	61.6	—	59.3
Number of transplant hospitals	38	4	6	7	20	1	29
Cadaveric kidneys retrieved	1,484	146	146	330	860	2	1,098
Recipients	3,756*	358	394	650	2,128	12	2,494

Sources: Cohen 1982; Bradley 1982.
* 214 recipients are listed in Eurotransplant files by arrangement with other European transplantation systems.

differences between transplant and organ procurement data. The Netherlands, for instance, procures about 50 percent more kidneys than it transplants.

Comparison and Evaluation of Organ Procurement Programs

Criteria

There are three general ways of usefully comparing organ procurement programs. First, they can be compared in terms of their effectiveness at obtaining organs. This is the most basic criterion. Second, they can be compared in terms of their effectiveness at critical intermediate tasks. As previously discussed a successful organ retrieval necessitates successful completion of the referral process and of the process of obtaining permission from the donor's family. Third, organ procurement agencies can be compared in terms of how they invest their resources, both money and the time of their critical personnel. The rationale for using the second and third categories of criteria lies in their assumed (or demonstrated) relationship with the first. Some relationships have been demonstrated within the United States (Prottas 1984) but not across national boundaries. In addition, data on referrals, permission rates, and resource allocation are very difficult to obtain for European programs. For these reasons we will largely limit ourselves to the more basic measures of organizational effectiveness at organ procurement.

There are several ways of operationalizing this core test of effectiveness. Ideally, one would start by comparing the number of organs procured with the total number of potentially suitable donors available in a given area. Unfortunately, no international data exists on the size of the donor pools. Even within the United States only the crudest estimates are possible and these only for the entire nation. The seminal work in this area by the Centers for Disease Control generated very broad ranges for estimating the donor pool, from 109 kidneys per million to 232 kidneys per million, depending on the medical criteria used (Bart et al. 1981a, 1981b). Moreover, it provided no algorithm for differentiating one population from another. Until some sophisticated ethodology for this is developed the pool of potential donors in any given area cannot be determined with enough accuracy to be used as a means of comparison.

In an earlier study of a small segment of American organ procurement agencies the author did try to estimate the pool of potential donors using data on deaths. Areas were compared in terms of the number of deaths occurring within certain age groups and from certain causes. The results did not substantially change the findings obtained simply by using total population as the unit of comparison, and so was dropped. In any case, comparability problems would probably make this approach impractical for international comparisons.

Using per capita results is clearly a second-best approach to doing comparisons. It assumes that the pool of potential donors represents the same part of the total population in all the programs being compared. This is almost certainly wrong but the issue is how wrong. For large populations in countries with similar levels of economic development and similar age distributions, I believe that the per capita approach is very reasonable. In addition, small differences among programs in terms of per capita recovery rates will not be considered significant in the analysis that follows and so small differences in the ratio of potential donors to total population will not be a difficulty. In any case, given present data, we have little alternative to using per capita comparisons if any comparisons are to be made at all.

The first measure of a program's effectiveness will simply be the number of organs it obtains per million population in its service area. However, not all kidneys retrieved are ultimately transplanted. Therefore, some would argue that the number of ultimately transplanted organs is the proper test of organizational output. From the point of view of social contribution, this is a very sound position. Its major shortcoming, from an analytical point of view, lies in assigning responsibility for the difference between retrieved and ultimately transplanted organs—known as organ wastage. Some sources of organ wastage lie within the control of the procurement agency. Poor donor maintenance, nephrectomy (surgical removal of a kidney) errors, preservation errors, etc., fall into this category. Some sources of wastage are beyond the control of any agency—anatomical or functional abnormalities in the retrieved organ, for example. The last source of organ wastage is shortcomings in the interagency exchange system. An efficient communication and transportation system can quickly locate a suitable recipient for an available organ; an inefficient one may fail at the task completely or fulfill it so slowly that the organ is outdated before a suitable recipient is found. Organ procurement agencies operating in different organ sharing systems may exhibit differences in the number

of transplanted organs that are somewhat independent of their own organizational effectiveness. On the other hand comparisons of national systems as a whole legitimately include comparisons of their organ sharing network.

In order to get at the differences reflected by the alternative measures of effectiveness *both* will be used: the number of organs obtained per million population and the number of transplanted organs per million population. The former to measure effectiveness at organ procurement per se and the other to measure the social contribution the entire system makes. In addition, the wastage rate will be compared independently both because it represents the difference between the two basic measures and because it measures an important characteristic itself. Human organs are in short supply and obtaining them represents a large investment of money and energy. It also represents an implied promise between organ procurement agencies and the families of donors. These families have acted, in the midst of grief, to help others. Every organ wasted nullifies their gift (if not the benefits of giving). Avoidable wastage of organs is, therefore, a problem both on economic and moral grounds.

Tests of Effectiveness: Organs Obtained Per Million Population

Among the six systems for which we have reliable data for 1982 the United States was the third most effective, following the Netherlands and Austria (see table 5). However, when the United States system is considered in its two parts, the independent and hospital-based agencies, we find that the better half of the United States system operates virtually as well as does the Netherlands and the other half falls well down in the list.

All of the figures in table 5 are for cadaveric kidneys only. Unlike Europe, a large percentage of kidney transplants done in the United States use organs obtained from living, related donors. In 1983 over 29 percent of all kidney transplants in the United States used living, related donors (Health Care Financing Administration 1983). Clearly, the use of such donors affects the availability of a transplant, but its bearing on the measurement of success of cadaveric organ procurement is less obvious. Organizationally, the process of obtaining a living, related donor is distinct from that of obtaining cadaveric donors; the

TABLE 5
Total Kidneys Obtained per Million Population (1982)

Netherlands	23.1
Independent Agencies (U.S.A.)	22.9
Austria	19.5
United States (Total)	18.3
U.K.	17.3
Eurotransplant Region	15.9
Hospital Agencies (U.S.A.)*	15.4
Belgium	14.7
Germany	14.0

Sources: All data in this and following tables on the United States come from the End-stage Renal Disease Program's Facility Survey and the author's own survey of OPAs. Eurotransplant data comes from its annual report and U.K. data from its official yearly reports. All figures are for cadaveric organs only.
* This is an estimate based on the assumption that those areas not served by independent agencies are served by hospital-based ones.

timing of the process, the key people involved, the ethical issues raised, and the personal skills required are quite different. On the other hand, in some instances transplant coordinators will play a role in living, related organ procurement: the survey discussed in the appendix found that, nation-wide, perhaps 5 percent to 8 percent of a transplant coordinator's time is dedicated to work done with living, related organ donations. A cost-based analysis would have to deal with this issue but its bearing on the kinds of measures being used here is obscure. Finding living donors has no meaningful impact on the potential availability of dead donors and including both when comparing effectiveness rates makes little sense. On the other hand, time spent with living donors is time not available for cadaveric organ procurement.

An integration of these two types of organ procurement would raise a number of very difficult and interesting methodological and substantive issues. No attempt to do so will be made here, but the reader ought to be aware of this difference between the United States and Europe while considering the evaluation that follows.

A certain restraint must be exercised when interpreting the figures in table 5. For one thing the differences in scale are a problem. The United States population is over 225 million and even the population served by the IOPAs exceeds 110 million. In contrast the Netherlands has a population of less than 15 million and Austria and Belgium

both fall short of 10 million. There are half a dozen individual American OPAs as large. Especially for these smaller systems the absolute size of the numbers involved is a problem. In Austria, for example, a single additional donor (two kidneys) would increase the national organ per million rate by almost .3!

One way of obtaining somewhat more reliable figures is to take the average number of organs procured over several years (see table 6). This suppresses any improvements a system may have experienced in the last few years but, when combined with present figures, gives a more comprehensive picture of performance.

It is not possible to estimate accurately the kidney-per-million rate of HOPAs during this period. All systems have shown apparent improvement over the last three years, except Belgium. Of the smaller nations, Austria and Belgium have shown the most variation over the years; the Netherlands, on the other hand, has been reasonably consistent.

These figures indicate that the United States system has been the strongest large system in the world over the last years. The United States overall average rate for the last three years is 16 percent higher than that of the United Kingdom, 26 percent higher than that of the Eurotransplant region, and 50 percent higher than Germany's (which is, it must be noted, two thirds of Eurotransplant's population base). These differences are only increased if the independent agencies in the United States are separately considered.

TABLE 6
Kidneys per Million (1980–1982)

	Three year average	1982	1981	1980
Independent Agency (U.S.A.)	21.4*	22.9	20.8	20.4
Netherlands	21.3	23.1	23.2	17.5
U.S.A. (Total)	17.7**	18.3	17.8	17.0
Belgium	16.8	14.7	16.8	18.9
Austria	16.4	19.5	16.5	13.3
U.K.	15.8	17.3	14.3	15.8
Eurotransplant Region	14.5	15.9	14.4	13.1
Germany	12.2	14.0	11.7	11.0

Source: Cohen 1980–1982.
* For the 15 IOPAs that have been in continuous operation since 1980. 1983 average for *all* IOPAs is 25.6 per million; 4 year average as of 1983 is 23.8.
** The 1983 average for U.S.A. is 21.8; 4 year average is 18.7.

The only national system we have data for that is more effective than the United States, and indeed is comparable to the best in the United States, is the Dutch system. Many factors may account for this but certainly one of them is the unusual international perspective of the program in the Netherlands. The people responsible for the Dutch national system are also the directors of the Eurotransplant Foundation. In that capacity, they have had extensive contact with many other organ procurement efforts throughout the world, largely via conferences and offers to share organs. The United States exports over 100 kidneys each year, many via the Eurotransplant Foundation. While their knowledge of United States practice is not systematic, it is far more accurate than that which exists in other nations. In recent years, it is the Dutch directors of Eurotransplant who have championed the introduction of certain American practices into Europe, especially the use of transplant coordinators.

The greater success at organ procurement enjoyed by United States agencies is largely the result of their widespread use of transplant coordinators. These employees of Organ Procurement Agencies are its primary "marketing" arm among medical professionals in nontransplant hospitals. Effective marketing of organ procurement among these nurses and doctors leads to increases in the number of potential donors identified and this, in turn, is one of the most critical factors influencing the number of organs retrieved (Prottas 1984, 1985). There are perhaps 200 transplant coordinators in the United States, one for every 1.1 to 1.2 million people. (As transplant coordinators actually work primarily with hospitals the number of hospitals that a coordinator works at is a more relevant figure. This is about 15.7 per coordinator in the United States. The equivalent figures cannot be calculated for Europe because the number of nontransplant hospitals cooperating in organ procurement is not known.)

The use of transplant coordinators is much more recent and less widespread in Europe. It is difficult to determine exactly how many people are working in that capacity in European countries because their reimbursement systems do not encourage hospitals to designate someone as a transplant coordinator who also serves other hospital functions—such as a transplant nurse. However, it is possible to make rough comparisons in terms of full-time coordinators. About 170 of the 200 or so American coordinators are full-time workers at that job. This is approximately one coordinator for every 1.3 to 1.4 million

people. The number of full-time European coordinators is far smaller, ranging in number from one coordinator per 2.8 million persons in the Netherlands to one coordinator per 11.9 million persons in the United Kingdom (table 7).

Test of Effectiveness: Transplanted Kidneys Per Million Population

Because the United States fails to transplant a large number of organs procured, its rate of ultimately transplanted kidneys procured per million is not as impressive vis à vis Europe as its rate of total kidneys procured. Table 8 presents a summary of this data.

While the United States does a very good job in terms of the total number of organs retrieved, its record in terms of organs retrieved and transplanted is worse. Its great success in locating and obtaining organs is apparently being squandered by its relative inability to bring those organs to people in need. This inability is measured by the wastage rate—the percentage of kidneys procured but not transplanted. A substantial improvement in this as in all other effectiveness measures was shown in 1983. Ultimately, transplanted kidneys were harvested at a rate of 18.3 kidneys per million in the United States in 1983. The IOPA figure was 21.8 per million.

TABLE 7
Full-Time Transplant Coordinators

	Number	Million population per coordinator
U.S.A.	170 (est)	1.3 – 1.4
Netherlands	6	2.4
Germany	16	3.8
Austria	2	3.8
Belgium	2	5.0
France	5	10.8
U.K.	5	11.9

Sources: U.S. data based on a survey of OPAs. European data based on interviews with representatives of Eurotransplant, U.K. Transplant, and the German and French systems.

TABLE 8
Transplanted Kidneys Obtained per Million Population

	Three year average	1982	1981	1980
Netherlands	20.2	21.9	22.2	16.5
IOPAs	17.4	19.4	16.7	16.0
Austria	15.5	18.8	15.2	12.5
Belgium	15.5	14.0	15.7	16.7
United States (Total)	14.0	14.7	13.9	13.3
Eurotransplant	13.6	15.1	13.6	12.0
Germany	11.4	13.2	11.0	10.1
U.K. Transplant	Data Not Available			

Wastage Rates

The apparent differences between reported wastage rates in Europe and the United States are phenomenal. Eurotransplant's annual report indicates that only about 5 percent of kidneys procured system-wide are not transplanted; in the United States that figure exceeds 19 percent. Table 9 records the rates reported by Eurotransplant for the constituent national systems and the rates computed by the author for the United States based on the required yearly reports American OPAs make to the federal government.

These European rates are difficult to reconcile with other kinds of information about organ procurement that the author has obtained.

TABLE 9
Wastage Rates (percent)*

	Average 1980–1982	1983	1982	1981	1980
United States	21.1%**	16.1%	19.7%	21.8%	21.9%
IOPA	18.7**	15.6	15.1	19.6	21.4
Belgium	7.7	—	4.8	6.5	11.6
Germany	6.6	—	5.7	6.0	8.2
Eurotransplant	6.2	—	5.0	5.6	8.4
Austria	5.5	—	3.6	7.9	6.0
Netherlands	5.2	—	5.2	4.3	5.7

* Data for HOPAs not available, nor can United Kindgom wastage rates be determined.
** 4 year average; U.S.A 19.9%, IOPAs 17.9%.

Transplant surgeons interviewed and directors of American organ procurement agencies generally say that about 10 percent of kidneys excised are unusable for anatomical or functional reasons. This is consistent with the report made to the 1984 annual meeting of the North American Transplant Coordinators Organization by Dr. John McDonald of Louisiana State University, a past president of the Southeastern Organ Procurement Foundation. In his presentation of that organization's experience in a variety of organ procurement activities, Dr. McDonald reported wastage rates and used a figure of 12 percent as a minimum wastage level.

In an attempt to reconcile this oddity, a more detailed examination of data obtained from Eurotransplant was done. The suspicion was that European methods of counting wastage differed from those in use in the United States. Because OPAs in the United States must account for their costs they count every donor they take into the operating room, even if those organs prove unusable upon initial examination. On the other hand, Eurotransplant is primarily concerned with organ sharing and may overlook some organs that are found useless soon after organ removal.

The Eurotransplant annual reports each contain a table listing "reasons for not using donors/kidneys" (usually table V.6). On this table are listed several categories including "medical reasons" and "no nephrectomy performed." This seems to imply that at least some of the donors in the former category were nephrectomized, or at least brought into the operating room. Table 10 was constructed based on the assumption that all donors in the "medical reasons" category would have been counted as actual donors by American practices.

These figures are more in line with the estimates of the prevalence of physical problems that exclude organs from use made by knowledegable Americans. However, it must be remembered that these figures represent

TABLE 10
Corrected Wastage Rates (percent)

	Average 1980–1982	1983	1982	1981	1980
United States	21.1%	16.1%	19.7%	21.8%	21.9%
IOPAs	18.7	15.1	15.8	19.6	21.4
Eurotransplant	11.4	—	11.4	10.7	12.9

the most extreme assumptions about this unclear category of donors and so are almost certainly too high.

The Eurotransplant staff reexamined their 1982 data to try to resolve this uncertainty. They discovered that some donors in the "medical reasons" category were in fact nephrectomized but were unable to determine, for certain, at what point the others were eliminated from consideration as donors. When the nephrectomized donors are included in the 1982 wastage rate for Eurotransplant that rate becomes 6.5 percent. The actual rate, therefore, lies between 6.5 and 11.4 percent, almost certainly much closer to the former. While this decreases the difference between American and European wastage rates the fact remains that American rates are 85 to 200 percent higher than those of Eurotransplant.

It is not possible authoritatively to account for this difference. In general, there are two possible causes of organ wastage that may play a part in an explanation. Some kidneys are wasted by errors made by the organ procurement agency. These errors might include surgical errors in the nephrectomy or problems with donor management or, less frequently, preservation problems. Some organs are wasted during the organ sharing process. The interagency sharing of organs can lead to wastage if it fails to find a suitable recipient (when one exists) or finds one so late that the organ is no longer suitable to transplant. These are the basic sources of organ wastage.

Many of the directors of organ procurement agencies consider that surgical errors in organ procurement is a significant cause of organ wastage. When surveyed, 16.7 percent stated that it was the most frequent reason for organ wastage and an additional 16.7 percent believed it to be the second most frequent cause. (This data and the analogous attitudinal data on the following pages were gathered via the national survey of OPAs mentioned in the appendix.) By and large few directors consider other forms of local errors to be important. While this may indicate that wastage rates can be decreased by more careful nephrectomies, an additional assumption must be made if it is to help explain the difference between American and European rates. It would be difficult to argue (as well as very unpopular) that American physicians removing kidneys are significantly less competent than their European counterparts! This is especially true as nephrectomies are most often done by transplant surgeons and American successes with kidney transplants are no worse than those in Europe.

On the other hand, there is a logical basis to believe that OPAs that procure more organs per capita (as do United States agencies compared to European) are willing to accept certain marginal donors that might be rejected by less aggressive agencies. There is, however, no direct evidence to support this proposition. There is no correlation between kidneys procured per capita and wastage rates among American OPAs (Prottas 1984).

An alternative, or indeed, a complementary argument is that a higher per capita procurement rate leads to wastage not because it produces more marginal organs but because it produces more organs per potential recipient. This could mean that perfectly usable organs are not transplanted because a good match between recipient and donor does not come about—that the system works so well that suitable recipients are in short supply, or that the standards of immunological matching expected by transplant surgeons is more rigorous when the supply of organs increases.

Indeed, the absence of a suitable match is given as the primary cause of organ wastage by over 37 percent of the directors of the nation's largest OPAs. An additional 21 percent believe that it is the second most common cause of wastage. However, failure to find an acceptable match for a donated organ can be explained by factors other than a shortage of recipients. It could represent inadequacies in the organ sharing network. There is some reason to believe the latter explanation.

In the first place, the United States does not transplant a particularly high percentage of its population, so a shortage of acceptable recipients relative to European standards is unlikely. In addition, the United States dialyzes a far higher percentage of its population, making its transplant/dialysis ratio unusually low (Prottas, Segal, and Sapolsky 1983) and it is from the ranks of dialysis patients that transplant patients come. This weakens the shortage-of-recipients argument.

Finally, organs not transplanted here are often exported to Europe with good results. In the first eighteen months of its operation, the Kidney Center, an organ sharing service associated with the major regional association of transplant hospitals, exported 128 kidneys. A large percentage of these went to the Eurotransplant region. The medical director of Eurotransplant estimated that his organization accepted about 40 kidneys from the United States last year. The success rate from the transplant of those organs was no different from

that experienced by organs obtained in Europe (which, in turn, is little different from the success rates for United States transplants). In his view, the recipient lists in the Eurotransplant region and the United States are not significantly different in medical terms. He believes that he was offered those organs only because of sharing problems among OPAs in the United States. A significant number of directors of OPAs have similar perceptions: 12.6 percent of them reported that inefficiencies in interagency organ sharing is the primary cause of organ wastage; an additional 20.8 percent believe it to be the second most common reason that organs are not transplanted. (Again these data come from the survey mentioned in the appendix.)

The structure of America's organ sharing system lends credence to these beliefs especially when contrasted to the system in use by Eurotransplant. In the Eurotransplant region, as in the U.K. Transplant region, two factors tend to minimize avoidable administrative/sharing cause of kidney wastage. First, there is agreement among transplant centers and organ procurement agencies on procedures and criteria. All laboratories do their tissue typing of organs using the same chemicals and methods and all typing is redone at the central laboratory as a cross-check on results. In this way, all involved in organ sharing can have a high degree of faith in each other's results. In addition, all transplant centers have agreed to criteria for sharing organs and so which patient ought to receive a kidney involves no additional discretion—the priority among patients is unambiguous. Finally, every agency shares specimens with every other via the Eurotransplant central offices. This is the linchpin of the system. It is not technically possible to determine if a given donor organ is suitable for a given recipient until specimens from the two are actually mixed. The immunological system is too complex and ill understood for a definitive compatibility determination to be made except in this empirical manner. In the Eurotransplant system every procurement center has samples of blood from every potential recipient. They can, therefore, test for compatibility with a newly obtained organ immediately. This results in a trustworthy list of patients for whom the organ is suitable. It only remains for the Eurotransplant (or U.K. Transplant) central office to apply the agreed-upon priority rules and contact the physicians of the recipient so selected. The organ can then be shipped to the recipient's hospital with virtual certainty that it will be used.

Almost none of these conditions exist in the United States. In the

first place, there are no agreed-upon criteria for an acceptable organ among United States transplant centers. They differ in terms of the permissible age of the organ, the lab values of certain tests, and, indeed, the minimal acceptable tissue match. Sharing organs, therefore, requires a rather extensive knowledge of the idiosyncrasies of some 90 individual agencies. Equally important is the fact that the existence of compatibility between donor and recipient cannot, in most cases, be determined before an organ is actually transported to the recipient's hospital. With a single, limited, exception, American agencies do not share recipient specimens. This means that the retrieving agencies cannot know if a specific recipient in another center is medically appropriate for the organ they have. They can, via a computerized listing system, eliminate from consideration many potential recipients, but they cannot know if a match does exist until they ship the organ and it is tested with the recipient's blood. This means that every time an organ is sent to another center a risk is taken. The procuring agency must sit with the listing of possible recipients and decide which agency to call and offer the organ to. They must make the decision based on their knowledge of that agency's practices, how long it will take to deliver the organ to the agency, and their estimate of the probability that the agency will actually be able to use the organ.

If a center is sent an organ it cannot use, there is a good chance that the organ will be too old to transplant before it can be sent to another location. Closer or more accessible agencies are, therefore, to be preferred so that re-export is possible. In addition, larger agencies are preferred because they may have several recipients who could prove suitable. This multiplies the probability that the organ can be used. Therefore, recipients in small or inaccessible centers are at a disadvantage. Lastly, the most sensitized patients are at a disadvantage.

Patients differ in terms of their sensitivity—the probability that even where a match is possible it will not prove to actually exist. It is possible to estimate this probability and it is recorded on everyone's, Europeans' and Americans', sharing lists. Highly sensitized patients tend to accumulate on waiting lists. In Europe, sensitized patients receive priority when a suitable organ is found because it is hard to find such organs. In the United States this generally does not work because of the risk faced by the exporting OPA. If an agency sends their kidney to a highly sensitized patient and it is, in fact, unusable

by him, it is likely to be lost, unless the receiving organization has another patient or is very good at re-exporting organs. Often, therefore, in order to be sure of using the kidney an OPA will prefer to offer it to a less sensitized patient. This tends to accelerate the accumulation of sensitized patients on waiting lists. Many waiting lists in the United States are, therefore, bimodal, with a concentration of new entrants and, at the other end, a concentration of sensitized patients who have been waiting a long time. The first six months on a waiting list is the most likely time to receive an organ.

This problem of sensitized patients is widely understood among OPAs and their regional association in the South has tried to deal with it by sharing specimens of sensitized patients among its members in much the same way that Eurotransplant shares specimens for all recipients.

This admirable, if limited, effort has met with only modest success because lack of systematic quality control and lack of agreed-upon sharing and testing criteria has made many OPAs unwilling to place their trust in other centers' specimens and/or test results. Taken together these serious operational problems in organ sharing in the United States tend to support explanations attributing at least part of our high wastage rate to system-wide organizational defects.

Summary and Conclusion

Organ procurement among the Atlantic community nations follows very similar lines. Despite legal and national differences, the basic task of obtaining human organs for transplant is much the same and is approached in much the same manner. Hospitals where potential donors die must be identified, critical-care medical personnel must be motivated to cooperate, and families of donors must be persuaded to grant permission for organ removal. Finally, mechanisms must be in place so as to allow retrieved organs to be offered to suitable recipients.

Both in Europe and the United States there are extensive networks of organizations to complete these tasks. In the United States the organ procurement system is relatively strong at the local level. Supported by federal money, the United States has developed locally run and locally oriented organ procurement agencies, many of which are unusually successful at developing a system of hospitals supportive of their efforts. As a result, the United States does better than Europe in the

location and procurement of organs. Europe, on the other hand, has had greater successes in developing interorganizational cooperation and central oversight of organ procurement. So while most European systems procure less organs per capita than does the United States, they make better use of those organs they do obtain. In this sense the decentralized model in use in the United States has shown a greater capacity to develop the nation's human organ resources but the more centralized European models have shown a greater ability to put their limited resources to use. The degree to which these two tendencies reflect more basic organizational, political, and indeed, cultural differences between Europe and the United States is an interesting subject for speculation but is beyond the scope of this article. The fact that there are signs of convergence in practice between the continents also raises interesting issues about the impact of technology and its organizational results on national policies and practices. Once again such a discussion would take us from our primary objective, but the concrete pattern of convergence in organ procurement is germane.

In Europe the movement to develop a professionalized local organ procurement capacity is developing. The European Transplant Coordinators Organization, an organization explicitly modeled after the older and larger North American Transplant Coordinators Organization, held its first meeting in Zurich in 1983. Various European nations have been increasing the number of their full-time organ procurement workers (transplant coordinators) operating roughly on the American model. Here, as in other areas, the Dutch are taking a role quite out of proportion to their size. As the home of Eurotransplant the Netherlands has had a particularly good appreciation of international developments in organ procurement.

At the same time modest efforts have been going on in the United States aimed at improving our nation-wide sharing system. Five years ago there were at least three recipient registries competitively operating in the United States. Today virtually every organ procurement agency that is involved in organ sharing is a member of the United Network for Organ Sharing (UNOS), which provides a comprehensive list of those awaiting kidney transplant. The South-Eastern Organ Procurement Foundation, a regional organization, has taken some additional steps to facilitate organ sharing, including sharing specimens of highly sensitized patients among its members. And the Kidney Center, an associated organization, has recently been established to help place

organs where they are needed across the nation. While neither of these efforts have achieved a success comparable to the success of European sharing systems, they at least represent an awareness of a serious problem and the beginning of a search for solutions on an interorganizational level.

There have even been signs of such awareness at the national level. There have been efforts in Congress to pass legislation aimed at strengthening organ procurement in various ways, including more centralized and effective organ sharing. From the executive branch there has been support for nongovernmental initiatives aimed at increasing cooperation among the various groups interested in organ procurement and transplant. Many of these steps are admirable and ought to be encouraged; they represent the first steps in a process that may, hopefully, lead to a more disciplined and effective structure for interorganizational exchange of human organs in the United States.

The technical and organizational demands of organ transplantation have led to the development of similar responses in Europe and the United States. Until recently these responses have developed largely in isolation and each continent has emphasized those aspects of the process that reflected its particular genius. Now we are beginning to learn from each other and a great convergence of practice can be anticipated. In Europe this will mean more organs retrieved; in the United States less organs wasted; in both, lives saved and suffering ameliorated.

Appendix

American Sources of Data

There are three basic sources of data for the discussion of the American organ procurement system: the End-Stage Renal Disease Facility survey, the cost reports of organ procurement agencies, and a nationwide survey of organ procurement agencies.

The Health Care Financing Administration (HCFA) requires all facilities providing care under the End-Stage Renal Disease Program to report information about their activities. The second part of this survey concerns organ transplantation and organ procurement activities. The facilities responding to this section are transplant hospitals. Because

many transplant hospitals are associated with Independent Organ Procurement Agencies (IOPAs) this data is not readily interpretable at the hospital level. However, it is invaluable when aggregated to the national level.

To obtain reliable information about the activities of individual organ procurement agencies it is necessary to examine the financial reports they make to HCFA. This represents no daunting problem with regard to the IOPAs because they all report to a single location and their reports contain only organ procurement information: numbers of organs locally procured, imported from other agencies, transplanted, etc., and cost data. Hospital-based agencies are a different matter. They report only through the parent hospital as part of the regular Medicare reporting system. This data is obtainable only by locating and examining, in detail, the reporting forms of hospitals involved in organ procurement. This is always very difficult, and quite impossible while the forms are being processed by HCFA. For this reason only one year's data are available, while several years are available for many IOPAs.

Finally, in order to obtain more detailed data on individual OPAs and the population areas in which they work a survey was done of all OPAs in the nation. This work was funded by HCFA and its major results are summarized in the report to HCFA cited in the references as Prottas 1984. In preparation for this survey, interviews were conducted with the directors, transplant coordinators, and associated medical personnel of about two dozen organ procurement agencies across the nation.

European Sources of Data

There were three major sources of data used for the discussion of the European systems. The European Dialysis and Transplant Association produces an annual report each year (edited by Alex Davison in 1983). This report is useful for transplant data but contains very little information directly dealing with organ procurement.

Two of the major European transplant systems publish annual reports that are reasonably accessible: Eurotransplant Foundation and U.K. Transplant. These provided detailed data on organ procurement in the British Isles, the Benelux countries, Austria, and Germany.

Finally, the author was able to interview representatives of many

European organ procurement programs during visits to Eurotransplant, U.K. Transplant, and the annual meeting of the European Transplant Coordinators Organization.

References

Bart, K., E. Macon, F. Whittier, R. Baldwin, and J. Blount. 1981a. Cadaveric Kidneys for Transplantation. *Transplantation* 31(5):379–82.

Bart, K., E. Macon, A. Humphries, R. Baldwin, P. Fitch, R. Pope, M. Litch, D. Langford, S. Teutsch, and J. Blount. 1981b. Increasing the Supply of Cadaveric Kidneys for Transplantation. *Transplantation* 31(5):383–87.

Bradely, B. 1982. *U.K. Transplant Service Annual Report.* Bristol.

Caplan, A. 1983. Organ Transplants: The Costs of Success. *Hastings Center Report,* December.

Cohen, B. 1980–1982. *Eurotransplant Foundation Annual Reports.* Leiden, The Netherlands.

Davison, A. 1983. Proceedings of the European Dialysis and Transplant Association. London: Pitman.

Evans, R. 1983. *Testimony Presented Before the Subcommittee on Health and the Environment,* U.S. House of Representatives, July 29.

Farfor, J.A. 1977. Organs for Transplant: Courageous Legislation. *British Medical Journal* 1:497–98.

Gallup Organization. 1983. Attitudes and Opinions of the American Public Towards Kidney Donations. Princeton, N.J.

Health Care Financing Administration. 1982. National Listing of Providers Furnishing Kidney Dialysis and Transplant Services, January. Washington.

———. 1983. National ESRD Facility Survey. (Unpublished.)

Kaufman, H., J. Huchton, M. McBride, C. Beardsley, and B. Kahan. 1979. Kidney Donation: Needs and Possibilities. *Neurosurgery* 5(2):237–44.

Moore, B., G. Clarke, B.R. Lewis, and N.P. Mallick. 1976. Public Attitudes Towards Kidney Transplantation. *British Medical Journal* 1 (March):629–31.

Prottas, J. 1982. *Organizational Effects in Organ Procurement,* Report to the Health Care Financing Administration, April, 91–103. (Mimeo.)

———. 1983. Encouraging Altruism: Public Attitudes and the Marketing of Organ Donation. *Milbank Memorial Fund Quarterly/Health and Society* 61(2):278–306.

———. 1984. *Analysis and Evaluation of the U.S. Organ Procurement System: Hospital and Independent Agencies Compared.* Report to Health Care Financing Administration, February.

———. 1985. Structure and Effectiveness of the American Organ Procurement System. (Forthcoming.)

Prottas, J., M. Segal, and H. Sapolsky. 1983. Cross-National Differences in Dialysis Rates. *Health Care Financing Review* 4(3):91–103.

Stuart, F., F. Zeith, and R. Cranford. 1981. Brain Death Laws and Patterns of Consent to Remove Organs for Transplantation From Cadavers in the United States and 28 Other Countries. *Transplantation* 31(4):238–44.

Acknowledgments: The research on which this paper is based was funded by a grant from the Health Care Financing Administration. Additional assistance was provided by the Eurotransplant Foundation.

Address correspondence to: Dr. Jeffrey M. Prottas, Health Policy Center, Heller Graduate School, Brandeis University, 415 South Street, Waltham, MA 02254.

Atty. #3
3-18-86

As Amended by Senate Committee

Session of 1986

SENATE BILL No. 532

By Senators Ehrlich and Steineger, Bogina, Burke, Doyen, Francisco, Langworthy, Morris, Mulich, Norvell, Reilly, Strick, Thiessen, Vidricksen, Warren, Winter and Yost

1-31

AN ACT relating to anatomical gifts; placing certain duties upon persons in charge of hospitals or their designees to request anatomical gifts.

Be it enacted by the Legislature of the State of Kansas:

hospital policies and procedures

Section 1. (a) Where, based on ~~hospital~~ accepted ~~criteria~~ for ~~organ~~ donations *of all or part of the body under the uniform anatomical gift act, a patient in any hospital located in this state is a suitable candidate for* ~~*organ*~~ ~~*or tissue*~~ ***such*** donation, the person in charge of the hospital or designated representative of the person in charge of the hospital, other than a person connected with the determination of death, shall at the time of death request any of the persons in the classes specified in items (1) through (5) of subsection (b) of K.S.A. 65-3210 and amendments thereto, in the order of priority stated when persons in prior classes are not available, ~~and in the absence of (1) actual notice of contrary intentions by the decedent, or (2) actual notice of opposition by a member of any of the classes specified in items (1) through (5) of subsection (b) of K.S.A. 65-3210 and amendments thereto, or (3) other reason to believe that an anatomical gift is contrary to the decedent's religious beliefs,~~ to consent to the gift of all or any part of the decedent's body for any purpose specified in K.S.A. 65-3211 and amendments thereto.

(b) Where the ~~hospital administrator or designee of the hospital administrator shall have received~~ *person in charge of the hospital or designated representative of the person in charge of the hospital has (1) actual notice that the decedent was opposed*

Atty. #3
3-18-86

HS. MHA

to an anatomical gift of all or part of the decedent's body or (2) actual notice of opposition ~~from any of the persons~~ *by a member of any of the classes* specified in items (1) through (5) of subsection (b) of K.S.A. 65-3210 and amendments thereto ~~or where there is otherwise~~ *or (3) other* reason to believe that an anatomical gift is contrary to the decedent's religious beliefs, such gift of all or any part of the decedent's body shall not be requested. Where a donation is requested, consent or refusal need only be obtained from the person or persons in the highest priority class available.

(c) Where a request for consent to an anatomical gift has been made, the person in charge of the hospital, or the designated representative of the person in charge of the hospital, shall verify such request in the patient's medical record. The verification of request for ~~organ or tissue~~ donation *under this section* shall include a statement to the effect that a request for consent to an anatomical gift has been made and shall further indicate thereupon whether or not consent was granted, the name of the person granting or refusing the consent and such person's relationship to the decedent. *Where a patient is a suitable candidate for an anatomical gift under this section and a request for consent to an anatomical gift has not been made, the person in charge of the hospital, or the designated representative of the person in charge of the hospital, shall include a statement in the patient's medical record that a request was not made and shall indicate thereupon why the request was not made.*

~~*(d) Every hospital in this state shall annually submit a written report to the secretary of health and environment, in the manner and form prescribed by the secretary, of the number of requests for anatomical gifts made under this section, the number of requests not made and the reason or reasons for not making the requests. The report shall not include the names of individuals.*~~

~~(d)~~ *(e)* Upon the consent to an anatomical gift, the hospital shall then notify an ~~organ or tissue procurement organization~~ *organization which procures anatomical gifts* and cooperate in the procurement of the anatomical gift or gifts pursuant to applicable provisions of the uniform anatomical gift act.

~~(e)~~ *(f)* ~~A request for consent to an anatomical gift under this section is not required if the hospital does not have the facilities necessary to maintain the potential donor in a condition which would allow for retrieval of the organ or tissue or~~ *anatomical gift and* ~~the potential donor cannot be transferred to a hospital that does have such facilities.~~

(g) In carrying out the provisions of this section, each hospital in this state shall adopt written policies relating thereto.

~~(f)~~ *(h)* This section shall be part of and supplemental to the uniform anatomical gift act.

Sec. 2. This act shall take effect and be in force from and after its publication in the statute book.

As Amended by Senate Committee

Session of 1985

Material within brackets would be deleted.

Attm. # 4
3-18-86

SENATE BILL No. 179

By Committee on Public Health and Welfare

2-7

AN ACT concerning ~~nurse anesthetists~~ [*the*] [*practice of nurse anesthesia*]; providing for the certification of [*certified*] registered nurse anesthetists; establishing an advisory council on nurse anesthetist certification standards; declaring certain acts to be unlawful and classifying the crime and the penalties therefor; *amending K.S.A.* [*1984*] *Supp. 40-3401 and repealing the existing section.*

nurse anesthetists

1985

Be it enacted by the Legislature of the State of Kansas:

New Section 1. As used in *sections 1 to 13, inclusive, of* this act:

(a) "Registered [*Certified registered*] nurse anesthetist" means a licensed professional nurse who [holds a certificate as a] [*certified*] registered nurse anesthetist.

Registered

is authorized to practice

(b) "Practice of *nurse* anesthesia" means the performance of or the assistance in any *nursing or medically delegated* act involving the determination, administration or monitoring of any drug used to render an individual insensible to pain for procedures requiring the presence of persons educated in the administration of anesthetics. This shall include the use of techniques which shall be deemed necessary for adequate performance of anesthesia administration ~~when those acts fall within the domain of professional nursing practices for which such nurse bears independent responsibility, and those medically delegated functions of an anesthesiological nature further delineated within the scope of practice~~ *but shall not include the administration of local anesthetics.*

HB, PHW 3-18-86 Attm. #4

(c) "Practitioner" means a person licensed to practice medicine and surgery; *or* a person licensed to practice dentistry ~~and a registered podiatrist~~.

(c) "Medically delegated" means an act delegated by the attending practitioner.

(d) "Board" means the board of nursing.

New Sec. 2. In order to obtain a certificate from the board of nursing as a *certified* registered nurse anesthetist an individual shall meet the following requirements:

(a) Is licensed to practice professional nursing under the Kansas nurse practice act;

(b) has successfully completed a course of study in *nurse* anesthesia in a school of nurse anesthesia accredited or approved by the board; and

(c) has successfully completed a certifying examination approved by the board or has been certified by a national organization whose certifying standards are approved by the board as equal to or greater than the corresponding standards established under this act for certification as a *certified* registered nurse anesthetist.

New Sec. 3. The board may grant a temporary certification in the practice of *nurse* anesthesia as a *certified* registered nurse anesthetist for a period of one year. ~~The temporary certificate may be extended for one additional period of one year at the discretion of the board for~~ *to* (a) graduates of an accredited school of nurse anesthesia pending results of the initial certifying examination, and *or* (b) ~~registered~~ nurse anesthetists currently licensed in another state pending completion of the application for Kansas certification.

New Sec. 4. Upon application to the board by any licensed professional nurse in this state and upon satisfaction of the standards and requirements established under this act, the board shall issue a certificate to such applicant authorizing the applicant to perform the duties of a *certified* registered nurse anesthetist. The application to the board shall be upon such form and contain such information as the board may require and shall be accompanied by a fee to assist in defraying the expenses in connection with the issuance of certificates as *certified* registered nurse anesthetists. The fee shall be established *fixed* by rules and regulations adopted by the board not to be less than

---

(b)

(c) "Local anesthetic" means infiltration anesthesia or anesthesia produced by direct infiltration of local anesthetic solution into the operative site.

(d) "Regional anesthesia" means the use of local anesthetic solutions to produc oss of sensation in circumscribed areas.

(e) "General anesthesia" means one that is complete and affecting the entire body, with the loss of consciousness.

authorization

to practice

an

obtaining authorization to practice

authorization to practice

not more than

a

accredited or approved by the board

or otherwise credentialed

an authorization to practice nurse anesthesia as a registered nurse anesthetist in this state

authorize

administration of the provisions of this act

$20 ~~nor more than $50~~ *of not more than $75* for an original application~~;~~ and not more than ~~$20~~ *$40* for the renewal of a certificate as a ***certified*** registered nurse anesthetist. The original application fee for a temporary certificate ~~and the fee for any extension of a temporary certificate authorized under section 3~~ shall be fixed by the board by rules and regulations and shall not be more than ~~$20~~ *$35*. The executive administrator of the board shall remit all moneys received pursuant to this section to the state treasurer as provided by K.S.A. 74-1108 and amendments thereto.

New Sec. 5. (a) All certificates issued under this act, whether initial or renewal, shall expire every two years. The expiration date shall be established by rules and regulations of the board. The board shall mail an application for renewal of the certificate to every ***certified*** registered nurse anesthetist at least 60 *90* days prior to the expiration date of such person's license. To renew such certificate the ***certified*** registered nurse anesthetist shall file with the board, ~~on or~~ before the date of expiration of such certificate, a renewal application together with the prescribed biennial renewal fee. Upon satisfaction of the following requirements the board shall grant a renewal certificate: (1) Receipt of such application; (2) payment of the designated fee; (3) compliance with the requirements established under this act ***for renewal of a certificate*** and in effect at the time of initial qualification of the applicant; and (4) verification of the accuracy of the application.

(b) Any person who fails to secure a renewal certificate prior to the expiration of the certificate may secure a renewal of such lapsed certificate by making application on a form provided by the board. Such renewal shall be granted upon receipt of proof that the applicant is competent and qualified to act as a ***certified*** registered nurse anesthetist, has satisfied all of the requirements for renewal set forth in subsection (a) and has paid the board a reinstatement fee as established by the board by rules and regulations.

New Sec. 6. ~~Any person engaged in the practice of anesthesia in this state as a licensed professional nurse on~~ ***A licensed***

in an amount not to exceed
to exceed
an authorization to practice as a
authorization
authorizations to practice
authorization to practice
of subsection (a) of section 9
the renewal of an authorization to practice as a registered nurse anesthetist to the applicant
the renewal of an authorization to practice
authorization
in an amount not to exceed $80

professional nurse engaged in the practice of nurse anesthesia in Kansas immediately preceding July 1, ~~1984~~ *1985*, and who has successfully passed a certifying examination approved by the board, or who holds a certification from a national organization whose certifying standards are approved by the board as equal to or greater than the corresponding standards established under this act for certification as a *certified* registered nurse anesthetist shall be issued a certificate by the board as a *certified* registered nurse anesthetist.

New Sec. 7. (a) Any licensed professional nurse who is certified by the ~~American association of nurse anesthetists~~ *council on certification of nurse anesthetists or its predecessor* prior to the effective date of this act *or any licensed professional nurse who holds a valid certificate of qualification as an advanced registered nurse practitioner in the category of certified registered nurse anesthetist prior to the effective date of this act* shall be issued a certificate by the board to practice as a *certified* registered nurse anesthetist.

(b) Any licensed professional nurse who has regularly administered anesthesia in this state for a period of not less than three years immediately preceding July 1, ~~1984~~ *1985*, and who by July 1, ~~1985~~ *1986*, is capable of demonstrating sufficient knowledge and competence in the science of anesthesia by means of an appropriate evaluation mechanism, which is recommended by the advisory council and approved by the board, shall be issued a certificate by the board as a *certified* registered nurse anesthetist.

New Sec. 8. ~~(a) The determination and administration of anesthesia care shall be performed by the registered nurse anesthetist in consultation and collaboration with a licensed practitioner.~~

(b) The following *medically delegated* duties and functions shall be considered as specific expanded role functions of the *certified* registered nurse anesthetist:

(1) Preanesthesia evaluation including physiological studies to determine anesthetic management;

~~(2)~~ selection of monitoring devices appropriate to anesthesia;

1986

authorization to practice as a

, upon application to the board and the payment of the application fee,

authorized

to practice as a

, upon application to the board and the payment of the application fee,

authorized

1986

1987

upon application to the board and the payment of the application fee,

authorized

to practice as a

(3) selection of anesthetic techniques;
(4) administration of and maintenance of anesthesia;
(5) evaluation and direction of immediate postanesthesia management and dismissal from postanesthesia care; and
(6) evaluation of postanesthesia course of patients.

~~(c)~~ *(b)* The determination of other ~~duties that are normally considered~~ medically delegated duties to the *certified* registered nurse anesthetist shall be the joint responsibility of the governing board of the ~~hospital~~ *medical care facility*, medical staff and *certified* registered nurse anesthetist personnel of any duly licensed medical care facility or, if in an office or clinic, the responsibility of a duly licensed practitioner. All such duties, except in cases of emergency shall be in writing in the form prescribed by ~~hospital~~ *medical care facility* or office policy.

New Sec. 9. (a) The applicant for renewal of a certificate as a *certified* registered nurse anesthetist:

(1) Shall have met the continuing education requirements for *a certified* registered nurse anesthetist as developed by the board or by a national organization whose certifying standards are approved by the board ~~of nursing~~ as equal to or greater than the corresponding standards established under this act;

(2) shall be currently licensed as a professional nurse; and

(3) shall have paid all applicable fees provided for in this act as fixed by rules and regulations of the board.

(b) Continuing education credits approved by the board for purposes of this subsection may be applied to satisfy the continuing education requirements established by the board for licensed professional nurses under K.S.A. 65-1117 and amendments thereto if the board finds such continuing education credits are equivalent to those required by the board under K.S.A. 65-1117 and amendments thereto.

New Sec. 10. (a) There is hereby established an advisory council on nurse anesthetists certification standards. The advisory council shall be attached to the board of nursing and shall be within the board of nursing as a part thereof. All budgeting purchasing and related management functions of the advisory council shall be administered under the direction and supervi-

(a) Each registered nurse anesthetist shall:
(1) Conduct a pre- and post-anesthesia visit and assessment with appropriate documentation;
(2) develop an anesthesia care plan with the physician or dentist which includ medications and anesthetic agents;
(3) induce and maintain anesthesia at the required levels;
(4) support life functions during the peri-operative period;
(5) recognize and take appropriate action with respect to patient responses during anesthesia;
(6) provide professional observation and management of the patient's emergence from anesthesia;
(7) participate in the life support of the patient;
(8) participate in periodic and joint evaluation of services rendered, including, but not limited to, chart reviews, case reviews, patient evaluation and outcome of case statistics; and
(9) participate in the joint reviews and revision of adopted protocols or guidelines.

(b) A registered nurse anesthetist shall perform duties and functions in an interdependent role as a member of a physician or dentist directed health care team.

an authorization to practice

sion of the board of nursing. All vouchers for expenditures of the advisory council shall be approved by the chairperson of the board or a person designated by the chairperson.

(b) The board shall appoint three registered ~~nurse anesthetists who are actively engaged in the practice of anesthesia~~ *nurses who are actively engaged in the practice of nurse anesthesia and who are certified registered nurse anesthetists or are eligible for certification under this act* to the advisory council. ~~Of the members first appointed to the advisory council, one shall be appointed for a term of one year, one shall be appointed for a term of two years and one shall be appointed for a term of three years. The board may make appointments of registered nurse anesthetists from a list of names submitted by the Kansas association of nurse anesthetists. Thereafter, one registered nurse anesthetist shall be appointed each year for a three-year term.~~ *The board shall make appointments under this section after consideration of a list of names submitted by the Kansas association of nurse anesthetists of not less than three times the number of nurse anesthetists to be appointed.* The board shall also appoint ~~for a term of two years~~ one nonvoting member who is a board certified anesthesiologist in active practice. The board of nursing may make appointments of the board certified anesthesiologist from a list of names submitted by the Kansas society of anesthesiologists. *The terms of the members of the advisory council shall expire on the date of expiration of this section under subsection (e).*

(c) The advisory council shall:

(1) Act as consultant to the board of nursing in matters pertaining to nurse anesthesia education and the scope of nurse anesthesia practice;

(2) function as a resource in matters pertaining to grievances or arbitration;

(3) consult with and ~~advise~~ the board of nursing in matters pertaining to disciplinary action; and

~~(4)~~ review certification requirements.

(d) Members of the advisory council attending meetings of such council, or attending a subcommittee thereof authorized by

Query: Suggested in line 196 that "chairperson" be changed to "executive director". Since under K.S.A. 74-1108 "president of board or person designated by president" signs vouchers from board of nursing fee fund, should not president sign vouchers here?

to the advisory council

to become registered nurse anesthetists

, at least one of whom shall be currently involved in nurse anesthesia education

The board shall also appoint one nonvoting member who is a member of the board of nursing, is a licensed professional nurse and is in active practice.

and

such council, shall be paid amounts provided in subsection (e) c
K.S.A. 75-3223 and amendments thereto.

(e) This section shall expire on July 1, [1987] 1988

New Sec. 11. The board may deny, revoke, suspend, limit o authorization to practice of a
refuse to renew the [certificate of a certified] registered nurs-
anesthetist if the person so certified has failed to comply with
the requirements established under this act for initial [certifica-
tion] or renewal of [a certificate], has willfully or repeatedly authorization
violated any provision of this act or any rule and regulation
adopted under any provision of this act or has committed any o
the acts enumerated in K.S.A. 65-1120 and amendments thereto
as applicable. The procedure for denial, revocation, suspension an authorization to practice as a registered nurse anethestist
limitation or refusal to renew [a certificate] under this act shall be
the same as that provided under the Kansas nurse practice act
for the denial, revocation, suspension, limitation or refusal to
renew the license of a licensed professional nurse under that act.

~~Sec. 11.~~ *New Sec. 12. [On and after January 1, 1986,] any* 1987
person, corporation, association or other entity [who] engages in (b)
any of the following activities shall be guilty of a class A mis- , except as otherwise provided in sections 1 to 13, inclusive,
demeanor:

[(a)] Except as otherwise provided in sections 1 to ~~12~~ *13*, (1)
inclusive, engaging in the practice of *nurse* anesthesia without
being issued a certificate as a *certified* registered nurse anes-
thetist by the board;

[(b)] employing or offering to employ any person as a [*certified*] authorized to practice
registered nurse anesthetist with knowledge that such person is
not [certified] as such by the board; (2)

[(c)] fraudulently seeking, obtaining or furnishing [a certificate] documents indicating that a person is authorized by the board to practice as a
as a *certified* registered nurse anesthetist, or aiding and abetting when such person is not so authorized
such activities; or (3)

[(d)] using in connection with one's name the title [*certified*] R.N.A.
registered nurse anesthetist, the abbreviation ~~R.N.A.~~ [*C.R.N.A.*],
or any other designation tending to imply that such person [holds] is authorized by the board to practice as a
a certificate from the board as a *certified* registered nurse anes-
thetist when such person [does not actually hold a certificate from] is not authorized by the board to practice as a
the board as a *certified* registered nurse anesthetist.

~~Sec. 12.~~ *New Sec. 13.* (a) Nothing in this act shall prohibit

(a) On and after January 1, 1988, except as otherwise provided in sections 1 to 13, inclusive, any licensed professional nurse or licensed practical nurse who engages in the administration of general or regional anesthesia without being authorized to practice as a registered nurse anethestist by the board shall be guilty of a class A misdemeanor.

administration of a drug by a duly licensed professional nurse, licensed practical nurse or other duly authorized person for the alleviation of pain, including administration of local anesthetics but not including regional techniques.

(b) Nothing in this act shall apply to the practice of anesthesia by a person licensed to practice medicine and surgery, a licensed dentist or a registered podiatrist.

(c) Nothing in this act shall prohibit the practice of nurse anesthesia by students enrolled in approved courses of study in the administration of anesthesia

as a part of or incidental to such approved course of study

Sec. 14. K.S.A. 1984 Supp. 40-3401 is hereby amended to read as follows: 40-3401. As used in this act the following terms shall have the meanings respectively ascribed to them herein:

(a) "Applicant" means any health care provider;

(b) "Basic coverage" means a policy of professional liability insurance required to be maintained by each health care provider pursuant to the provisions of subsection (a) or (b) of K.S.A. 40-3402 and amendments thereto;

(c) "Commissioner" means the commissioner of insurance;

(d) "Fiscal year" means the year commencing on the effective date of this act and each year, commencing on the first day of that month, thereafter;

(e) "Fund" means the health care stabilization fund established pursuant to subsection (a) of K.S.A. 40-3403 and amendments thereto;

(f) "Health care provider" means a person licensed to practice any branch of the healing arts by the state board of healing arts, a person who holds a temporary permit to practice any branch of the healing arts issued by the state board of healing arts, a person engaged in a postgraduate training program approved by the state board of healing arts, a medical care facility licensed by the department of health and environment, a health maintenance organization issued a certificate of authority by the commissioner of insurance, an optometrist licensed by the board of examiners in optometry, a podiatrist registered by the state board of healing arts, a pharmacist registered by the state board of pharmacy, a licensed professional nurse who is

(d) Nothing in this act shall apply to the administration of a pudental block by a person who holds a valid certificate of qualification as an advanced registered nurse practitioner in the category of nurse-midwife.

(e) Nothing in this act shall apply to the administration by a licensed professional nurse of an anesthetic for a dental operation under the direct supervision of a licensed dentist or person licensed to practice medicine and surgery.

Note: Amend 40-3401 to reflect 1985 amendment.

~~licensed by the board of nursing and certified as a nurse anesthetist by the American association of nurse anesthetists~~ *holds a certificate as a certified registered nurse anesthetist, a licensed professional nurse who has been granted temporary certification in the practice of nurse anesthesia under section 3, a professional corporation organized pursuant to the professional corporation law of Kansas by persons who are authorized by such law to form such a corporation and who are health care providers as defined by this subsection, a Kansas not-for-profit corporation organized for the purpose of rendering professional services by persons who are health care providers as defined by this subsection (f), a dentist certified by the state board of healing arts to administer anesthetics under K.S.A. 65-2899 and amendments thereto, a physical therapist registered by the state board of healing arts, or a mental health center or mental health clinic licensed by the secretary of social and rehabilitation services, except that health care provider does not include any state institution for the mentally retarded;*

(g) "Inactive health care provider" means a person or other entity who purchased basic coverage or qualified as a self-insurer on or subsequent to the effective date of this act but who, at the time a claim is made for personal injury or death arising out of the rendering of or the failure to render professional services by such health care provider, does not have basic coverage or self-insurance in effect solely because such person is no longer engaged in rendering professional service as a health care provider;

(h) "Insurer" means any corporation, association, reciprocal exchange, inter-insurer and any other legal entity authorized to write bodily injury or property damage liability insurance in this state, including workmen's compensation and automobile liability insurance, pursuant to the provisions of the acts contained in article 9, 11, 12 or 16 of chapter 40 of Kansas Statutes Annotated;

(i) "Plan" means the operating and administrative rules and procedures developed by insurers and rating organizations or the commissioner to make professional liability insurance avail-

able to health care providers;

(j) "Professional liability insurance" means insurance providing coverage for legal liability arising out of the performance of professional services rendered or which should have been rendered by a health care provider;

(k) "Rating organization" means a corporation, an unincorporated association, a partnership or an individual licensed pursuant to K.S.A. 40-930 or 40-1114, or both sections, and amendments to those sections to make rates for professional liability insurance;

(l) "Self-insurer" means a health care provider who has qualified as a self-insurer pursuant to K.S.A. 40-3414 and amendments thereto;

(m) "Medical care facility" means the same when used in the health care provider insurance availability act as the meaning ascribed to that term in K.S.A. 65-425 and amendments thereto; except that as used in the health care provider insurance availability act such term, as it relates to insurance coverage under the health care provider insurance availability act, also includes any director, trustee, officer or administrator of a medical care facility;

(n) "Mental health center" means a mental health center licensed by the secretary of social and rehabilitation services under K.S.A. 75-3307b and amendments thereto, except that as used in the health care provider insurance availability act such term, as it relates to insurance coverage under the health care provider insurance availability act, also includes any director, trustee, officer or administrator of a mental health center;

(o) "Mental health clinic" means a mental health clinic licensed by the secretary of social and rehabilitation services under K.S.A. 75-3307b and amendments thereto, except that as used in the health care provider insurance availability act such term, as it relates to insurance coverage under the health care provider insurance availability act, also includes any director, trustee, officer or administrator of a mental health clinic;

(p) "State institution for the mentally retarded" means Norton state hospital, Winfield state hospital and training center,

Parsons state hospital and training center and the Kansas neurological institute.

Sec. 15. K.S.A. 1984 Supp. 40-3401 is hereby repealed. 1985

Sec. 43 *16.* This act shall take effect and be in force from and after its publication in the statute book..

Attn. #5
3-18-86

THE KANSAS PHARMACISTS ASSOCIATION
1308 WEST 10TH
PHONE (913) 232-0439
TOPEKA, KANSAS 66604

KENNETH W. SCHAFERMEYER, M.S., CAE
PHARMACIST
EXECUTIVE DIRECTOR

TO: Marvin Littlejohn, Chairman
House Public Health and Welfare Committee

FROM: Kenneth W. Schafermeyer KWS
Executive Director

SUBJECT: SB 501 - Regarding Board of Pharmacy authority to reschedule controlled substances

DATE: March 13, 1986

Since I am unable to attend the hearing on Senate Bill 501, I did want to provide some written comments. The Kansas Pharmacists Association supports this bill and would appreciate favorable action by the committee.

The purpose of this bill is to allow the Board of Pharmacy to put certain drugs into a new sub-classification under Schedule I of the Kansas Controlled Substances Act. In this manner, a drug may be prescribed or dispensed in Kansas provided that the drug may be prescribed and dispensed under Federal law. Since the penalties for unauthorized possession and distribution would remain the same as they are under Schedule I, the Legislature would not be improperly delegating legislative authority to the Board of Pharmacy. This bill would shorten the amount of time necessary to allow certain drug products to be used in this state and would help protect the public health and welfare.

This bill was reported favorably from the Senate Public Health and Welfare Committee without dissent and was passed by the Senate by a vote of 39-0. If the committee felt that it was appropriate to recommend passage of this bill and place it on the Consent Calendar, we would appreciate this action very much. Thank you for your consideration of this bill.

Attm. #5
3-18-86
Hs. PHW

KS:plh

April 25, 1985, when it was rescheduled in Kansas by an act of the Legislature, that the physicians could use the drug. This was a period of eleven months that Kansans, undergoing surgery, were deprived of the safety and rapid recovery from anesthesia offered by Sufentanil.

If Senate Bill 501 is passed, an important new or rescheduled drug could be made available, possibly within thirty to sixty days of the time it was released federally.

The Kansas State Board of Pharmacy considers this to be a very important bill and its passage would be in conformance with their charged responsibility of protecting the public health and welfare.

ELW:arb

#1
3-18-86

LAW OFFICES
HIATT & CARPENTER, CHARTERED
627 S. TOPEKA AVENUE
TOPEKA, KANSAS 66603-3294

EUGENE W. HIATT
EDWIN P. CARPENTER
RONALD R. HEIN
DAVID C. CARPENTER
STEPHEN P. WEIR

TELEPHONE
AREA CODE (913)
232-7263

HOUSE PUBLIC HEALTH AND WELFARE COMMITTEE
RE: SB501 ON MARCH 18, 1986

MR. CHAIRMAN, AND MEMBERS OF THE COMMITTEE:

I am Ron Hein, legislative counsel for Johnson and Johnson. I speak today in support of SB501. Two years ago, Janssen Pharmaceutica, a subsidiary of Johnson and Johnson, was permitted to market a new anesthetic (sufentanil) after extensive investigation and approval by the Food and Drug Administration and the Drug Enforcement Agency at the federal level. In most states, the federal rescheduling was followed by state action automatically, by regulatory action, or by virtue of the Legislature being still in session. In Kansas, however, there was no mechanism to permit rescheduling, albeit that the federal government permitted it. Sufentanil offered significant advantages to patients over previously available drugs, so there was considerable desire by physicians to utilize the drug for the benefit of the patients in Kansas. However, that could not be done. It was not until the Legislature reconvened in 1985 that sufentanil was subsequently rescheduled in Kansas. (See attachment)

This last year, it came to my attention that a form of treatment for chemotherapy treatment patients designed to mitigate or eliminate nausea during the cancer treatment itself might face a similar fate. The National Cancer Institute was distributing a drug under a research grant of authority to various hospitals in Kansas, and finally the drug was apparently going to be rescheduled by the DEA. However, it was conceivable that Kansans who had previously been able to utilize the drug would, ironically, be unable to use the drug after the feds permitted the drug to be marketed commercially, since the NCI could no longer make the drug available on a research basis. Until Kansas rescheduled, it would not be legal to distribute commercially here.

I made numerous legislators aware of this anomaly in our Uniform Controlled Substances Act this last fall. Throughout the summer, various groups concerned with this met to consider alternative solutions. Our proposed solution is SB501. This mechanism will permit drugs which have been rescheduled at the federal level and which have now been found to have medical purposes to be prescribed and dispensed for the benefit of patients in Kansas during the period of time that the Legislature is not in session.

Johnson and Johnson wholeheartedly supports this effort to ensure that Kansas citizens are not denied, even for a 9-month period, the opportunity to benefit from new found medical breakthroughs and advances. We feel that the criteria set out in the legislation insures against any abuse.

I would be happy to answer any questions that the committee might have.

Attm. #6
3-18-86
Hs. PHW

Ronald R. Hein
Legislative Counsel
Johnson and Johnson

ATTACHMENT I

SUFENTA® (sufentanil citrate) Injection
NDA approved May 4, 1984
Rescheduled by DEA May 25, 1984

STATE	DATE AVAILABLE AS CII
Alabama	June 25, 1984
Alaska	May 25, 1984
Arizona	May 25, 1984
Arkansas	July 1, 1984
California	May 25, 1984
Colorado	May 25, 1984
Connecticut	May 25, 1984 [May 8, 1985]
Delaware	May 25, 1984
Florida	[August 1 - October 1, 1984] September 14, 1984; June 20, 1985
Georgia	May 25, 1984
Hawaii	June 18, 1984
Idaho	September 10, 1984
Illinois	October 19, 1984
Indiana	May 25, 1984
Iowa	August 10, 1984
Kansas	April 25, 1985
Kentucky	May 25, 1984
Louisiana	May 25, 1984
Maine	May 25, 1984
Maryland	May 25, 1984
Massachusetts	May 25, 1984
Michigan	May 25, 1984
Minnesota	January 26, 1985
Mississippi	July 1, 1985
Missouri	July 2, 1984
Montana	October 13, 1984
Nebraska	May 25, 1984
Nevada	May 25, 1984
New Hampshire	May 25, 1984
New Jersey	May 25, 1984
New Mexico	August 6, 1984
New York	May 25, 1984
North Carolina	October 1, 1984
North Dakota	June 24, 1984
Ohio	May 25, 1984
Oklahoma	May 25, 1984
Oregon	May 25, 1984
Pennsylvania	May 25, 1984
Puerto Rico	November 3, 1984
Rhode Island	July 24, 1984
South Carolina	May 25, 1984
South Dakota	May 25, 1984
Tennessee	May 25, 1984
Texas	May 25, 1984
Utah	May 25, 1984
Vermont	May 25, 1984
Virginia	May 25, 1984
Washington	August 16, 1984
Washington, D.C.	July 13, 1984
West Virginia	June 13, 1985
Wisconsin	November 1, 1984
Wyoming	May 25, 1984

Kansas State Board of Pharmacy

503 KANSAS AVENUE, SUITE 328
P.O. BOX 1007
TOPEKA, KANSAS 66601-1007
PHONE (913) 296-4056

STATE OF KANSAS

JOHN CARLIN
GOVERNOR

EVERETT L. WILLOUGHBY
EXECUTIVE SECRETARY

LYNN E. EBEL
BOARD ATTORNEY

SENATE BILL 501

CONTROLLED SUBSTANCES ACT

Everett L. Willoughby, Executive Secretary
Kansas State Board of Pharmacy

Senate Bill 501, if passed would give the Kansas State Board of Pharmacy the authority to pass rules and regulations specifying certain Schedule I controlled substances as a Schedule I designated prescription substance.

The key to this statement is the word "designated." This designation would be done only for a controlled substance that has been rescheduled federally by the Drug Enforcement Administration from a Schedule I to a Schedule II or a newly approved drug which is scheduled federally but would not be scheduled in Kansas until done so by a vote of the Legislature.

After the Board of Pharmacy passes a regulation designating the substance a Schedule I designated prescription substance, it could be prescribed and dispensed in Kansas until the Legislature could approve the rescheduling to a Schedule II controlled substance.

In conformance with the Federal Controlled Substances Act of 1970, a controlled substance is placed in Schedule I when the Food and Drug Administration has determined, after clinical investigation of presently known facts, that the substance has no known medically accepted use. Occasionally, after new clinical evidence has been presented and investigated and the evidence of medical value outweighs possible side effects and potential for abuse, the substance is rescheduled from a Schedule I to a Schedule II.

Presently, controlled substances in Kansas can be scheduled or rescheduled only by the Legislature when it is in session. This has led to instances which have prevented the people of Kansas from being treated with a drug which has been rescheduled federally, but not in our state. This has deprived our citizens of the use of some of the latest scientific and medical advances.

A case in support was the federal rescheduling on May 25, 1984 of Sufentanil Citrate, a potent analgesic/anesthetic used during surgery, from a Schedule I to a Schedule II. It was not until

Attm. #7 Hs. PHW
3-18-86

April 25, 1985, when it was rescheduled in Kansas by an act of the Legislature, that the physicians could use the drug. This was a period of eleven months that Kansans, undergoing surgery, were deprived of the safety and rapid recovery from anesthesia offered by Sufentanil.

If Senate Bill 501 is passed, an important new or rescheduled drug could be made available, possibly within thirty to sixty days of the time it was released federally.

The Kansas State Board of Pharmacy considers this to be a very important bill and its passage would be in conformance with their charged responsibility of protecting the public health and welfare.

ELW:arb

SUMMARY OF TESTIMONY
BEFORE THE HOUSE COMMITTEE ON PUBLIC HEALTH AND WELFARE

SENATE BILL 542

PRESENTED BY THE KANSAS HIGHWAY PATROL

March 18, 1986

APPEARED IN SUPPORT

The Kansas Highway Patrol and the State Emergency Medical Services Council support Senate Bill 542. This will extend the legislation passed in 1985 to permit the pilot program created to be continued one year.

As stated in the report to the legislature covering the results of the first six months of the pilot program the incidence of treatable cardiac arrests in the target area of the study was only 65% of the number anticipated based on 1983 data. The numbers are insufficient to complete the study.

The following facts have been established and are relevant in the consideration of this bill.

1. We anticipate the continued participation of essentially all of the selected services if the pilot program is extended.

2. A spot check of qualified personnel was conducted in five cities in November and we concluded the skills were being adequately retained by participation in monthly drills.

3. Based on these five visits the attrition rate of qualified personnel appears to be acceptable with only a minimal loss due to attendants moving to other cities.

4. The consensus of ambulance directors was that patient care was improved in the participating services.

The extension of this bill should be considered on the basis of potential future enabling legislation to create authority for select services to provide this level of service. It is clear the requirement for such service by all of the communities in Kansas is not feasible. Consequently the required training should be offered in only those communities desiring such service and with the support of the medical community.

Attm #8
3-18-86
Hs. PHW

REPORT TO THE LEGISLATURE

(June 15, 1985 to December 15, 1985)

AS REQUIRED BY SENATE BILL 81

INTRODUCTION

The 1985 Kansas Legislature passed legislation authorizing a pilot study to determine the effectiveness of training select basic emergency medical technicians to defibrillate the hearts of patients who were victims of sudden unexpected cardiac arrest. These patients are clinically dead and in certain instances immediate defibrillation can be lifesaving if provided before biological death occurs. This procedure is already an authorized activity for Kansas Mobile Intensive Care Technicians (Paramedics) who presently serve about 65% of the population. The pilot study was created for the purpose of serving smaller communities not able to provide full paramedic services.

The pilot study authorized no more than 12 ambulance services to be granted certificates of authority to defibrillate utilizing qualified personnel (EMT-D). Up to 12 additional services were authorized to perform only electrocardiographic monitoring to serve as a control group (EMT-M). K.A.R. 109-3-1 through 109-3-4 were adopted subsequent to the legislation.

All of the basic life support services in Kansas were surveyed to determine their interest in participating in the study. Those interested were notified of the substantial committment of time and budget.

EMT-D REQUIREMENTS: (Defibrillator group)

1. To provide a physician medical advisor
2. To provide a course coordinator (M.D. - D.O. - R.N. - M.I.C.T.)
3. To cause course coordinator to attend 2 day workshop
4. To provide a 26 hour training program to authorized personnel
5. To provide monthly drills for authorized personnel
6. To provide a monitor-defibrillator with a two channel cassette recording capability
7. To provide service on at least one vehicle staffed with authorized personnel 24 hours a day every day of the year
8. To utilize the cardiac arrest protocol developed by the University of Kansas Medical Center (see attachment)
9. To submit reports to the Bureau of Emergency Medical Services and the University of Kansas Medical Center as required. (see attached)
10. To submit a cassette tape to KUMC of each cardiac arrest event containing the voice of the technician synchronized with the electrocardiographic pattern
11. To review and critique each event within 14 days.

Ambulance services in the following cities were selected to participate utilizing defibrillators (EMT-D)

Kingman	Buhler
Leoti	Great Bend
Abilene	Elkhart
Emporia	Pratt
Minneola	Derby
Colby	

EMT-M REQUIREMENTS: (Monitor Control group)

1. To provide a physician medical advisor
2. To provide a course coordinator (M.D. - D.O. - R.N. - M.I.C.T.)
3. To provide a 5 hour training program to EMT personnel
4. To provide a cardiac monitor
5. To provide service on at least one vehicle staffed with trained personnel (EMT-M) 24 hours a day every day of the year
6. To utilize the cardiac arrest protocol developed by the University of Kansas Medical Center (see attachment)
7. To submit reports to the Bureau of Emergency Medical Services and the University of Kansas Medical Center as required (see attachment)

Ambulance services in the following cities were selected to participate utilizing cardiac monitors (EMT-M)

Halstead	Johnson
Sublette	Bennington
Burlington	Marion
Sedan	Hoxie
Florence	Cottonwood Falls

One service following their appointment elected not to participate.

Following the appointment of the participating services the Bureau of Emergency Medical Services and KUMC developed forms to report each event and established protocols in order to provide a uniform study.

A workshop was presented to course coordinators in Salina to review protocols, reporting forms and pilot study procedures. The course curriculum as developed by KUMC consisting of 26 contact hours was reviewed.

Following the workshop the course was delivered to all participating personnel. Representatives from the Bureau of Emergency Medical Services visited each city to test all of the applicants for certification as authorized personnel. There were 100 applicants. Of these 94 ultimately completed the examination successfully. Twenty-two required retesting to become qualified.

Testing of the monitor group (EMT-M) was delegated to the course coordinators in each city. Each applicant was given a written and practical examination. There were 102 applicants. Twelve required retesting to become qualified.

Representatives from the Bureau of Emergency Medical Services visited five of the EMT-D services during November and randomly spot checked personnel for performance of the protocol. Additionally, the service directors were questioned about future participation, continuing education and continued committment of their personnel. Each director (1) stated his/her intention to continue (2) expressed support for monthly drills and (3) expressed continuing committment of their personnel.

RESULTS OF THE STUDY (6-16-85 to 12-15-85)

EMT-D SERVICES

There were 57 sudden unexpected cardiac arrests reported in the area served by EMT's providing defibrillation. Of these 25 received no treatment since they were either obviously dead or the time of arrest was known to be too long to attempt resuscitation. There were 32 patients who received some treatment. Of these 11 received one or more defibrillatory shocks. One additional patient was countershocked by a physician. One additional patient presented in a rhythm indicating countershock but equipment failure did not permit a countershock. Four patients are classified as "field saves" in that they were resuscitated and admitted to the hospital. Of these two died within 24 hours. The remaining 2 patients were both discharged from the hospital and are alive as of this date. These cardiac arrests occurred on July 17, 1985 and November 18, 1985. Both of these arrests occurred as witnessed in the ambulance vehicle. One was counter-shocked and the other was treated only by CPR and agressive ventilation.

EMT - MONITOR SERVICES

There were 24 sudden unexpected deaths reported in the area served by the monitor control group. Of these 14 received CPR and monitor only. None of the monitor control group survived.

CONCLUSIONS

The target areas for the pilot program provided substantially less treatable cardiac arrests than the base data for 1983 upon which the study is based. It is possible that 1983 was a year with substantially more cardiac arrests than normal or 1985 had substantially fewer cardiac arrests.

In the EMT-D area there were 100 cardiac arrests treated by CPR in 1983. The same area generated 32 treatable cardiac arrests during six months and projected to a one full year total of 64, a difference of 36 patients.

In the EMT-M area there were 34 cardiac arrests treated by CPR in 1983. The same area generated 14 treatable cardiac arrests during six months and projected to a one full year total of 28, a difference of 6.

The study areas provided only 68% of the cardiac arrests expected. The data is not conclusive at this time. The Bureau of Emergency Medical Services and the University of Kansas Medical Center recommended a one year extension of the pilot program to the State Emergency Medical Services Council on November 15, 1985. The council decided to request legislation extending the pilot program until June 30, 1987 with a report to the governor and the legislature on December 31, 1986.

Two patients survived to be discharged from the hospital. Key personnel in each community thought this pilot program contributed substantially to their survival.

RECOMMENDATION

The State Emergency Medical Services Council recommends a one year extension of the pilot program.