Testimony

Testimony of
George F. Grob
Deputy Inspector General
for Evaluation and Inspections
U.S. Department of Health and Human Services

Good Morning, Madam Chairman. Human tissue is an important source of medical treatment, benefitting thousands of Americans every year. However, concerns have been raised about current practices and the future developments of this field.

Last year, more than 750,000 pieces of human skin, bone, and heart valves were distributed for transplantation. This does not include eyes and other types of human cells or tissue. It came from over 20,000 donors and their families who so generously made this important gift at the time of a loved one's death. These families and a relatively small number of tissue banks, who procure, process, store, and distribute tissue, have been the foundation of this medical service for many years. Recently, however, the tissue banking industry has expanded and become more complex. Tissue is being put to new uses, and processing has grown more sophisticated. Entrepreneurial firms have stepped in to develop and market new products and treatments from human tissue. Unfortunately, standards of practice have not kept pace with this growth and development.

Earlier this year, the Office of Inspector General issued two reports on tissue banking. We have provided copies of both reports to the members of this Subcommittee. Our reports address the adequacy of the quality assurance oversight mechanisms for this industry and the extent to which donor families can make informed decisions about consenting to donation. I will discuss both these facets of tissue banking and offer recommendations to improve them.

OVERSIGHT OF TISSUE BANKING

External oversight of the tissue banking industry is currently limited, although recent actions by the Food and Drug Administration have improved the situation. Regulations now under development will result in even stronger, and much needed, supervision of the industry. Portions

of the industry have developed their own accreditation system, and two States license and inspect tissue banks. However, as of now, serious gaps remain.

The Food and Drug Administration

The Food and Drug Administration (FDA) focuses on preventing transmission of communicable disease by requiring donor screening and testing. No new cases of disease transmission through human tissue have been identified since the FDA's initial regulation of tissue in 1993. This absence of new cases points to significant strengths and accomplishments in the current system. Nevertheless, we identified situations that show the need for continued vigilance and monitoring. For example, FDA inspectors have found serious deficiencies in tissue banks' screening and testing practices where they have conducted inspections. It is reasonable to believe that similar problems exist where they have not conducted them.

Inspections. FDA has conducted 188 inspections of 118 tissue banks since 1993. However, at the time of our study some tissue banks had never been inspected by FDA. We found at least 36 tissue banks that have never been inspected, out of 154 tissue establishments that we identified. FDA has indicated that because regulation of tissue banks is an unfunded mandate, it has had to borrow resources from other programs to carry out these inspections.

FDA lacks a prescribed cycle for reinspection of tissue banks. At the time of our study, out of 118 tissue banks that FDA had inspected, 68 were inspected only once. Due to limited resources, the agency has established a priority list for follow-up inspections, focusing on banks with the most serious deficiencies.

Since we issued our report, FDA has begun inspecting all known tissue banks.

Registration. At the time of our study, the number and location of tissue banks were unknown. Information was unavailable about the number of tissue banks in operation and the products they produce and distribute. Subsequently, on January 19 of this year, FDA published a final rule requiring the registration and listing of all tissue banks.

Quality Control. FDA has also been developing two additional regulations that would provide stronger assurances regarding the handling and use of human tissues. The first, on good tissue manufacturing practices, was issued as a draft on January 8 of this year. The closing date for public comments was May 8. The second, on suitability of donors and tissue products, had been issued as a draft rule

in September, 1999. The comment period was extended through July of last year, and comments are now being analyzed. The scope of FDA's current regulation is limited to donor screening and testing to prevent transmission of HIV and Hepatitis.

The American Association of Tissue Banks

The American Association of Tissue Banks (AATB) conducts a voluntary accreditation program. It currently accredits 58 tissue banks. Accreditation addresses not only donor screening and testing practices, but operational and organizational aspects, such as qualifications of tissue bank personnel and banks' safety practices, equipment testing, facilities, labeling, and quality assurance programs. Some banks have failed to meet basic standards of the AATB and have been denied accreditation.

Seeking accreditation is purely voluntary. We identified 90 tissue banks that are not accredited. These banks are under no obligation to meet the standards or policies set by the association, and for many banks there is no incentive to seek accreditation.

States

New York and Florida are the only two States to license and inspect tissue banks. In addition to screening and testing, these States require banks to report adverse incidents. They also address areas such as how tissue is recovered and tracked, emergency procedures, equipment standards, conflict of interest, community involvement, labeling standards, laboratory testing, and disposition of unused tissue. A few States, including California, Georgia, and Maryland, require tissue banks to be licensed by the State.

Overall

Until FDA's proposed rule on good tissue practices is finalized, tissue banks have no external requirements for quality and handling of tissue if they are not accredited by AATB or licensed by New York or Florida. Of the 154 tissue banks we identified, 67 are neither accredited by AATB nor inspected by Florida or New York.

Recommendations Regarding FDA Oversight

In our reports, we called upon the Food and Drug Administration to take a number of steps to ensure the safety and quality of tissue transplanted in this country. Needless to say, FDA should move forward with pending oversight efforts. As noted earlier, we recommended that FDA set a realistic, yet aggressive, date by which it would complete an

initial inspection of all tissue banks and determine an appropriate minimum cycle for tissue bank inspections.

We also believe FDA should examine whether there are areas in which oversight can be coordinated with other entities. We called on FDA to work with States and professional associations to determine in what areas, if any, oversight activities could be coordinated. If this approach were appropriate, it could help maximize agency resources and reduce redundant regulatory burden on tissue banks.

DONOR CONSENT

Expectations of Donor Families

Donor families have some basic expectations about their decision to donate a loved one's tissue. These relate to the way the donated tissue is used and to the respect of the donor, even after death.

Intended Use and Supply. Families expect that their loved one's tissue will be used to improve the lives of people with medical needs, either through transplantation or medical research. For many families, donation is seen as a way of creating something positive from the death of their loved one. However, concerns have been raised that some tissue may be used for purposes other than those intended by the donor. For example, donors may intend or believe that their skin will be used for the treatment of burn victims. However, in some cases it might be used for elective cosmetic surgery. Some believe that this might contribute to a shortage of skin for essential medical uses. However, there is no national system for tracking the availability and use of tissue and determining where there may be a shortage. It is not clear how much tissue goes for cosmetic uses or whether such use contributes to a shortage.

After we began our inspection, both the American Association of Tissue Banks and the American Burn Association published results of surveys which they took to determine the adequacy of the supply of skin for burn surgery. Their reports indicate that supplies were tight, with surgeons having to delay or make do with alternative treatments in some cases. However, these surveys were not detailed enough to know if any burn victims were unable to get the treatment they needed, or if any supply shortages occurred as a result of diverting skin to lower priority usages.

Respect. Families we talked to emphasized their desire that the donor will be treated with respect during the surgical processes of tissue

recovery, during funeral preparations, and while tissue is processed, distributed, and transplanted. Once it has been processed, however, tissue is treated more like a commodity than a donation. The packages in which human tissue is supplied—bottles, vials, containers shrink-wrapped in plastic—resemble many other medical supplies. The packaging does not indicate the special nature of the donation that underlies the enclosed materials. Nor do marketing materials indicate the nature of the donation. These product brochures look like typical medical supply catalogues, contributing to a perception that tissue is no different than any other supply. Neither of these practices reinforces the respect that donor families expect to be given for the donated gift of human tissue.

The Process of Obtaining Consent and Donations

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

Circumstances and Timing. Tissue banks must obtain consent for donation within hours following the death of a loved one. The recent, often sudden and unexpected, death of a loved one means that families may be upset at the time they are asked for consent to donation. In the face of sudden tragedy, they may simply be unable to understand detailed information about a topic as complex as tissue donation. Because of the circumstances, detailed discussion about 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.

At the same time, families may not wish to receive detailed information about tissue banking. Families may want to consent to donation, but do not want to hear specific details about the invasive surgical procedures associated with recovering tissues. As the mother of one tissue donor 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." At the same time, however, 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 whether the tissue may be used only for transplantation, or for other uses such as research and education.

Request by Telephone. Tissue banks often 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.

Staff Supervision. Many tissue banks rely on staff from other organizations to obtain consent. These external requestors could be staff from organ procurement organizations, telephone triage agencies, hospital staff, chaplains, or social workers.

Those banks that make the request directly are able to train and monitor the performance of their own staff. However, training and oversight are much more limited for external requestors. Those training programs tend to be shorter, and few tissue banks provide continuing education or follow-up training to these requestors. Tissue banks also do less direct monitoring of these requestors' performance, and we found that few tissue banks actively assess the performance of external requestors.

Written Materials. Tissue banks provide donor families with little written material at the time of donation. Few tissue banks routinely give families a copy of the form that they have signed, giving their consent to donation. The consent form is more than a receipt. It is the legal authorization governing the removal of tissue and specifying purposes for which the tissue may be used.

Following donation, it is general practice for tissue banks to send families a letter thanking them for the gift and expressing condolences. Aside from this letter, tissue banks provide little additional written information to families about tissue use, processing, or other entities with whom they have financial arrangements.

Because, as we noted above, families may not understand everything that is told to them at the time of donation, more information may be beneficial at a later date, so that the family could refer to it as desired.

Standards for Obtaining Consent

Until recently, standards governing how families are approached and what they are told about tissue donation have been sparse. Neither Federal law, such as the National Organ Transplant Act, nor the individual States' Anatomical Gift Acts address what information tissue banks should provide in obtaining consent. However, some initial progress toward development of standards has occurred.

Donor Family Advocates. Last Fall, the National Donor Family Council proposed key elements that should be included when tissue banks approach families for donation. These elements include:

- Explanation of how tissue is recovered, processed, stored and distributed;

- Explanation 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.

Tissue Industry. Also in the midst of our inquiry last Fall, The American Association of tissue Banks, the Association of Organ Procurement Organizations, and the Eye Bank Association of America issued a joint statement that addresses elements of informed consent. This statement encourages the provision of information to families including:

- 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.

The full text of the statements from both of these groups is in our reports.

Recommendations Regarding Donor Consent

We have called upon the Department of Health and Human Services to provide assistance to efforts to develop standards. For example, we encourage the Health Resources and Services Administration (which

houses the Division of Transplantation) to work with donor family groups representing the tissue banking industry. We believe that they could help these organizations develop guidelines for conveying information to families about tissue donation. We also have called upon the Health Care Financing Administration to address informed consent for tissue donation through its oversight of the organ procurement system.

Although the Department can provide guidance and assistance, the basic responsibility for ensuring that families are informed about all aspects of tissue donation must rest with the tissue banks themselves. The tissue banks and their staff and contractors are the ones who interact with the donor family at the time of requesting consent.

Because each case and each situation is unique, those who interact with families to request donation must have the flexibility to recognize the individual concerns present at that moment in time and to adapt their discussion to the unique needs and responses of each donor family. We do believe, however, that some essential precepts should govern the interaction that tissue banks have with families.

Written Materials. First, 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 would serve as one way to supplement the information that requestors give the family during their conversation about donation. At the same time, it would provide 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.

Recognition of Donors. Second, 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. However, 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 are derived from donated human tissue; and

- Indicate clearly on all marketing and informational material that these products are derived from donated human tissue.

Conduct of Requestors. Third, 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 whom they work. These organizations should:

- Ensure that requestors—both from their own organizations and elsewhere—are fully and appropriately trained;

- Provide continuing education for requestors; and

- Conduct an ongoing assessment of requestor performance to ensure they are providing full and accurate information to families approached for donation.

Public Disclosure. Fourth, the tissue banking industry should work with groups representing donor families to explore a process for periodic public disclosure about tissue banks' financing. Such disclosure would 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 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.

Supply and Usage. The tissue banking industry should refine and periodically repeat its surveys regarding the availability of tissue. The refinements should provide more precise information about the extent to which patients' needs are being met. Tissue banks should also try to obtain more information about the uses made of the tissue that passes through their operations. This will enable them to provide better information on this subject to donors. Finally, some upgrading of inventory measurement and control systems should be adopted within the industry, probably through automated data systems, in order to allow for more effective sharing of tissues among tissue banks to meet situations where supplies are low and needs are critical.

CONCLUSION

Both FDA and the tissue banking industry have made progress toward improving the consent and donation processes and quality assurance oversight mechanisms for processing human tissue. But gaps remain. The recent gains need to be rounded out and solidified. Standards of operation still have to catch up with the growth and complexity of this health care sector. I hope the findings and recommendations in our reports will be helpful in this regard.