Informed Consent in Tissue Donation

Expectations and Realities
OFFICE OF INSPECTOR GENERAL

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, is to protect the integrity of the Department of Health and Human Services programs as well as the health and welfare of beneficiaries served by them. This statutory mission is carried out through a nationwide program of audits, investigations, inspections, sanctions, and fraud alerts. The Inspector General informs the Secretary of program and management problems and recommends legislative, regulatory, and operational approaches to correct them.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) is one of several components of the Office of Inspector General. It conducts short-term management and program evaluations (called inspections) that focus on issues of concern to the Department, the Congress, and the public. The inspection reports provide findings and recommendations on the efficiency, vulnerability, and effectiveness of departmental programs.

OEI’s Boston Office prepared this report under the direction of Mark R. Yessian, Ph.D., Regional Inspector General. Principal OEI staff included:

BOSTON
Russell W. Hereford, Ph.D., Project Leader
Maria E. Maddaloni, M.A., Program Analyst
Elizabeth A. Robboy, M.M.H.S, Program Analyst
China D. Eng, M.P.H., Program Analyst

HEADQUARTERS
Alan Levine, Program Specialist

To obtain copies of this report, please call the Boston Regional Office at 617-565-1050. Reports are also available on the World Wide Web at our home page address:

http://www.hhs.gov/oig/oei
EXECUTIVE SUMMARY

PURPOSE

To assess expectations for and limitations of informed consent for tissue donation.

BACKGROUND

Human tissue is an important source of medical treatment. The specific number of tissue donors in this country is unknown. It is clear, though, that the numbers are growing. In 1999, more than 20,000 donors provided cadaveric tissue, up from perhaps 6,000 donors in 1994. Tissue banks distributed over 750,000 allografts for transplantation in 1999.

A first step in tissue donation is obtaining consent from a deceased individual’s family. Even if the individual had indicated willingness to donate organs (e.g., on the driver’s license), it is practice in this country to obtain consent from the next-of-kin.

Tissue banking is subject to more limited regulation than is the nation’s organ procurement system, even though both organ procurement organizations (OPOs) and tissue banks are involved in approaching families to request consent for donation. For example, the National Organ Transplant Act requires OPOs to meet certain organizational and staffing requirements; the Act also requires OPOs to assist hospitals in establishing and implementing protocols for making routine inquiries about organ donation by potential donors. No similar requirements exist for tissue banks.

This report responds to a request from the Secretary of Health and Human Services, asking the Office of Inspector General to examine issues related to informed consent for tissue donation. We base our report on interviews with 30 organizations involved in tissue recovery and processing; responses from more than 50 donor families to questions posted on an Internet web site; interviews with officials of associations representing sectors of the tissue banking industry; and a review of laws, regulations, and association standards for tissue banking.

In this report, we use the term “tissue banks” to refer to entities involved in procuring, processing, storing, and distributing tissue. We use the term “tissue” to refer to skin, heart valves, and musculoskeletal tissue such as bone, cartilage, ligaments, and tendons.

FINDINGS

The expectations and altruistic motives of donor families are the foundation of tissue banking. Donor families and tissue bank staff told us that in agreeing to donation, families make some basic assumptions:

- **Enhancing the lives of others.** Tissue will be used to meet important medical needs.
- **Respect for the donor and the family.** The donor’s body will be respected during tissue recovery, the gift will be recognized as coming from donated human tissue, and
the donor family’s emotional needs will be respected.

- **Trust in the tissue banking community.** Organizations involved in procuring and using the donation will act as stewards of the gift.

**However, the reality of tissue banking raises some underlying tension with families’ assumptions.**

- **Commercialization of tissue banking.** Large scale financial operations may overshadow the underlying altruistic nature of tissue donation.
- **Tissue viewed as a commodity.** After processing, tissue and products containing tissue often are marketed and sold as a medical supply, rather than as a donation.
- **Cosmetic uses of tissue.** Some tissue, particularly skin, may be processed into products that are used for cosmetic purposes that may not be medically indicated.

**Fundamental factors limit the amount of information that is given to families.**

- Families are asked to give their consent at a point in time when they are extremely vulnerable.
- Families may not wish to receive detailed information about tissue banking.
- Obtaining consent and documenting a donor’s medical suitability require time-consuming and invasive questioning about a recently deceased loved one.

**Current practices in requesting consent raise concerns about how and what information is provided to families.**

- Tissue banks often request consent over the telephone, rather than in person.
- Many tissue banks rely on staff from other organizations to obtain consent. There may be little training and accountability of external tissue requestors.
- Tissue banks provide donor families with little written material at the time of donation.

**Until recently, standards governing how families are approached and what they are told about tissue donation have been nonexistent. However, some advice and guidance have emerged.**

- Federal laws and regulations do not address the manner in which tissue banks obtain consent.
- States’ Uniform Anatomical Gift Acts do not address what information tissue banks should provide in obtaining consent.
- The National Donor Family Council has proposed key elements of an informed consent policy for tissue donation.
- Organizations representing the tissue banking industry have issued a statement that addresses elements of informed consent. These organizations include the American Association of Tissue Banks (AATB), the Association of Organ Procurement Organizations, and the Eye Bank Association of America. The AATB is incorporating this statement into its accreditation standards for tissue banks.
CONCLUSION

Tissue banking and processing practices have gradually diverged from donor families’ expectations in recent years. The tissue banking industry has expanded and become more complex and costly. New ways of using tissue for medical treatment have been developed. Processed tissue often is marketed and sold like any other medical product. For some people, these practices call into question the non-profit basis of the tissue banking community. Despite these changes, the industry’s foundation remains that of human tissue altruistically donated by individuals and their families at an extraordinarily sensitive time. The special nature of this product, and the circumstances under which it is made available, call for steps to be taken above and beyond those that would apply to most other business or philanthropic enterprises.

RECOMMENDATIONS

Importance of increasing donation. The Office of Inspector General has examined issues related to organ, tissue, and bone marrow donation, allocation, and transplantation for more than a decade. The principles underlying our work have focused consistently on enhancing equity for patients, improving access to transplantation, and encouraging donation.

Encouraging donation was of paramount importance to us as we developed our recommendations. It is our hope that these recommendations will encourage donation. Our recommendations encourage joint action among groups representing the tissue banking industry, donor families, and the government.

RECOMMENDATIONS TO THE DEPARTMENT

The Health Resources and Services Administration should work with groups representing donor families and the tissue banking industry to develop guidelines for conveying information to families about tissue donation.

HRSA’s Division of Transplantation supports the development of programs to increase donation. In that role, HRSA has gained considerable expertise about effective practices in requesting consent. The agency could act as a resource to tissue banks and families.

HRSA’s efforts could focus on such areas as:

- Identifying principles and guidelines that should underpin consent requests, such as those outlined recently by the National Donor Family Council and by industry groups;
- Making suggestions as to the type, format, and content of written information about donation that tissue banks could share with families.
- Making recommendations on information that would be useful for training tissue bank staff and external requestors; and
- Making recommendations on assessment tools that would be useful in evaluating the effectiveness of requestors.
The Health Care Financing Administration should address informed consent for tissue donation through the Medicare conditions of participation.

HCFA requires hospitals to assure that the family of each potential donor is aware of its options to donate tissues, organs, and eyes. Elsewhere in this report, we call upon donor family groups, the tissue banking industry, and HRSA to develop guidelines for conveying information to families about tissue donation. HCFA could use these guidelines as it provides information about the conditions of participation for organ, tissue, and eye donation. The agency could publicize these principles through the HCFA Internet site.

In the longer term, the agency may wish to examine the Medicare conditions of coverage governing organ procurement organizations. In that examination, the agency could consider additional requirements to strengthen working relationships between OPOs and tissue banks. Such requirements might include:

- Holding OPOs responsible for informed consent for tissue donor families when they request consent on behalf of tissue banks; and
- Requiring OPOs to include tissue banks in the training that they conduct for designated requestors.

RECOMMENDATIONS TO THE INDUSTRY

At the time of obtaining consent, tissue banks should provide families with written materials that provide fuller disclosure about the uses of tissue and the nature of the gift.

Tissue banks should give written material to families at the time the banks ask for consent to donation, or in the days immediately following the request. The material should be appropriately thorough. It would serve as one way to supplement the information that requestors provide to the family during their conversation about donation, while providing requestors with flexibility to adapt that conversation to the unique needs and responses of each donor family. At a minimum, this material should include:

- A copy of the signed consent form;
- Written material on how to follow up with the tissue bank if concerns arise;
- A full description of the uses to which donated tissue may be put; and
- A list and description of other companies and entities with which the bank has relationships for processing and distributing tissue.

Tissue processors and distributors should ensure that information accompanying their product clearly indicates it is derived from donated human tissue.

Such a step would require only minor changes in packaging and marketing materials. But it would go a long way towards showing ongoing respect for the donor, the family, and the gift of donation. Tissue banks should:

- Indicate clearly on all tissue packaging that the contents derive from donated human tissue; and
Indicate clearly on all marketing and informational material that these products derive from donated human tissue.

**Tissue banks should foster greater accountability for the performance of those who request consent for donation.**

Responsibility for ensuring that requestors are providing accurate, sensitive, and appropriate information rests with tissue banks and the processors with which they work. These organizations should:

- Ensure that requestors — both from their own organizations and from hospitals — are fully and appropriately trained;
- Provide continuing education for requestors; and
- Conduct an ongoing assessment of requestor performance as a means of ensuring that they are providing full and accurate information to families approached for donation.

**The tissue banking industry should work with groups representing donor families to explore a process for periodic public disclosure about tissue banks’ financing.**

The purpose of the examination we recommend here is to respond to family and general public concerns about knowing the sources of funding for tissue banks and other entities with which the bank has financial arrangements. The examination would consider whether financial information would be useful as part of a package of information provided to donor families. The examination would consider:

- What types and how much financial information would be useful for families and individuals in making decisions about donation;
- The advantages and disadvantages of disclosure, including the potential impact of financial disclosure on donation;
- Whether the information should be provided in all cases, or only if requested by a family; and
- The content, style, and format of disclosure.

**COMMENTS ON THE REPORT**

We received comments on a draft of this report from the Department of Health and Human Services. They are supportive of our findings and recommendations. The full text is included in Appendix C.

Our work in tissue banking continues. We will maintain an active watch on how the tissue banking community responds to the concerns we have raised.
INTRODUCTION

PURPOSE

To assess expectations for and limitations of informed consent for tissue donation.

BACKGROUND

Transplantation of Human Tissue

Human tissue is an important resource used in medical treatment. Physicians and dentists use cadaveric human tissue for a variety of medical purposes. Donated skin can meet critical needs in healing burn victims and in reconstructive surgery. Donated bone can be implanted to replace cancerous bone, for knee and hip replacements, and for spinal surgery; it can be processed into powder for use in dental surgery. Donated heart valves can replace defective valves in young children, saving their lives.

The exact number of tissue donors in this country is unknown. It is clear, though, that the numbers are increasing. In 1999, more than 20,000 donors provided cadaveric tissue, up from perhaps 6,000 donors in 1994. Tissue banks distributed over 750,000 allografts for transplantation in 1999.

Consent for Donation

A first step in tissue donation is obtaining the consent of a deceased individual’s family. Even if the individual had indicated willingness to donate organs and tissues (e.g., on the driver’s license), it is practice in this country to obtain consent from the next-of-kin. A family may refuse to give consent, or it may give consent for donation of all or only some tissues.

Tissue banking is subject to more limited regulation than the nation’s organ procurement system, even though both organ procurement organizations (OPOs) and tissue banks are involved in approaching families for consent. For example, the National Organ Transplant Act requires OPOs to meet certain organizational and staffing requirements; the Act also requires OPOs to assist hospitals in establishing and implementing protocols for making routine inquiries about organ donation by potential donors. No similar requirements exist for tissue banks.¹

Concerns about Tissue Banking

Several press reports in the Spring of 2000, appearing in the Orange County Register and the Chicago Tribune, raised a number of concerns about tissue banking. A particular focus of these articles related to financial aspects of the tissue banking industry. Several members of Congress asked the Secretary of Health and Human Services to examine the
tissue banking industry, including the extent to which families were informed about financial arrangements or uses to which tissue might be put.

This Inquiry

The Secretary asked the Office of Inspector General to review two aspects of tissue banking: consent for donation and the overall regulatory structure governing the industry. This report responds to the first of those requests, focusing on informed consent. Our companion report, Tissue Banking Oversight (OEI-01-00-00441), provides a profile of the oversight system for tissue banking and addresses limitations in that system.

We use the term “tissue” to refer to skin, heart valves, and musculoskeletal tissue such as bone, cartilage, ligaments, and tendons. Our report does not address eyes and reproductive tissue.

METHODOLOGY

We conducted interviews with senior staff from 30 organizations involved in obtaining, processing, and distributing human tissue; 25 of these organizations were involved in obtaining consent and recovering human tissue. Our interviews focused on their policies, practices, and experiences relative to consent.

With assistance from the National Kidney Foundation, we posted a series of questions on the web site of the National Donor Family Council. These questions sought to provide us with a donor family perspective of experiences with the donation process. We received 50 responses from donor families through this web site. We recognize that the findings from this posting do not constitute a random sample from which projections can be made. Nevertheless, we believe that the responses provide important information and a valuable perspective on the process of obtaining consent.

We interviewed officials and staff, and reviewed documents, from associations involved with tissue banking, including the American Association of Tissue Banks (AATB), National Donor Family Council, Eye Bank Association of America, Association of Organ Procurement Organizations, and North American Transplant Coordinators Organization.

We reviewed State and Federal laws and regulations related to tissue banking, and standards from the AATB.

We conducted this inspection in accordance with the Quality Standards for Inspections issued by the President’s Council on Integrity and Efficiency.
FINDINGS

The expectations and altruistic motives of donor families are the foundation of tissue donation. Donor families and tissue bank staff told us that in agreeing to donation, families carry some basic assumptions:

Expectation that the donation will enhance the lives of others.

Families expect that their loved one’s tissue will be used in meeting important medical needs. The primary expectation is that the tissue will be used for transplantation, as a way of improving the lives of people with medical needs. Many families also provide consent to use tissue for medical research and medical education.

Families may view donation as a way of creating something positive from the death of their loved one. The mother of one tissue donor captured this view when she told us, “If my son helped just one person live a better life, then his donation was worth it.” This expectation is reflected in the comments we received from a number of donor families. These families hoped for some type of follow-up with people who had benefitted from their loved one’s gift of tissues, as a way of confirming the usefulness of and appreciation for the gift.

Respect for the donor and the family.

Respect has two broad components. First, families anticipate that the donor will be respected. This respect should last through the entire donation process. It includes, for example, respect for the donor’s body during tissue recovery. Tissue recovery requires invasive surgery. For families, respect entails that no more harm is done to the body than absolutely necessary.

During processing, distribution, and transplantation, respect entails that the gift be recognized as coming from a donation of human tissue. Musculoskeletal tissue often is processed into many forms. These forms include bone screws, dowels, and bone chips, which have many different medical uses. These final products often bear little resemblance to human tissue; in fact, they look more like tools, hardware, supplies, and devices than what most people would call human tissue. The mother of a donor exemplified the concern that respect be maintained for the donor when she told us, “That ‘screw’ is not a screw to me — it came from somebody’s loved one or child.”

Second, donor families expect that their own needs will be respected by the tissue banks. Respect for the family includes discussing the option of donation in a sensitive manner, answering all questions, and ensuring that the timing of and plans for funeral arrangements are not disrupted by tissue recovery.
The AATB’s Statement of Principles reflects the importance that the association and its members accord to the importance of respect. Member banks pledge “to honor and treat with respect the gifts that have been donated and to reflect this in all activities related to cell and tissue procurement.”

**Trust in the organizations involved in procuring and using the donation.**

At the time of their loss, families are asked to place enormous trust in tissue banks. Prior to requesting donation, it is unlikely that any relationship existed between the donor family and the tissue bank. Quite possibly, the family may never have heard of tissue donation. Tissue banks request a donation of their loved one’s body at the time the family is grieving. As a member of one donor family noted, “It is an extremely emotional display of trust, to allow someone to take parts of a loved one.”

Tissue banks we spoke with echoed the sentiments of donor families. One tissue bank director viewed tissue procurement as a public service and said that the bank has the responsibility for ensuring that tissue is “used for the right purposes.” Another tissue bank director shared her view of this responsibility: “We are stewards of the gift the family is giving, and it is up to us to handle it in an appropriate manner.”

**However, the reality of tissue banking raises some underlying tension with families’ assumptions.**

**Commercialization of tissue banking**

Families view tissue donation as an altruistic act. This perspective is buttressed by the National Organ Transplant Act, which states that it is “unlawful to acquire, receive or otherwise transfer any human organ [including several defined types of tissue] for valuable consideration for use in human transplantation.” Although the act permits recovery of reasonable costs associated with activities such as retrieval and processing, concerns have been raised about whether individuals and firms may be receiving unreasonable financial enrichment from procuring, processing, or distributing the altruistic donation.

No one denies that there are costs associated with processing tissue, conducting research, developing new products and uses, and advancing science. However, the large-scale financial aspects of tissue banking create tensions with an altruistic act.

These tensions have particular relevance to the operation of for-profit firms in what is, at least nominally, an altruistic enterprise based on donation. Publicly-traded companies have raised capital and brought entrepreneurial energy to tissue processing, leading to the development of new processes and products. Yet, it is precisely at this point that tension arises. The concern may be best characterized as unease about a focus on the “bottom line,” as portrayed in the following question: If a company’s primary interest is financial benefit to its stockholders, is it making choices to put tissue to more lucrative uses over
medical needs? 

A second facet of tension with commercialization relates to the level of salaries and costs incurred by both non-profit and for-profit firms. Although reasonable costs are permitted, there is no definition of, and undoubtedly no consensus about, what constitutes “unreasonable costs.” In fact, no guidelines are in place regarding disclosure of costs, and no comparative data are available publicly on the range of costs that would permit such a determination.

Finally, the industry is intensely competitive, with firms establishing proprietary patents on a number of products and processes. Some observers view this as primarily an effort to gain competitive advantage and market share in the distribution of tissues.

In a vacuum, these issues do not raise concerns. Yet in an industry that is premised on donation of parts of a loved one’s body, it should not be surprising that donor families could feel misled as they question why “everyone is making money off of this altruistic gift except the donor and the donor’s family.”

The importance of concerns about commercialization for informed consent relates to whether families may wish to know about commercial relationships that exist between the agency to which it makes an altruistic donation, and an entity — be it non-profit or for-profit — that realizes revenue from the gift. If they are not made aware of these relationships, it may be difficult to say that their consent truly is informed.

**Tissue viewed as a commodity**

Maintaining respect for the donor and the donor’s family is an underpinning of the tissue system. As we discuss above, tissue is processed extensively for many different uses. The marketing of human tissue as a commodity bears particular relevance to donor families’ assumption that their loved one’s tissue will be treated with respect and honor, and that it will be respected by the users and the recipients of tissue.

The packages in which human tissue is supplied — bottles, vials, containers shrink-wrapped in plastic — resemble many other medical supplies. The labeling does state that the contents are human tissue, but this is related to concerns about safety and disease transmission rather than respect for the donor. The packaging does not indicate that the enclosed materials derive from *donated* human tissue.

We reviewed marketing materials from both for-profit and non-profit companies. These product brochures look like typical medical supply catalogues, contributing to a perception that tissue is no different from other supplies. As with the packaging, the marketing materials rarely indicate that the materials derive from *donated* human tissue.

**Cosmetic uses of tissue**

A number of products used in reconstructive surgery utilize donated tissue, particularly
skin. These products are used in procedures that most people would, no doubt, consider medically appropriate and necessary. Examples of such procedures include alleviating serious scarring or constructing a bladder sling for treatment of urinary incontinence.

On the other hand, there clearly are some uses of these products that many people would consider to be non-essential cosmetic uses. It is not clear how much tissue goes for such cosmetic uses; because the actual use of these products is determined by physicians and patients, tissue banks that manufacture them do not have that information. However, a family may be reluctant to give its consent for donation if it is aware that the gift would be used for purposes that are not medically indicated.

The American Medical Association’s policy provides a useful framework for considering the differences between cosmetic and reconstructive surgery. That policy states that “cosmetic surgery is performed to reshape normal structures of the body in order to improve the patient's appearance and self-esteem. Reconstructive surgery is performed on abnormal structures of the body, caused by congenital defects, developmental abnormalities, trauma, infection, tumors or disease. It is generally performed to improve function, but may also be done to approximate a normal appearance.”

Fundamental factors limit the amount of information that is given to families.

Families are asked to give their consent at a point in time when they are extremely vulnerable.

The recent, often sudden and unexpected, death of a loved one means that families are likely to be distraught when they are asked for consent to donate. In the face of sudden tragedy, they may simply be unable to understand detailed information about tissue donation.

Tissue donation is a complex topic. Tissue banks must obtain consent for donation within hours following the death of a loved one. Because the family may be in shock, discussing multiple aspects of tissue donation and tissue banking — recovery, processing, distribution, commercial relationships — may go well beyond the capacity of families to comprehend what they are hearing. The father of a tissue donor echoed this sentiment when he commented to us, “I doubt donor families can process much information; they hear very little at a time when they are immersed in profound shock and grief.”

At the same time, families may not wish to receive detailed information about tissue banking.

Often, families know they want to consent to donation, but do not want to hear specific details about the process. As one tissue donor mother told us, “I really didn’t need any more information than what was provided; frankly, I wouldn’t have been able to deal with much more at that point.” Her thoughts were echoed by a tissue bank director who told
us that it is crucial to be able to give families as much or as little information as they want, depending on where they are in the grief process.

Tissue bank staff with whom we spoke cited the balance they must strike when speaking with families. Much information needs to be communicated to the family at the time of consent; at a minimum, authorization for removal of specific tissues is required. Families also must agree to whether the tissue may be used only for transplantation, or for other uses such as research and education.

Tissue bank staff told us that families generally have two primary concerns: whether the family will incur any costs for donating tissue and whether the body will be suitable for an open-casket viewing. They noted that it is rare for families to ask about other concerns. On the other hand, some families may wish to have more information to help them reach a decision, or they may wish to receive more information that they could reflect upon at a later date. The challenge for those seeking consent is to gauge how much detail a particular family wishes to receive.

Obtaining consent and documenting a donor’s medical suitability require time-consuming and invasive questioning about a recently deceased loved one.

Because tissue can transmit disease, FDA requires tissue banks to screen donors for evidence of behaviors that place them at high risk for HIV and hepatitis. This screening requires completion of a lengthy medical and social history questionnaire as part of determining donor suitability. Tissue bank personnel who administer the medical and social history questionnaire to families note that the process may take as long as an hour or more to complete. The tissue bank staff must administer this questionnaire shortly after the family consents to donation.

Donor families must answer questions about the deceased’s medical history and personal behaviors, including uncomfortable questions about drug and alcohol use, and about sexual behavior. Under any circumstances, questions such as these are intrusive. After the death of a loved one, this effect undoubtedly is amplified.

Current practices in requesting consent raise concerns about how and what information is provided to families.

Many tissue banks rely on staff from other organizations to obtain consent.

We interviewed staff from 25 banks that recover tissue; 14 of these banks rely primarily on their own staff to request consent from families, and 11 banks rely on others to make the requests. The American Association of Tissue Banks conducted an informal survey of its members. AATB found that 42 percent of accredited tissue banks use their own staff to request consent for tissue donation, while the other 58 percent of banks use individuals not employed by the bank for requesting.

About half of the external requestors are staff from organ procurement organizations.
OPOs (Organ Procurement Organizations) play an important role in tissue donation, even if they do not operate a tissue bank. Recent changes to the Medicare conditions of participation for hospitals gave OPOs an important gatekeeping function by requiring a hospital to notify its OPO of all deaths. Thus, even for persons who do not meet the stringent criteria for organ donation, OPOs play a role in referring the call to the appropriate tissue bank and, in some cases, seek consent from the family for tissue donation.

External requestors include staff from telephone triage agencies with which the tissue bank contracts for the specific purposes of requesting consent. Tissue banks also rely on hospital staff, primarily nurses, chaplains, and social workers, to obtain consent from families. These staff may wish to keep hospital staff involved in and committed to donation. These staff may well have been in close contact with the family, and families may be more trusting and receptive to donation when it is discussed by these caregivers.

Other tissue banks prefer to handle the consent process themselves. The director of one OPO that also operates a tissue bank told us she “simply feels more comfortable knowing that trained coordinators are doing the requesting.” This approach also benefits hospitals; it is a way of relieving a hospital of liability for its own staff should problems arise.

Tissue banks often request consent over the telephone, rather than in person.

Consent requests for tissues contrast sharply with requests for organ donation. In requesting organ donation, OPO staff seek consent from the family while they are still at the hospital. OPO staff often have spent long hours with the family prior to disconnecting the ventilator, and they likely have established a rapport with that family.

In our interviews, 16 of 25 tissue banks that recover tissue said that they primarily request consent over the telephone, rather than in person. In most cases, tissue banks make these requests after the family has left the hospital. Tissue bank staff told us that it is more productive to give the family time to return to the familiar surroundings of home, rather than the coldness of a hospital. At a practical level, it also would be quite difficult for the tissue bank staff to travel to every hospital when someone has died in order to request donation.

There may be little training and accountability of external requestors.

Tissue banks train and monitor their own staff who request consent. Training programs typically include classroom lectures, written materials, presentations, observing other requestors, role playing, and mentoring by seasoned requestors. Many banks send requestors to training courses offered by organizations with longstanding expertise in the field. Most tissue banks we spoke with also provide their staff with continuing education.

Training programs for tissue requestors not employed by the bank tend to be briefer. Training programs for external requestors at tissue banks we spoke with ran about 4 hours on average. Training generally comprises presentations by tissue bank staff and covers topics including how to interact with families, the use of tissues, and how tissues are recovered. A few tissue banks offer longer programs that include role-playing exercises.
After the initial training, only a small number of tissue banks we spoke with offer continuing education or follow-up training to external tissue requestors.

Training for tissue donation also may take place through an OPO’s designated requestor training program. Yet, as we have shown elsewhere, few OPOs conduct this training. Tissue bank staff we interviewed also indicated that OPOs give only limited attention to training about requesting tissue donation, because organ donation is often seen as a higher priority than tissue donation. This difference in emphasis is likely to be more pronounced in areas where there is competition between the tissue bank and the OPO.

Providing in-depth training of external requestors faces some major constraints. Tissue bank directors we interviewed noted that it is difficult for hospital staff to take time from their duties for intensive training as a tissue requestor. Additionally, tissue banks that rely on hospital staff to request consent may be unable to select the hospital staff to be trained. Thus, staff who may not want to be tissue requestors may be trained for the process and, subsequently, may do a poor job of it.

Even among those tissue banks that train external requestors, we found that few actively assess their performance. The primary vehicle we found for assuring accountability was that some tissue banks use their own staff to contact the donor family at home to complete the medical-social history questionnaire. These banks told us that having their own staff speak with the donor family provides a checkpoint for the consent process, because staff can answer questions, provide more information, and reaffirm the consent.

**Tissue banks provide donor families with little written material at the time of donation.**

Few tissue banks routinely give families a copy of the signed consent form. The consent form, however, is the legal authorization governing the removal of tissue and specifying purposes for which the tissue may be used. One tissue bank told us that it asks family members if they want to receive more information. Other tissue banks indicated that they would give the family the form if someone requested it. However, requiring a family to make such a request places it in a deferential position, when the bank could proactively make the consent form available.

Following donation, it is general practice for tissue banks to send families a letter thanking them for the gift and expressing condolences. We reviewed copies of these letters from 11 tissue banks; about half gave a general description of which tissues were recovered, and the other half conveyed information in broad, generic terms about how tissue can be used to improve people’s lives. Many of the tissue banks we spoke with provide additional materials about grieving and about support groups.

Aside from this letter, tissue banks provide little additional written information to families about tissue use, processing, or other entities with which they have financial arrangements. Tissue bank staff we spoke with told us they are hesitant to provide more information to families, either at the time of consent or afterwards, because the family is
grieving and may not want to think about the donation.

Many donor families told us that consenting to donation was a positive outcome that came from their loved one’s death. Because families may not comprehend everything that is told to them at the time of donation, more information may be beneficial at a later date. One donor mother captured this sentiment when she told us, “I know there are many families who would like to have some reading material to refer to when or if they are ready, since there is so much information that is not heard within this horrific moment.”

Until recently, standards governing how families are approached and what they are told about tissue donation have been nonexistent. However, some advice and guidance have emerged.

Federal laws and regulations do not address the manner in which tissue banks obtain consent.

The Health Care Financing Administration has no statutory or regulatory authority over tissue banks. However, the 1998 Medicare conditions of participation for hospitals relating to organ, tissue, and eye donation require hospitals and tissue banks to work together to establish donor suitability criteria. The regulations also require hospitals to ensure that all families of potential donors are informed of their options to donate organs, tissues, and eyes, and that programs for training hospital-based requestors are designed in conjunction with the local tissue banking community. However, the regulation does not provide specific guidelines on the content, circumstances, or manner of approaching donor families.

The Health Resources and Services Administration (HRSA) provides resources and support to the transplantation community. HRSA recently published a resource guide that provides information and approaches on training hospital staff and procurement agencies in working and communicating with grieving families as part of the donation process.

The Food and Drug Administration’s (FDA) authority over tissue banks derives from Public Health Service Act provisions authorizing regulations to prevent the spread of communicable diseases. The agency requires that donor screening and testing for HIV-1 and -2 and for Hepatitis B and C. FDA regulations do not address the issue of obtaining consent for donation; however, the regulations do require tissue banks to interview someone such as a close relative about the donor’s medical history and social behavior.

States’ Uniform Anatomical Gift Acts do not address what information tissue banks should provide in obtaining consent.

All States and the District of Columbia have enacted versions of the Uniform Anatomical Gift Act. These laws establish procedures for competent adults to make anatomical gifts by completing and signing a legal document. These gifts are irrevocable at the donor’s death. The laws also include some stipulations on obtaining consent, such as the
order in which next-of-kin may make decisions, documentation required, or the number of persons who must provide legal witness. However, these laws do not address the content of informed consent.

The gift acts in some States specify the informed consent document that must be signed. The consent form itself, however, is a legal document, not a mechanism for sharing pertinent information about donation with the family.

The National Donor Family Council has proposed key elements of an informed consent policy for tissue donation.

The National Donor Family Council (NDFC) represents about 8,000 donor families. The NDFC recently approved a position statement on tissue donation that addresses important considerations for discussing donation with donor families. The full position statement appears in Appendix A. Key elements include:

- Explanations on how tissue is recovered, processed, stored and distributed;
- Explanations that the tissue may be used or modified for transplantation;
- Explanation that the family may limit or restrict the use of tissue; and
- Requirements that the consent form be reviewed with families and that a copy be offered to the family.

Organizations representing the tissue banking industry have issued a statement that addresses elements of informed consent to be included in discussions with families.

The American Association of Tissue Banks (AATB), the Association of Organ Procurement Organizations, and the Eye Bank Association of America, issued a joint statement in December, 2000. The full position statement appears in Appendix B. AATB, which accredits 58 cadaveric tissue banks, is incorporating the elements contained in this statement into its accreditation standards. The updated standards are scheduled for publication in January, 2001.

The statement addresses basic elements of informed consent which should be provided to all families. These basic elements include:

- Identification of specific tissues that are being requested for donation;
- Explanation that retrieved tissues may be used for transplantation, therapy, research, or education; and
- A general description of the recovery process.

The statement also recognizes that families may seek additional information about donation. If so, additional explanations should be provided to address such issues as:

- The possibility that the gift may take a different form than originally recovered;
- Transplantation may include reconstructive and aesthetic surgery; and
- Multiple organizations (non profit and/or for profit) may be involved in facilitating the gift.
CONCLUSION

Tissue banking and processing practices have gradually diverged from donor families’ expectations in recent years. For donor families, the altruistic donation of tissue from a loved one is a charitable act. Donation is made with few expectations other than that it will be used to enhance the lives of others, that the donor will be treated with respect, and that the organizations with whom tissue banks work will take special care to ensure that the gift is used for these purposes.

Today’s tissue banking industry and the beneficial uses of human tissues and related products have become more complex and costly. New ways of using tissue for medical treatment have been developed. Tissue banking has been infused with capital and entrepreneurial practices. Processed tissue often is marketed and sold like any other medical product. For some, these practices call into question the non-profit basis of the tissue banking community.

Despite these changes, the foundation of the industry remains that of human tissue freely donated by individuals and their families at a most difficult and extraordinarily sensitive time.

The special nature of human tissue, and the circumstances under which it is made available, call for certain steps to be taken above and beyond those that would apply to most other business or philanthropic enterprises. In the following section, we share our recommendations that take these into account.
RECOMMENDATIONS

Importance of Increasing Donation

The Office of Inspector General has examined issues related to organ, tissue, and bone marrow donation, allocation, and transplantation for more than a decade. The principles underlying our work have consistently focused on enhancing equity for patients, improving access to transplantation, and encouraging donation.

Encouraging donation was of paramount importance to us as we developed these recommendations. It is our hope that these recommendations will encourage donation. Our recommendations encourage joint action among groups representing the tissue banking industry, donor families, and the government.

The Department of Health and Human Services

The Health Resources and Services Administration should work with groups representing donor families and the tissue banking industry to develop guidelines for conveying information to families about tissue donation.

HRSA’s Division of Transplantation supports the development of programs to increase donation. In that role, HRSA has gained considerable expertise about effective practices in requesting consent. The agency could act as a resource to convey information about donation to tissue banks and families.

HRSA’s efforts could focus on such areas as:

- Identifying principles and guidelines that should underpin consent requests, such as those outlined recently by the National Donor Family Council and jointly by the American Association of Tissue Banks, Association of Organ Procurement Organizations, and the Eye Bank Association of America;
- Making suggestions as to the type, format, and content of written information about donation that tissue banks could share with families;
- Making recommendations on information that would be useful for training tissue bank staff and external requestors; and
- Making recommendations on assessment tools that would be useful in evaluating the effectiveness of requestors.

The Health Care Financing Administration should address informed consent for tissue donation through the conditions of participation for hospitals and for organ procurement organizations.

As we note above, HCFA requires hospitals to assure that the family of each potential donor is aware of its options to donate. This requirement applies to tissue donation, as
well as to donation of organs and eyes.

Elsewhere in this report, we recommend that HRSA work with donor family groups and the tissue banking industry to develop guidelines for conveying information to families about tissue donation. HCFA could use these guidelines as it provides information about the hospital conditions of participation for organ, tissue, and eye donation. The agency could publicize these principles through the “Questions and Answers” document posted on the HCFA Internet site. For example, the agency may wish to encourage hospitals to include a protocol for informed consent in their agreements with tissue banks, using the recommended guidelines in those protocols.

In the longer term, the agency may wish to examine the Medicare conditions of coverage governing organ procurement organizations. In that examination, the agency could consider whether it would be beneficial to include additional requirements to strengthen working relationships between OPOs and tissue banks. Such requirements might include:

- Holding OPOs responsible for informed consent for tissue donor families when requesting consent on behalf of tissue banks; and
- Requiring OPOs to include tissue banks in the training that they conduct for designated requestors.

The Tissue Banking Industry

At the time of obtaining consent, tissue banks should provide families with written materials that provide fuller disclosure about the uses of tissue and the nature of the gift.

Tissue banks could do a better job of providing basic information to families, either at the time they ask them to consent to donation, or in the days immediately following that decision. At a minimum, this material should include:

- A copy of the signed consent form. We believe that this is a basic legal protection for the family, as well as a recognition of the nature of the gift to which they have consented;
- Written information to the family on how it can follow up with the tissue bank in the case concerns arise;
- A full description of the uses to which donated tissue may be put; and
- A list and description of other entities with which the bank has relationships for processing and distributing tissue.

Written materials should be appropriately thorough. Such materials would serve as a way to supplement the information that requestors provide to the family during their conversation about donation, while providing requestors with the flexibility to adapt that discussion to the unique needs and responses of each donor family.
Tissue processors and distributors should ensure that information accompanying their product clearly indicates it is derived from donated human tissue.

The FDA does not currently have labeling requirements for packaged tissue, and the AATB’s standards (which apply only to banks accredited by the association) address labeling within the context of ensuring that users know it is a biologically-based product, capable of transmitting disease. Neither set of standards addresses donor families’ concerns that recognition be given to the fact that the products are the result of a freely made donation of human tissues.

The following steps could help to address perceived concerns that donated human tissue is no different from any other medical product. Tissue banks should:

- Indicate clearly on all tissue packaging that the contents derive from donated human tissue; and
- Indicate clearly on all marketing and informational brochures that these products derive from donated human tissue.

This recommendation responds to concerns that tissue is viewed as a commodity, rather than an altruistic donation. Implementing it would require only minor changes in packaging and marketing materials. But it would go a long way towards showing ongoing respect for the donor and the gift of donation.

Tissue banks should foster greater accountability for the performance of those who request consent for donation.

We found wide variation in practices among tissue banks with respect to how consent for donation is requested, who requests consent, and how these individuals are trained and monitored. There is no doubt that the responsibility for ensuring that requestors are providing accurate, sensitive, and appropriate information rests directly with the tissue bank. To ensure greater accountability of requestors, tissue banks should:

- Ensure that their requestors are fully and appropriately trained. This applies both to requestors from their own organizations as well as other entities, such as hospitals;
- Provide continuing education for requestors; and
- Conduct ongoing assessments of requestor performance to ensure that they are providing full and accurate information to families approached for donation.

The tissue banking industry should work with representatives of groups representing donor families to explore a process for periodic public disclosure about tissue banks’ financing.

Non-profit entities are already required to disclose information about the sources and uses of funds received; publicly-owned businesses submit annual public reports to the Securities and Exchange Commission. These disclosures contribute to public accountability
and can serve as a basis for building greater trust among donors, families, and tissue banks.

The purpose of the examination we recommend here is to respond to family and general public concerns about knowing the type and extent of financial arrangements which the tissue bank has with other entities, both nonprofit and for profit. The examination would consider whether financial information would be useful as part of a package of information provided to donor families. The examination would consider:

- What types and how much financial information would be useful for families and individuals in making decisions about donation;
- The advantages and disadvantages of financial disclosure, including its potential impact on donation; and
- The content, style, and format of disclosure.

**COMMENTS ON THE REPORT**

We received comments on a draft of this report from the Department of Health and Human Services. They are supportive of our findings and recommendations. The full text is included in Appendix C.

Our work in tissue banking continues. We will maintain an active watch on how the tissue banking community responds to the concerns that we have raised.
NATIONAL DONOR FAMILY COUNCIL
EXECUTIVE COMMITTEE

POSITION STATEMENT ON TISSUE DONATION

The National Donor Family Council (NDFC) of the National Kidney Foundation recognizes and supports tissue donation as an end-of-life option for donor families and recognizes its life-enhancing capacity to help thousands who are awaiting tissue transplantation.

The NDFC strives to enhance the sensitivity and effectiveness of the organ and tissue procurement process. To further this mission, the NDFC believes that tissue donation should always be treated as a gift of life. We believe that the tissue community as a whole must promote sensitivity to and support for organ and tissue donor families.

While the NDFC recognizes that financial resources are an important factor in maintaining the highest quality of tissue services, it is our position that tissues must be collected, processed, stored and distributed in an efficient manner that minimizes costs and maximizes the benefit to patients. The NDFC believes that donated tissue must be used in a way that promotes healing for people with the greatest need.

The tissue community should resist the tendency to make the generous gift of donated tissue a commodity. Professionals should refrain from referring to donated tissue as a “product.” All packaging for donated tissue should include a statement indicating that the package contains donated tissue and is a gift of life. The tissue community should educate health care professionals, including physicians who use donated tissue, about the donor family perspective and the nature of the gift. The tissue community should also work to raise awareness among funeral services professionals and strengthen their commitment to follow the wishes of donor families. The tissue community must pay all expenses incurred by the donor family that are directly associated with tissue donation, including any increased funeral charges.

As approved by the NKF National Donor Family Council Executive Committee and the NKF Board of Directors, September 25, 2000

NOTE: This Policy Statement is subject to further revision based on a survey of donor families currently in progress.
NATIONAL DONOR FAMILY COUNCIL
EXECUTIVE COMMITTEE

INFORMED CONSENT POLICY FOR TISSUE DONATION

As with organ donation, the National Donor Family Council (NDFC) of the National Kidney Foundation believes that a crucial element of the tissue donation process is the informed consent of the donor family. With respect to tissue donation, the informed consent of the donor family must, at an absolute minimum, include a voluntary decision based on full disclosure of the facts.

Full disclosure includes the following elements:

1. Donor families should be given a general explanation of the tissue process, including:
   - medical and social history
   - communicable disease testing
   - laboratory testing
   - medical suitability
   - how tissue is recovered, processed, stored and distributed

2. Donor families must be told what tissue can be recovered from their loved ones based on medical suitability. If heart valves will be recovered, families must be informed that the heart will be removed from the donor’s chest and sent to a facility where the valves will be removed. If the entire eye will be removed for corneal donation, families should be informed.

3. Donor families must be informed that tissue can be used or modified in various ways for transplantation in a life-saving capacity, transplantation in a life-enhancing capacity, and medical research or education.

4. Donor families must be told that they have the right to limit or restrict the use of the tissue.

5. Donor families must be told about the likelihood that the donated tissue will be stored, how it will be stored, the duration of storage, and the possibility that the tissue may not be utilized.

6. The completed consent form must be reviewed with the donor family before final consent, and a copy should be offered to the family. Other written material explaining tissue donation should be offered to the family.

7. Donor families must be given the option of receiving acknowledgment of their gifts. This acknowledgment should include both disposition and any recipient information available at that time, while protecting the anonymity of both donor and recipients. To obtain additional information about the gift, the donor family should be provided with contact information (including phone number and address) for the recovery agency.

As approved by the NKF National Donor Family Council Executive Committee and the NKF Board of Directors, September 25, 2000

NOTE: This Policy Statement is subject to further revision based on a survey of donor families currently in progress
Human organ and tissue transplantation has become an important and growing part of modern medical practice. Advances in medical science have made it possible for millions of Americans to receive these life-saving and life-enhancing gifts. None of this would be possible, however, were it not for the tens of thousands of donors and donor families who give their organs and tissues to help their fellow men and women.

The decision to donate must, therefore, be an informed consent, and it must be conducted under circumstances that are sensitive to the consenting person’s situation. Information concerning the donation should be presented in language and in terms that are easily understood by the consenting person. The consent should be obtained under circumstances that provide an opportunity to ask questions and receive informative responses. An offer should be made regarding the availability of a copy of the signed consent form, and information should be provided regarding ways to reach the recovery organization following donation. Consent should be obtained in accordance with federal, state and/or local laws and/or regulations. The person seeking the consent should be trained to appropriately answer any questions that the consenting person may have. In addition, coercion should not be exerted in any manner, nor monetary inducement offered to obtain consent for donation. The identification of who may be the appropriate person to consent to donation, and whether the consent of any person in addition to the donor needs be obtained, should be evaluated in accordance with the applicable laws and organizational policy and is not addressed in this statement.

The following list of “Basic Elements of Informed Consent” is intended to highlight the information that may be considered critical to informed decision making by a family member or other legally authorized person, who is being approached for consent to organ and/or tissue donation. This listing, whether communicated verbally or included on consent forms, is not intended to preempt any applicable federal, state, or local laws or regulations that may require more or less information to be disclosed for informed consent to be legally effective.

Basic Elements of Informed Consent

In seeking informed consent, the following information should be provided to the person(s) being approached for consent:

- A confirmation/validation of the donor’s identity and his or her clinical terminal condition.
- A general description of the purposes (benefits) of donation.
Policy Statement on Informed Consent
Page 2

- Identification of specific organs and/or tissues (including cells) that are being requested for donation (with subsequent information provided on specific gifts recovered).

- An explanation that the retrieved organs/tissues may be used for transplantation, therapy, medical research, or educational purposes.

- A general description of the recovery process (including timing, relocation of donor if applicable, contact information, etc.).

- An explanation that laboratory tests and a medical/social history will be completed to determine the medical suitability of the donor, including an explanation that blood samples from the donor will be tested for certain transmissible diseases.

- An explanation that the spleen, lymph nodes, and blood may be removed, and cultures may be performed, for the purpose of determining donor suitability and/or used to determine compatibility of donor and recipient.

- A statement granting access to the donor’s medical records, and that the medical records may be released to other appropriate parties.

- An explanation that costs directly related to the evaluation, recovery, preservation, and placement of the organs and tissues will not be charged to the family.

- An explanation regarding the impact the donation process may have on burial arrangements and on appearance of the body.

- Any additional information required by federal, state and/or local laws and/or regulations.

Additional Elements of Informed Consent

In some situations, there may be additional information that should be known by the consenting person(s), or that might be helpful for family decision making. At a minimum, if the donor family inquires about any of these or additional matters, explanations should be provided.

The guiding principle for the use of these “Additional Elements of Informed Consent” is to advance simplicity and reasonableness in seeking informed consent, i.e. include these elements or additional comments if they are appropriate and might clarify any
Policy Statement on Informed Consent
Page 3

exigencies. For example, if there is the likelihood that the patient will become a Medical Examiner’s case, then it should be appropriate to so inform the family. If it is unlikely that donated tissue is going to be used for aesthetic surgery, then it would not be reasonable to address this issue in the family approach.

One or more of the following elements of information may also be appropriate for communication to the person(s) being approached for consent, depending upon the circumstances surrounding the donation and the potential gift(s):

• A description of any involvement by the Medical Examiner and/or Coroner, including an explanation that an autopsy may be performed.

• An explanation that transplantation may include reconstructive and aesthetic surgery.

• A reference to the possibility that the final gift may take a different form than originally recovered.

• An explanation that multiple organizations (nonprofit and/or for profit) may be involved in facilitating the gift(s).

• Reference to the possibility that tissue and/or organs may be transplanted abroad.

American Association of Tissue Banks

Association of Organ Procurement Organizations

Eye Bank Association of America

November 30, 2000
TO: Inspector General, HHS

SUBJECT: Department Comments on OIG Report on Informed Consent in Tissue Donation

I commend the Office of the Inspector General (OIG) for its quick response to my request to review the status of informed consent for tissue donors.

The Department finds considerable merit in the OIG’s recommendations toward making more -- and more meaningful -- information available to tissue donors and tissue donor families. Working with the industry and donor families to facilitate better understanding of this process is likely to produce positive results.

The Department notes that important activities relevant to the OIG’s recommendations are underway:

   The Health Resources and Services Administration (HRSA) already works closely with donor and recipient families and other representative groups to develop educational information about organ and tissue donation. To include tissue banks in such activities would be a logical extension.

   The Health Care Financing Administration (HCFA) currently is engaged in several activities with hospitals, organ procurement organizations, and tissue banks to increase organ and tissue donation. The OIG recommendations for additional efforts toward ensuring that donors and donor families receive information adequate for informed consent is consonant with the current activities and should be readily accommodated. While tissue banks are not directly under HCFA’s jurisdiction, they have worked closely with HCFA and organ procurement organizations with a view to having appropriate donors referred to them.

If the OIG’s recommendations that are directed toward the tissue industry were to be implemented in full and promptly, such action could go far toward easeing the concerns that have been raised about the uses to which donated tissues are put. Tissue donors and tissue donor families undoubtedly would welcome increased efforts toward ensuring informed consent, giving explicit recognition for the donation on the packaging associated with tissues or products prepared from them, and providing more insight about the fiscal aspects of tissue handling and processing. Although the Department has no way to compel action in these areas by the tissue industry, the pertinent agencies of the Department are prepared to support the industry in taking such steps.

Kevin Thurm

THE DEPUTY SECRETARY OF HEALTH AND HUMAN SERVICES

WASHINGTON, D.C.  20201

DEC 26 2000
Endnotes

1. The National Organ Transplant Act specifies that organ procurement organizations must be nonprofit entities, establishes requirements for their service area, and imposes certain organizational and staffing requirements. (42 U.S.C., Section 273(b))

2. Of the tissue bank officials we interviewed, five banks only process and distribute tissue; they do not recover tissue and would not be directly involved in obtaining consent. In addition, eight banks that recover tissue also do some processing and distribution.


4. 42 U.S.C., Section 274e. This is the one provision of the National Organ Transplant Act that specifically addresses human tissue. The act defines organ to include “bone marrow, cornea, eye, bone, and skin or any subpart thereof,” as well as vascular organs such as kidney, liver, heart, lung, and pancreas.

5. The Act specifies that the term “‘valuable consideration’ does not include the reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ.”

6. The web sites of the major processing firm contain information and press releases on new products and uses. Web sites of all the for-profit firms that we examined have a prominently displayed category addressing investor relations, as well.

7. Often cited examples include enhancements of lips or other body parts among Hollywood starlets. During our visit to one tissue processing firm, we were struck by framed blowups of covers from various fashion magazines that were displayed prominently on the walls of the reception area.

8. American Medical Association Policy H-475.992


10. Organ donation generally requires that the donor be declared brain dead (i.e., death through cessation of neurologic function), rather than suffering cardiac death. A small number of total deaths — perhaps 12,000 - 15,000 at the most — meet this criteria in any given year.


14. 21 C.F.R., Parts 16 and 1270, added at 62 Fed. Reg. 40,429, July 29, 1997. The FDA issued these regulations under the legal authority of section 361 of the Public Health Service Act. This section authorizes the Secretary to make and enforce regulations judged necessary to prevent the introduction, transmission, or spread of communicable diseases.

15. The original Uniform Anatomical Gift Act was first developed in 1968 by the National Conference of Commissioners on Uniform State Laws. Many States have incorporated the features of a revised version developed in 1987.