I am honored to have the opportunity to serve as visiting professor in my home state. Some time in the late 17 or very early 18 hundreds a McDonald straggled into the virgin northeast Mississippi territory and started clearing land. He was my grandfather's great grandfather. Thus, McDonalds have experienced the triumphs and tragedies of Mississippi for many years. It has been with great pride that I have observed the progress of the State at large and this fine medical school in particular in the past 20-30 years. I confess to twinges of guilt from time to time in not having my own shoulder to the wheel closer to home. Yet, my opportunities have been in our sister state of Louisiana where I have worked with similar circumstances for some 20 years.

Since for some reason not everyone in this audience has the same intellectual interest in the science of transplantation as Dr. Raju and I, I have elected to talk about transplantation from a broader view. Thus, my title "The Politics of Transplantation". The development of this young discipline is unique in American medicine and it is evolving in such a way as to ultimately have an impact on all physicians and possibly upon the fundamental way medicine is practiced in these United States.

Several characteristics of the transplantation movement have conspired to make it susceptable to substantive political forces.

First, it has developed so rapidly. In about 25 years transplantation has moved from science fiction to practical reality.

Second: The complexities of organ procurement have compelled public education and thus high visibility, as well as interinstitutional collaboration. National delivery systems had to be

developed under almost microscopic scrutiny.

Third: Expense along with public interest quickly involved the federal government. Laws have been passed, special interest groups have devleoped, and a national policy and system are essentially in place which so far as I can see, can act as prototypes for other forms of complex care. Considering the demand for highly technical expensive care combined with financial exigencies, this possibility seems a certainty.

Events have conspired to place me in the center of these developments for several years and at the epicenter for two. I will outline for you some of these developments and conclude by stressing some of the advantages and pitfalls. I invite you to look at transplantation and think about cancer centers, burns and trauma care, neonatology, open heart surgery, etc.

Some seven years ago Cyclosporin, an exceptional

SLIDE 1 (Cyclosporin)

immunosuppressive agent came into common clinical use, and at about that time monoclonal antibody technology produced an agent that was

SLIDE 2 (OK-T3)

exceptionally effective in treating rejection episodes. These agents substantially improved the results of renal transplantation and revolutionalized extrarenal transplantation.

SLIDE 3 (# kid Tx last 6 years)

Consequently the annual number of kidney transplants performed in this country has more than doubled in the past six years.

SLIDE 4 (# liver Tx last y years)

The number of liver transplants has increased six or seven times.

SLIDE 5 (# heart Tx last 6 years)

The number of heart transplants increased over thirty times.

This rapid increase in demand greatly exceeded the supply of organs. It literally overwhelmed the organ procurement system. This discrepancy led to many human tragedies, and the dilemma interested peoples representatives, the media, and consummers. As the system was publically examined, numerous deficiencies and inconsistencies were found. There developed some four to five years ago almost a crisis in confidence between the profession and the public. Frequently the transplant and medical community was portrayed as being self-serving and insensitive. A great clamor for legislation arose and ultimately the National Transplant Act of 1984, commonly called the Gore-Hatch Bill was inacted. This was a landmark act and placed the government directly into transplantation and indirectly into a national transplant policy.

SLIDE 6 (Provisions of Tx Act)

That bill established a task force to survey the field of transplantation and advised the secretary as to how to implement this law. It provided for a National Organ Procurement and Transplant Network which was to be operated as a private entity by contract. The law provided assistance to organ procurement agencies. It established a National Scientific Registry and outlawed the sale of human organs, therefore, mandating a means of monitoring organ traffic. This legislation had virtually unanimous support from every transplant-oriented, scientific, and consummer organization in the country.

SLIDE 7 (Picture-Report of Task Force)

The Transplantation Task Force was duly appointed, deliberated, and

reported. In that report,

SLIDE 8 (Recommendations of Task Force)

there were several very specific recommendations. There should be a single national system of organ sharing. That there should be a national scientific data base. The allocation of organs should be based on medical criteria, publicly stated, and fairly applied. There was to be no favoritism; that is, that patients receive no advantage in receiving organs by virtue of financial advantage, national origin, creed, or race.

SLIDE 9 (Recommendations of Task Force)

It specifically forbade the exportation and importation of organs except when arranged by the OPTN and it also recommended that all transplant centers be designated by specific criteria.

SLIDE 10 (OBRA Act)

In 1986, Congress further strengthened the national OPTN in the annual Budget Reconcilation Act by passing a requirement that all transplant centers must be a member of the OPTN and must abide by the rules of the OPTN. The Department of Health and Human Services was required to decline payment for all Medicare activities to those institutions which persisted in transplantation, but were not members of nor abiding by the rules of the OPTN. Subsequently, the Office of Transplantation, a subdivision of Health Resources and Services Administration, which is in turn a division of the Department of Health and Human Services, devised a request for contracts to implement the Transplant Act of 1984. This office took the report of the Task Force almost literally and has diligently assisted in the development of the national OPTN along the lines expected by Congress

and the Task Force. The first contract awarded to UNOS included the following tasks:

SLIDE 11 (1st contract tasks[1])

SLIDE 12 (1st contract tasks[2])

This was an enormous amount of work which, by contract, had to be completed within the first year of operation. Within the body of the contract there were several specific requirements as to how these tasks were to be completed.

SLIDE 13 (Specifics of contract)

First, the contract specifically designated the composition of the governing body or the Board of Directors. It specifically required UNOS to establish membership criteria for transplant centers, to obtain data on all organs harvested, to guarantee equitable access to and allocation of organs, to monitor the meeting of membership requirements and to maintain and enforce compliance with the policies. From the onset the congress and the congressional task force envisioned a private group of professionals and consumers which would devise and implement policy along broadly outlined principles.

SLIDE 14 (UNOS regions)

UNOS is organized in the following fashion. There are ten regions as shown here. In accord with the requirements of the Task Force it is a representative democracy, not unlike a private corporation, in which authority is basically delegated to a Board of Directors who are elected annually by the members. The members may vote the Board in or out, but may not change the policy of the Board. The Board envisioned that each region would function as a microcosm of the national organization. Some regions have been very active in the

development of this infrastructure and others are still in the fairly preliminary stages. Composition of the Board of Directors was delineated in the original contract. Fifty percent of its members must be comprised of individuals who are not directly involved in the transplantation of organs. As it developed, there are five officers.

SLIDE 15 (Officers)

The following sequence of slides are the officers and Board during the first two years of contracts. These names have changed as of the first of July, but these will serve to emphasize the structure.

There are five officers as shown in this slide and a series of ten councillors shown in the next slide,

SLIDE 16 (Councillors)

each councillor elected by the designated representative of each transplant center of each region. They are shown here. That is, each region elects one councillor. All of these people are directly involved in the transplantation of tissues and this is a very distinguished group of transplant professionals. The remainder of the Board is comprised as follows:

SLIDE 17 (ASHI and NATCO)

Two representatives are nominated from the tissue typing community, one is a professor of immunogenetics at Johns Hopkins and the other is a renown immunogeneticist from the Cleveland Clinic. There were two transplant coordinators nominated by the North American Transplant Coordinators Organization, both of which are past presidents of that organization.

SLIDE 18 (IOPA)

Similarly, two members were nominated by the Organization of Indepen-

dent Organ Procurement Agencies and they are shown in this slide. All of these nominees were elected ultimately by the members after being nominated by the parent organizations.

SLIDE 19 (Philantrophic Organizations)

A number of Board members are called public members. Those elected to the first Board as representatives of volunteer health organizations as shown in this slide. The American Red Cross, the American Liver Foundation, the American Kidney Fund, the National Association of Patients on Hemodialysis, and the National Kidney Foundation.

SLIDE 20 (General Public)

The Board was completed by five representatives of the general public shown here. They are, the parent of a transplant patient and a patient advocate, an ethicist and professor of philosophy, a professor of law, a noted medical sociologist, and a Jesuit priest. This Board was very careful to work within a broad committee framework.

SLIDE 21 (Committees)

This slide shows the eleven standing committees of UNOS to which relevant matters are referred, deliberated, and policies or recommendations brought forth to the Board. There are also several ad hoc committees. Each of these committees is structured so that there is at least one representative from each of the ten UNOS regions, and an additional five or ten representatives appointed by the President in order to ensure that the nationally recognized expertise is present on each committee. No policy has been developed by the Board of Directors that was not preliminarily deliberated upon by an appropriate committee. I am sorry time does not allow me to show the members of all these committees because, as a whole, this group

includes at least 200 experts and provides with very broad representation from the transplantation and consumer community. I calculate that these people donated over 40,000 hours of their time between 1986-88.

There has been some public criticism of UNOS regarding the setting of public policies, some felt there was inadequate opportunity for public comment on proposed policies before they were approved. This criticism was fair, but UNOS was compelled by contract to complete certain stages of its activities within the framework of a twelve-month period. This time restriction simply did not allow for this type of participation, initially. Subsequent to the first year's contract UNOS has established opportunities for public comment and debate of all future proposed policies. Nevertheless, I wish to emphasize that all UNOS policies were developed through the participation of many experts in the field and were not created in a vacuum. The system is evolving into a fairly slow moving, careful mechanism for establishing policy. The Board is becoming similar to a legislative body. In my view, this is proper.

SLIDE 22 (Membership Standards)

UNOS was required by the Organ Transplant Act to establish a network that included all transplant centers in the country and this required the development of membership standards and the application of those standards. Thus, every center had to apply and be evaluated. The membership standards were developed by several groups working on behalf of the Board of Directors and were based on the training and/or experience of the personnel involved in the program, the institutional resources or the environment of the transplant center, and the

willingness to submit data and have results reviewed. What is not in these standards is a numerical requirement for activity, nor a specific success rate. It appears that some thirty odd years after the first renal transplant it would be reasonable to have people with formal training in renal transplantation to perform this procedure. Similarly, some formal experience in liver and heart transplantation would seem appropriate, although there are fewer training programs and these techniques have a much shorter history. At times the same degree of formal training in extrarenal transplantation as is available in renal transplantation is impossible. So the standards for these types of programs are somewhat different and less restrictive. Since there has never been any evidence that the number of transplants performed by a center is directly related to its results, a minimal numbers requirement was rejected by the Board, but through the Scientific Data Registry on an annual basis, all transplant centers with results statistically significantly below the mean are subject by review by the OPTN to determine what problems they have and how they may be solved. If the problems are insoluble, it is possible for such a center to be decertified, but the emphasis on this effort is to try to develop quality standards and to assist these programs rather than to disqualify them.

SLIDE 23 (Goals of Membership Standards)

The goals in the membership criteria were to assure the patients that they would receive appropriate care, to ensure acceptable standards of quality in the practice of the art,

SLIDE 24

and to ensure an open and fair application process in which all

applicants would be judged by uniform criteria.

SLIDE 25

It will be noted that hospitals are not members of UNOS. Rather, transplant centers which are based in one or more hospitals may be members.

SLIDE 26

The criteria for institutional membership are based as previously stated on the facilities and services that are available in the institution providing the service, as well as the qualifications of the personnel, the adequacy of the tissue typing program, and the organ procurement agency.

SLIDE 27

The requirements for the transplant surgeon are that he e board certified. He must have formal training in transplantation and the degree of training is varied depending upon the maturity of the discipline. Certain experience in transplantation is acceptable for those people who have been involved in the field for some time and have established credentials.

SLIDE 28

Transplant physicians similarly require formal training in the same way as a transplant surgeon. We encountered some problems in the implementation of these standards. There was a legitimate question of due process and whether or not a given institution had ample opportunity to meet these standards between the time they were established and implemented. Therefore, we eventually established two categories of membership. All institutions that met standards at the end of October, 1987 were accepted into the national network. All

those who had a history of previously performing transplants, but did not meet those standards, were admitted as provisional members. Those institutions had one, or in the case of heart transplantation, two years to meet the standards. They are being monitored on a quarterly basis and will be decertified at the end of their provisional membership if the standards have not been met. I should emphasize, that it has never been the policy of UNOS to restrict the number of transplant centers in any way but to focus on insuring the public that those centers transplanting organs had the resources to do so.

This is a meaningful and honest effort to establish quality control, a goal which I submit is laudable and has never been successfully attained in American medicine.

The number of national policies established have been few but meaningful. Examples follow:

SLIDE 29 (Policies)

All recipients waiting on an organ transplant must be listed in the national computer. All perfectly matched kidneys must be shared. That means that when any organs become available from any donor in the country, the people retrieving organs from that donor must access the national computer to determine if there is a perfect match for kidneys anywhere in the country. If that is the case, the organs must be offered to that individual. Further, organs are to be transplanted according to blood groups so that organs from O donors are not transplanted into A donors, thus eliminating A's from the list. This leads to the failure to use a number of A blood group organs. An allocation system has been developed to establish the prioritization for distribution of organs. This applies primarily on the local level

so that any patient on the local level can be provided with information on how each organ recipient is selected, by what policies, and why he did or did not receive that organ. The allocation system is in a state of evolution and it is not as effective on a national level as some would wish, but will be much more effective as time progresses as national concensus develops.

SLIDE 30 (UNOS Standards)

Minimum standards for organ procurement have been established.

SLIDE 31 (UNOS Standards)

No organs are exported or imported into or out of the country without that being managed by the Organ Center at the UNOS national office. This is necessary to ensure that human organs are not sold for profit.

SLIDE 32 (UNOS Policy)

A policy has been developed concerning the transplantation of non-resident aliens in this country. Patient's selection must be based on scientific grounds without favoritism. There must be no discrimination based upon race or national origin. There must be no financial incentive; that is, foreign nationals are not to pay more than the standard rate that everyone else pays in that institution. There are to be no contracts between an individual center and a foreign government, since that is likely to require certain quotas, but patients are to be referred to those centers on an individual basis. Each center that transplants non-resident alies must have some form of community committee to oversee their policies, to ensure that organs harvested from a certain community are being distributed in accordance with the wishes of that community. All patients who are non-resident aliens must be listed on the UNOS computer. Finally, any

center transplanting foreign nationals must be willing to have its policies and programs audited on a periodic basis to ascertain that these policies are being followed.

SLIDE 33 (UNOS Policy)

A policy is now in effect relative to acquired immune deficiency syndrome that involves the donor and the recipient. This is basically a process of protecting the recipient from being innoculated and also to ascertain whether patients carrying the AIDS virus should be transplanted.

SLIDE 34 (AIDS)

Finally, the Scientific Registry is an extraordinarily important part of the program. Data must be submitted on every donor, the distribution of every organ, where it went, why it went, and its outcome. Extensive data are to be recorded on every transplant performed in this country, as well as its outcome. This is a terribly important process because much of the difficulty in establishing national policies comes from the lack of adequate scientific data from which to draw these policies. In the near future, this will no longer be the case. Further, I do not know of a comparable collection of medical data that has existed anywhere in the world in medical history.

Thus, a national system which will meet the needs and desires of the American public has come into being. This is a unique organization and is legislatively unique, in that it is an official agency established by law with regulatory authority established by law and sufficient power to enforce its policies. Yet, it is operated by the professional providers and consummers in the field affected.

Thus, it may be a potential prototype for other systems of the delivery of complex medical care in which national standards and policies may be generated in the best interest of our citizenry without the intrusiveness of a federal bureaucracy.

It has other unique aspects. It provides for the collection of a comprehensive set of scientific data upon which to base policy. It provides a mechanism for selective payment. Historically, if some agency agreed to insure liver transplantation, it would have paid for it wherever it was performed. In this senario it would only pay where established approved programs exist.

There remains one major obstacle in the general acceptance of this system. That oddly enough has come from the Health Care Finance Administration. They have attempted to be intrusive and obstructive repeatedly in the past year. It appears that they simply cannot abide a system in which a group of professionals and consummers can mandate their payment policies. It is a matter of giving up power which they are reluctant to do.

Thus far these obstructions have been successfully dealt with, but as you know in political matters wars never end, one only moves from one battle to another.

This system may be the last good opportunity for the medical profession to demonstrate that it can realistically regulate itself. I commend it to you for your meditation.

Thank you.