Tissue Donations:

Issues and Options in Oversight, Regulation and Consent

Prepared for
Senator Jackie Speier

California Senate Office of Research

April 2003

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Introduction

Human tissues are used in a variety of medical procedures that significantly enhance the quality of life for thousands of individuals throughout the United States each year. "Tissues" in this sense refer to skin, heart valves and musculoskeletal tissues such as bone, cartilage, ligaments, and tendons. Skin, ligaments, bones, arteries, veins and heart valves from a single donor can be used for treating burns or cancer, repairing knees, replacing hips, restoring circulation and transplanting heart tissue. Tissue is also used in reconstructive and cosmetic surgeries. Tissue donations are called *allografts*.

The rate of tissue transplantation has grown enormously in recent years. The American Association of Tissue Banks estimates that 21,600 donors provided tissue in 2001, up from perhaps 6,000 donors in 1994. Tissue banks distributed an estimated 900,000 or more allografts for transplant in 2001.

In 2000, several newspaper articles alleged some questionable practices in the tissue bank industry that warranted investigation. In response to these articles, Donna Shalala, then director of the U.S. Department of Health and Human Services, requested that the Office of the Inspector General review the operations of tissue banks. The resulting reports, *Oversight of Tissue Banking* and *Informed Consent in Tissue Donation,* were released in January 2001 and included a number of recommendations for reforms in the industry.

In May of 2001, the Permanent Subcommittee on Investigations of the U.S. Senate Committee on Governmental Affairs also held a hearing on the question of whether the federal government's oversight of the tissue bank industry is adequate.

The dominant issues in these two investigations included:

- The adequacy of the federal, state and private licensing and accreditation of this industry;

- Whether the informed-consent process includes disclosure of important issues to family members;
- Whether individuals involved in requesting the consent of the donor family as well as those who actually procure the tissue have been properly trained; and
- The role of for-profit versus nonprofit organizations in the procurement, processing, storing and distribution of human tissue.

Oversight of Tissue Banks

The state Department of Health Services advises that there are 260 tissue banks licensed to do business in California. These tissue banks can be divided into the following types:

Anatomical Tissue Banks (Deceased Donors)

Eye banks	17
Out-of-state tissue banks	26
Cadaver tissue banks that process, store, distribute tissues (but do not collect cadavers)	93

Living-Donor Tissue Banks

Bone marrow and other non-reproductive human cells	20
Human milk	2
Reproductive tissue	92

Oversight of tissue banks in California is handled in three ways:

- Food and Drug Administration (FDA) regulations,
- Accreditation by the American Association of Tissue Banks and the Eye Bank Association of America, and
- California state licensing requirements.

Each of these is discussed below.

Food and Drug Administration

In 1998, the FDA adopted regulations requiring tissue banks to maintain appropriate records and to screen and test donors for HIV-1 and HIV-2 and for hepatitis B and C. These regulations also provide for FDA inspection of tissue banks and retention, recall or destruction of tissues that don't meet requirements.

More recently, the FDA is nearing adoption of two new rules governing tissue banks. One of these would mandate increased disease screening and testing of tissue donors for Creutzfeldt Jakob disease and syphilis, and the other would require that tissue banks follow "good tissue practice" standards. "Good tissue practices" require establishment of a quality-control program that governs the methods, facilities and controls used in tissue processing. It is expected that these final rules will be adopted in late 2003 or early 2004. The FDA also finalized a rule in January of 2001 that requires the registration of all tissue banks.

FDA staffing in California is not at a level that would assure proper oversight of the industry to enforce these new regulations, according to the congressional testimony presented in 2001. That year, FDA inspectors in California inspected 13 tissue banks (some of these tissue banks had more than one inspection). In 2002, just nine inspections were completed. As Kathryn Zoon, director of the FDA's Center for Biologics Evaluation and Research, pointed out in her testimony before the Permanent Subcommittee on Investigations in May 2001: "It will do little good to enact a statute or launch a tissue regulation program without the resources to establish the program and sustain the program over time."

The FDA has adopted a prioritized list for inspections beginning with tissue banks with previous violations, nonprofit and for-profit organizations that process tissue and have been a subject of complaints, organizations or tissue banks that have never been inspected and those that lack accreditation by the American Association of Tissue Banks (AATB) or the Eye Bank Association of America (EBAA).

George Grob, a deputy inspector general for the U.S. Department of Health and Human Services, testified before the subcommittee that the FDA found problems in about half of the banks it inspected, and that some of these were serious and required official action. Mr. Grob stated that there were scores of tissue banks that had not been subject to federal, state or industry oversight. Further, Mr. Grob stated, "We have to assume that if they (FDA) find problems in the banks that they inspect, then there are probably those same problems, if not more of them, in the banks that have never been inspected."

The FDA reports that there were 34 voluntary recalls in 2000-01 and another 37 in 2001-02. In August 2002, the FDA ordered Cryolife, Inc., of Kennesaw, GA, to recall all distributed human allograft tissues – other

than allograft heart valves – that it had processed since October 3, 2001. It also warned physicians to consider using heart valves from other manufacturers and to discuss the potentially higher risk for infection if Cryolife's heart valves are used. Because Cryolife is the largest processor of cardiovascular tissue in the country, the potential exists for many patients to be affected. The recall order followed discovery by the FDA of regulatory violations by Cryolife related to the processing of human tissue, documented fungal and bacterial contamination of Cryolife tissues, and failure by Cryolife to fully implement corrective actions. Tissue processed by Cryolife from a donor during this period was associated with the November 2001 death of a patient who received a soft-tissue implant during reconstructive knee surgery. Several other incidents of contamination also were associated with Cryolife during this time.

The FDA last year reported that at least 40 people received tissue or organ transplants contaminated with hepatitis C from a donor whose infection wasn't detected by a Portland, OR, tissue bank that processed the tissues. Also last year, the FDA issued a seven-page warning to AlloSource, Inc., in Englewood, CO, stating that the company had failed to follow its own policies for handling cadaver skeletal and muscular tissue, thus risking tissue contamination.

American Association of Tissue Banks

The AATB has a voluntary accreditation program that includes an onsite, independent inspection. Members must be re-accredited every three years. The AATB's only enforcement mechanism is to withdraw accreditation. Of the 116 tissue banks that have been provided accreditation since AATB's inception in 1986, approximately 20 have failed to demonstrate compliance with AATB's standards and accreditation was withdrawn. When tissue banks are found out of compliance with AATB's standards, AATB does not notify the FDA due to the AATB's assurances of confidentiality to the banks that it evaluates.

Among an estimated 350 tissue banks nationwide, AATB currently provides accreditation to 71. Of the 221 tissue banks doing business in California eligible to seek AATB accreditation, only eight have obtained it. (AATB does not accredit eye banks, human milk or bone marrow and other non-reproductive human cell tissue banks.)

AATB's standards for tissue banking are consistent with, and in most areas exceed, FDA standards. AATB's accreditation is based not only on donor screening and testing practices, but also on operational and organizational issues such as the qualifications of tissue-bank personnel, safety practices, equipment testing and quality assurance. The FDA's standards are not as detailed as those of AATB. The FDA may set a goal, but not prescribe the detailed actions necessary to reach that goal.

Robert Rigney, chief executive officer of the AATB, testified at the congressional subcommittee hearing that during the past seven years, AATB-accredited tissue banks have distributed more than 2 million allografts to surgeons without a single reported case of disease transmission from donor to recipient.

It is important to recognize, however, that there are no requirements to track recipients of tissue. It is conceivable that a case of disease transmission could occur without being reported to a tissue bank or to any government authorities.

State Licensing

California law requires licensure of all banks that collect, process, store or distribute any human tissue for transplantation. Although California, Georgia, Maryland, New York and Florida all require tissue banks to be licensed, only New York and Florida require tissue banks to pass an inspection prior to licensing.

Because California requires its tissue banks to be licensed, it also can revoke licenses. It requires testing for sexually transmitted diseases (e.g. for HTLV-1 and syphilis) beyond that currently required by federal regulations. (When the proposed federal regulations are adopted, screenings and testing requirements will include donor screening for Creutzfeldt Jakob disease and testing for syphilis.) The state Department of Health Services (DHS) also requires that all hospitals and clinics that store human tissue be licensed as tissue banks, although the FDA does not regulate such hospitals and clinics. DHS requires licensure of all reproductive-tissue and human-milk facilities, while the FDA requires registration of facilities that collect reproductive tissue but imposes no other requirements.

Regulation Issues

AB 2209 (Speier), Chapter 801, Statutes of 1991, established a number of requirements for California tissue banks, including that they obtain a renewable tissue-bank license from DHS and pay a licensing fee for support of DHS activities. DHS is authorized to enter, announced or unannounced, to inspect any tissue bank and to require a licensed tissue bank to demonstrate satisfactory proficiency on testing for laboratory procedures. This law also authorizes DHS to adopt rules and regulations to address standards in several areas, including:

- Safe preservation, transportation, storage, and handling of tissue;
- Donor testing;
- Equipment;
- Methods; and
- Personnel qualifications.

DHS advises that such regulations have not been developed to date, since DHS believes it already has sufficient authority to regulate tissue bank activities under SB 2209. The law requires applicants for tissue-bank licenses to provide DHS with information on their methods for safe preservation, transportation, storage and handling of tissue, and for donor testing. It also authorizes DHS to revoke a tissue-bank license for reasons that include conduct inimical to the public health.

Another likely reason regulations have not been adopted may be a lack of staff needed to promulgate extensive regulations of this type. Although some regulations would be common to all types of tissue banks, subsets of regulations may be needed for each type of tissue usage, such as cardiovascular, osteoarticular, musculoskeletal, reproductive and others. New York state's regulations covering various types of tissue banks fill up 80 pages. According to Tom Favor, tissue bank coordinator for the state of New York, the latest update of New York's regulations took approximately four years to complete.

Recently enacted legislation – SB 1135 (Polanco), Chapter 929, Statutes of 2002 – would have required DHS to adopt rules and regulations by July 1, 2004, governing licensed tissue banks engaged in the *collection* of human musculoskeletal tissue. However, this legislation will not be implemented since the Department of Finance has ruled that needed funding was not included in it. DHS has advised that this legislation would have affected fewer than a dozen tissue banks: those that collect musculoskeletal tissue, skin and veins. The new law did not call for regulation of those banks that process, store and distribute tissue, but *do not collect* it. This law would have required DHS to base its regulations upon criteria established by the Eye Bank Association of America and the American Association of Tissue Banks, and the scientific and technical data submitted by individual tissue banks.

DHS is considering moving ahead to adopt regulations for all tissue banks. An advisory committee of tissue-bank representatives recommended that DHS adopt national standards, such as those of the AATB. This could be achieved by referencing the AATB standards in California's statutes.

The advantage of doing this would be the ability to expedite the regulatory process and enable the state to keep pace with ever-changing advances in technology. Otherwise DHS would have a very difficult time keeping state regulations up to date with the newest technological advances. DHS advises that there is precedent in this approach, as state law requires blood banks to conform to the American Association of Blood Bank Standards.

It may be that the state's regulatory policy would parallel the standards of the AATB at all times if the state adopted AATB' s standards. However, it is certainly conceivable that this might not always be the case, and it would be necessary to make exceptions in those instances.

New York initially considered adopting AATB standards, but a New York law prohibits any public agency from adopting the standards of any trade association. Also, in a number of instances the AATB's standards were permissive and New York authorities wanted the standards mandatory.

Inspections, Complaints and Adverse Outcomes

Since 1991, DHS has inspected approximately 100 tissue banks, five of them more than once. Since July of 2000, DHS has been able to assign one full-time position predominantly to inspections. Complaints are given first priority, routine inspections second, and initial inspections third. In 2001, DHS inspected two tissue banks. In 2002, six inspections were made – three as a result of complaints and three as part of a routine inspection process. In addition, this surveyor reviewed 11 tissue banks in 2001 and 11 tissue banks in 2002 as part of an unpublished report required by legislation, AB 2167, discussed on page 13. He was also heavily involved in writing the report.

Although no tissue bank has had its licensed revoked by DHS, two tissue banks have been denied renewal of their licenses. One denial was in response to allegations of fraud and the second was due to unsanitary working conditions and failure to disclose requested records. One of these banks no longer exists. The other was issued a cease and desist order in a court hearing.

DHS has been receiving about two complaints a year, on average. Most involve patients' interaction with reproductive-tissue banks and relate to financial arrangements and family law, especially spousal relationships. Because DHS' s tissue-bank licensure program addresses the technical operation of tissue banks, it is not able to help in these matters.

Several complaints have involved alleged process problems (that is, complaints about a tissue bank's business practices, rather than about the bank's technical practices). Recently, the program received a complaint regarding the consent process and one concerning the handling of a donor's body. These complaints are still under investigation.

California law does not mandate that tissue banks advise DHS when there is an adverse incident or outcome, although they are encouraged to do so. Florida and New York require tissue banks to report all adverse events that could affect tissue recipients' medical conditions within 24 hours. A few tissue banks have policies in their written procedures to notify DHS in event of misconduct or adverse outcomes. The FDA will soon be requiring all tissue banks to notify it of adverse incidents.

Fees

The annual licensing fee for tissue banks in California is $975, which generates enough revenue to finance three full-time positions: a program manager, a field examiner and an office assistant. At a rate of four inspections a month, the program will be able to visit each bank about once every five years. Assuming current staffing levels, the interval between DHS inspection visits will increase as the number of licensed facilities increases.

Additional field positions would be required to increase the number of inspections and reduce the interval between inspections to one survey every two years. Florida has two surveyors who are responsible for and manage to inspect 50 facilities on a biennial basis. Twenty-eight of these facilities are physically located outside of Florida but serve residents of the state. These two surveyors have additional responsibilities and do not devote full time to inspections.

Florida requires an initial fee of $1,000 for organ procurement organizations (OPOs) and tissue banks and $500 for eye banks. In addition, Florida assesses annual fees that are used for its certification program, an advisory board, maintenance of its organ and tissue donor

registry and its organ and tissue donor education program. Each licensed OPO and tissue bank pays the greater of $1,000 or 0.25 percent of its total revenues each year from procurement and processing activities in Florida. In 1991, five OPOs, eight eye banks and 33 tissue banks had total revenues of $180 million with an assessment of $215,010. Since California has a significantly greater number of tissue banks doing business here, such a revenue enhancement could provide sufficient funds to finance the necessary oversight for this industry.

Options

- DHS could adopt AATB standards by reference, which would free up its single staff position to devote full time to inspections.

- Since the pending federal regulations on "Good Tissue Practices and Donor Suitability" would apply to California tissue banks, the state could adopt separate regulations after the federal regulations take effect to enhance the federal rules where desired. The state also may want to act separately in instances where the state regulates types of tissue banks but the federal government does not.

- Since new regulations of the FDA will require tissue banks to report adverse incidents and outcomes to the FDA, California should require that the DHS be notified at the same time.

- Tissue banks could be required to pay an annual fee based upon a percentage of their revenues received in California. These fees, which could be earmarked for the Tissue Bank License Fund, could be used to hire additional inspectors so that inspections of facilities could occur every two years rather than every five. This would bring tissue banks in line with the inspection schedule of blood banks.

Informed Consent

Background

The process for obtaining consent for donation of *tissues* is very different from the procedures used by organ procurement organizations (OPOs) for the donation of *organs*. Solicitation of an organ occurs while the donor is still on life support, where there is time for the family to consider all ramifications of an organ donation, and reach a decision without undo pressure. By contrast, tissue donation is often not considered until after a person is deceased, often unexpectedly, such as in a fatal car accident, and the procurement must be completed within 24 hours of death.

As a condition of Medicare participation, all hospitals are required to have a contract with an OPO, a tissue bank and an eye bank to be notified in a timely manner about individuals who die or whose death is imminent at the hospital. The regulations also require that families of potential donors be informed of their options to donate tissues, eyes, and organs. However, the regulations do not provide guidelines on the circumstances or manner for approaching donor families.

Oftentimes requests for tissue donations are made over the telephone. Because this is a time of severe emotional distress, tissue banks have found that in some cases families are not up to discussing issues such as whether a for-profit organization may be involved or whether some portion of the donated skin may be used for cosmetic purposes. However, unless the families are made aware of these issues, it may be difficult to assert that genuine informed consent was obtained.

In Northern California, hospitals use an 800 number to have calls triaged and sent to a designated OPO or tissue bank, depending upon the condition of the prospective donor. If the potential donor is on life support, the call will be referred to the OPO. If the patient is deceased, the call would be triaged to the designated tissue bank. If an OPO is notified that there is a potential organ donation, it will simultaneously obtain the consent for tissue donation so that the family need not

interact with two different organizations. The Northern California Transplant Donor Network reports that its consent rate for receiving organs from all families who are approached is 60 percent. Among those, about 60 percent also give consent for tissue donations.

Commerce and Cosmetic Surgery

Because of the altruistic nature of the donation, families have an expectation that their loved one's tissue will be used in meeting important medical needs and that their own needs will be respected by the tissue banks. Few families are aware of the potential for commercialization in tissue banking. In most cases nonprofit tissue banks make the actual request and procurement of the tissue. However, the tissue is often processed by for-profit companies.

These companies use the majority of the tissues for medically necessary or medically useful purposes. A portion may also be used for cosmetic purposes. In a May 19, 2000, article by Arthur Allen,[1] Glenn Greenleaf, a LifeCell official, stated that 80 percent of Alloderm, a LifeCell product, goes to treat burn victims while the remaining 20 percent is shipped to plastic surgeons who may use tissue for both reconstructive and cosmetic surgery.

To understand the difference between reconstructive and cosmetic surgery, it may be useful to turn to the American Medical Association's definition. *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.

Examples of off-label usage of tissue products manufactured for cosmetic surgery or the treatment of burns include enhancement of lips or other body parts, including penile enlargements. The U.S. Department of Health and Human Services' Office of Inspector General (OIG) reported in its 2001 study of oversight and informed-consent issues: "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."

The OIG found that donors were very concerned with whether donated tissue was being used for some commercial purpose that they did not have in mind. In response to criticism brought out in various newspaper articles, some tissue banks are reviewing this practice and have at least included these points in the *written* informed-consent form. A few have included this information in the telephone request. No federal or state law requires that a written consent form be given to a donating family.

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[1] www.salon.com/health/log/2000/05/19/selling_body_parts.

Responses to Consent Issues

The National Donor Family Council (NDFC), representing 8,000 donor families, released a statement in October of 2000 calling upon the tissue community to give families all the information they need and want to make an informed decision at the time of donation.

The NDFC stated that the informed consent of the donor family must involve a voluntary decision based on full disclosure of the facts prior to the consent. Full disclosure, it states, includes several key elements:

- General information on the tissue-donation process;
- What tissues can be recovered based on medical suitability;
- How tissues can be used or modified in transplantation, for medical research and/or for education;
- The fact that use of tissues can be limited or restricted by the donor family.

In addition, NDFC believes that a completed consent form must be reviewed with the donor family before final consent, and a copy of it offered to the family.

AATB, the Association of Organ Procurement Organizations and the Eye Bank Association of America collaborated and developed a white paper entitled *Model Elements of Informed Consent for Organ and Tissue Donation* that lays out all of the components of informed consent they believe should be covered. *Optional* elements that could be discussed, when a donor family inquires, include an explanation that transplantation may include reconstructive and aesthetic surgery and an explanation that multiple organizations (nonprofit and/or for-profit) may be involved in facilitating gifts of tissue.

Some individual tissue banks have exceeded these standards by including in their telephonic and/or written informed-consent procedures and documents that for-profit companies may be involved and/or that some tissues may be used for cosmetic purposes. Examples of organizations operating in California that have done this include DCI Donor Services; UCSF Tissue Bank; Tissue Banks International, Inc.; Inland Eye and Tissue Bank; California Transplant Donor Network; and Sierra Eye and Tissue Donor Services.

Examples of tissue banks operating in California that do not include information on their consent forms relative to the involvement of for-profit companies or the fact that some tissue may be used for cosmetic purposes include California Transplant Services, Inc., in Carlsbad; Orange County Eye and Tissue Bank; and the Pacific Coast Tissue Bank.

In its capacity as the operator of the University of California, San Francisco, Tissue Bank (UCSFTB), a spokesperson for the nonprofit Musculoskeletal Transplant Foundation (MTF) advises that UCSFTB provides its donor families with the ability to "opt out" of having their tissue donations processed by for-profit companies or used for cosmetic purposes. A potential donor family is told by UCSFTB that tissue may be used for cosmetic purposes, or that a for-profit company may be involved. If the family objects, their concerns/requests are noted in a space provided on UCSFTB's informed-consent form.

According to LifeCell (where UCSFTB sends donor tissue for processing), if a family objected to cosmetic use, LifeCell would not provide the product to a non-hospital facility, since that's where most cosmetic surgeries are performed. If a family doesn't want a for-profit company to process the musculoskeletal tissues, UCSFTB can offer that option. MTF processes 75 percent of all musculoskeletal tissue sent to it by various recovery organizations, with the remaining 25 percent being processed contractually by Osteotech, a for-profit company. MTF and UCSFTB advise that they have experienced only a very rare refusal to donate as a result of providing this information to the family members.

Unless tissue banks make special arrangements with a tissue processor, as UCSFTB/MTF have done with LifeCell, it can be difficult to track use of allografts produced by companies such as LifeCell. LifeCell manufactures Alloderm, which is processed from donated skin and provided to surgeons for use in both reconstructive and cosmetic surgeries. Once Alloderm has been provided to a surgeon, it is difficult to monitor whether the allograft will be used for reconstructive or cosmetic surgery. However, as stated above, UCSFTB/MTF have been able to establish a process with LifeCell to accommodate family wishes to avoid use of particular skin-tissue donations for cosmetic purposes.

According to Tissue Bank International, it would be difficult to confine the use of donated *cardiovascular* tissues to charity or nonprofit organizations, since nearly all of the processors are commercial organizations or use commercial organizations to distribute processed valves and vascular conduits. There is some charity cardiovascular distribution, but it would be difficult to ensure all tissues from a particular donor could be distributed exclusively for charity work. DCI Donor Services advises that if a donor or donor family objects to cardiovascular tissue being utilized by for-profit companies, they comply with those wishes and do not recover that particular tissue.

Legislation was adopted in 2000 – AB 2167 (Gallegos), Chapter 829 – that requires DHS to examine and evaluate many of these same issues related to tissue banks and report back to the Legislature by January 1, 2003. This report has not been released as of this writing. The legislation requested DHS to look at the administrative expenditures of tissue banks and their use of informed consent, including recommendations for

improving and expanding informed consent policy. It also requires DHS to review the requirements for full disclosure by tissue banks to donors of all potential uses of donated and recovered tissue. DHS was to evaluate a system in which individuals with medically necessary conditions would be given priority for donated tissues and the feasibility of state subsidies to implement the system. Finally, DHS also was to evaluate the process for tissue recovery and distribution, including recommendations for improvement where necessary.

Options

- Require that each OPO, hospital, tissue bank and any other entity that recovers tissue to include information on its informed-consent form that it works with both nonprofit and for-profit tissue processors and that there is a possibility that some tissue may be used for cosmetic purposes.

- Require that a copy of the signed informed-consent form be offered to the donor's family.

- Require tissue banks to accommodate the wishes of donor families whenever feasible should they not want donated skin to be used by a for-profit tissue bank or for cosmetic purposes.

Training of Personnel

There have been news reports of improper solicitation methods being used by an employee of one tissue bank in California. In the instance described, an employee told a woman whose son had died in an automobile accident that there was a burn victim in dire need of her son's skin. Although she hesitated at first, upon hearing of this, she agreed to donate her son's tissue to the tissue bank. However, no such burn victim existed.

In Florida and in California, there were reports of tissue banks paying their employees bonuses based upon the number of consents they were able to obtain.

It is not known whether practices of this type are widespread. However, the staff of the U.S. Senate Committee on Governmental Affairs has expressed concerns over the widely divergent training given to persons who solicit tissue donations on behalf of tissue banks.

Many tissue banks rely on staff from other organizations to obtain consent. The OIG interviewed 25 banks that recover tissue. It found that 14 of them relied primarily on their own staff to request consent from families, while 11 relied on others to make the requests. The AATB, in an informal survey of its members, found that 42 percent of accredited tissue banks used their own staff to request consent for tissue donations, while the other 58 percent used individuals not employed by the bank. About half of the external requestors were from OPOs. Other requestors may come from telephone triage agencies, or be chaplains or social workers. OPOs who are responsible for training hospital personnel on seeking organ donations will also train hospital employees in seeking tissue donations.

When tissue banks use their own personnel, the banks conduct the training and monitoring of their own employees. This training is usually quite extensive and is carried out by organizations with long-standing experience. However, it is much more difficult for tissue banks to assure

that employees from other organizations, other than the OPOs, are sufficiently trained.

The AATB offers a certification program for tissue-bank personnel. In addition, training of all employees will be required when the FDA's "Good Tissue Practices" regulations are adopted this year or in 2004.

As mentioned previously, AB 2209 (Speier/Chapter 801/1991) called upon DHS to adopt regulations relating to training of tissue-bank personnel, but this has not been completed to date.

Options

- As a condition of state licensure, require all tissue banks to certify that their donation requestors, whether full-time or per-diem employees, have received training equivalent to the certification program offered by AATB.

- Wait until the federal regulations on "Good Tissue Practices" are adopted and determine what, if any, enhancements are needed to those requirements.

- Prohibit tissue banks from paying employees bonuses based upon the number of donation consents received

For-Profit and Nonprofit Tissue Banks

Tissue banking is a fast-growing industry. It is anticipated that within three years the industry will have achieved revenues approaching $1 billion. According to an Orange County Register article published in 2000:

> *A typical donor produces $14,000 to $34,000 in sales for the nonprofits, but yields can be far greater. Skin, tendons, heart valves, veins and corneas are listed at about $110,000. Add bone from the same body and one cadaver can be worth about $220,000. Tissue banks and companies often share revenue.*[2]

The National Organ Transplant Act 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." The act permits recovery of reasonable costs associated with activities such as retrieval and processing, although the courts have never defined the term "reasonable costs."

There is no question that for-profit firms provide a vital service in developing new products and advancing science. These advances are achieved through investment in research and technology that are made possible through the profits associated with the sale of medical products made from donated tissue.

According to Martha Anderson, chief of donor services for the Musculoskeletal Transplant Foundation, it is likely that only the largest of the nonprofit tissue banks are, or will be, in a financial position to compete with the for-profits in this regard. The reality is that hospitals and surgeons demand these tissue products in order to treat their patients, and, for the most part, the for-profit sector of tissue banking has been the only sector capable of meeting the demand.

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[2] Katches, Mark, et al., *Donors don't realize they are fueling a lucrative business,* Orange County Register*,* April 6, 2000.

Tissue banks associate with for-profit companies in order to benefit from new technology and research. They also associate with these processing companies to assure that there is a consistent need for the tissue they procure. Burn centers, for instance, cannot anticipate the volume of skin that will be needed to treat burn victims and their needs are not consistent.

There have been examples of for-profit companies investing in the startup of nonprofit companies and vice versa. For example, Musculoskeletal Transplant Foundation, a nonprofit company, was started by a $10 million investment from Osteotech, a for-profit company that processes bone, tendons and ligaments into various kinds of grafts that are used for orthopedic and neurosurgical patients. According to MTF, if it didn't use Osteotech for processing, the bone itself could not be used in as many medically beneficial ways.

In Florida, the nonprofit University of Florida Tissue Bank spun off a private firm, Regeneration Technologies, Inc. According to the Orange County Register article:

> *The nonprofit's top executive, Nancy Holland, doubles as the private company's vice president. She keeps both business cards on hand. The tissue bank and the private firm share office space and phone lines. The nonprofit tissue bank sends bone to the for-profit firm.*

According to Jim Warren, editor and publisher of Transplant News, all the major tissue-banking entities have alliances and agreements with one another. For example, one chart he has seen shows that five major nonprofit tissue banks – LifeLink, LifeNet, AlloSources, American Red Cross and Musculoskeletal Foundation all have agreements with multiple for-profit tissue companies.

As a condition for Medicare participation, OPOs are specifically required to include on their boards of directors not only members who represent hospital administrators, tissue banks, voluntary health associations and emergency room personnel, but several members who represent the public residing in that area. No such requirements exist for the nonprofit or for-profit tissue banks.

In interviews with donors, the Office of the Inspector General found that families did not seem overly concerned that a profit is made by those tissue banks that process and develop tissue into various life-saving or life-enhancing products – but families did not want excessive profiteering. The OIG could not find a handle on what is excessive or what constitutes profiteering, however. It decided that the key lies in providing information so that the donors can make up their own minds about what to do.

The OIG in its report, *Informed Consent in Tissue Donation,* released in January of 2001, stated:

> *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 the financial benefit to its stockholders, is it making choices to put tissue to more lucrative uses over medical needs?*

Nonprofit tissue banks have expressed concern that for-profit companies are able to pay more for skin tissue than they can. The Orange County Register quoted LifeCell President Paul Thomas as saying, "Plastic surgery is a much bigger opportunity and offers better reimbursement." Companies charge plastic surgeons more for skin products than they charge to burn centers – nearly four times as much. The OIG report also states:

> *A second facet of tension with commercialization relates to the level of salaries and costs incurred by both nonprofit 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.*

Nonprofits are required to file IRS Form 990, a useful document for understanding some aspects of the mission, programs and finances of an organization. Included in this document is a listing of the salaries paid to top management and a listing of sources from which revenue is derived. Musculoskeletal Transplant Foundation, one of the largest nonprofit tissue banks in the country, disclosed in its Form 990 for 2000 that it paid its CEO a salary of $367,951.

Pacific Coast Tissue Bank, a nonprofit located in Los Angeles, paid its president, Ed Gendler, $427,160 during that same year, down from $533,450 in 1997 and 1998. The president's wife, Simona Gendler, runs a for-profit company, Perfomat, Inc., and received $20.6 million in fees from Pacific Coast Tissue Bank. This represents 50 percent of Pacific Coast's revenue for processing. The state attorney general is investigating whether Pacific Coast directs too much money to the for-profit venture of the family.

On the for-profit side, Cryolife, the largest processor of cardiovascular tissue, paid its CEO $600,000 and a bonus of $300,000 during a recent annual reporting period. The CEO also owns stock in the company worth tens of millions of dollars.

As the OIG's report states:

> *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."*

Arthur Caplan, Ph.D, who is chair of the Department of Medical Ethics and director of the Center for Bioethics at the University of Pennsylvania, further told the California Senate Office of Research in an e-mailed comment:

> *Huge salaries and generous compensation are not part of the ethos that defines organ and tissue donation. The altruistic donation of tissue makes it obligatory that those involved not be seen as profiteering from the gifts of the dead. Moreover, incestuous relationships and tie-ins between profit and nonprofit companies in this area will be a disaster for public altruism.*

In a paper written by Dr. Caplan and others, funded by a grant from the Agency for Health Care Policy and Research, there is a discussion regarding altruism serving as the basis for organ and tissue donation:

> *For decades public policymakers and ethicists have argued over whether donor families should be recompensed financially for organs or tissues procurement. The argument that has prevailed was that public policy and law should favor both voluntary choice and altruism because these moral values were consistent with the desire of Americans to respect individual autonomy and liberty and that public policies based on these values might permit an adequate supply of organ and tissues to be obtained from cadaver sources if adequate efforts were made to encourage public altruism.*

In order to acknowledge the altruism involved in tissue donation, the OIG recommended that all tissue processors and distributors should ensure

that information accompanying their products clearly indicates it is derived from *donated* human tissue. According to the OIG:

> *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 should indicate clearly on all marketing and informational material that these products derive from donated human tissue.*

Updating the Issue of Tissue Shortages

The Orange County Register in its April 2000 series on tissue donations reported instances in California and elsewhere in the United States where a number of burn centers were having difficulty obtaining tissue needed for skin grafts.

To determine whether skin for grafts for burn victims is *currently* in short supply, the California Senate Office of Research requested that DHS contact the 15 burn centers located in California with this question. The department was able to contact 13 of the centers and was informed that no burn center had experienced a shortage of supply of skin to treat burn victims within the last several years. In addition, DHS advises that the tissue-licensure program has not received a single report of a shortage of any tissue since it was created in 1992.

The AATB also surveyed its members to determine if there is a shortage of skin, and was able to identify 1,500 to 2,000 square feet of available skin at any one time. In March of 2001, AATB set up an 800-number emergency hotline that burn centers could contact should they experience a shortage of skin. More than 150 letters announcing the 800 number were sent to burn center directors throughout the United States. If a center was experiencing a skin shortage, it was instructed to call the hotline, and the AATB would help locate available skin. A second mailing was sent on April 11. To date, no calls have been received on this hotline.

Options

- Require for-profit tissue-processing companies to file annually with DHS a form, similar to the Form 990 that is required of all nonprofit tissue-processors, detailing sources of revenue, annual salaries paid to top management, purposes for which tissues are used, etc.

- In order to produce much greater transparency in the financial operations of tissue banks, require both nonprofits and for-profits to disclose all entities with which they have financial arrangements. This disclosure could be required as part of the information on the form

mentioned above or in the requirements for initial state licensure and updated with each renewal. It could also be required on the informed-consent form.

- Require for-profit and nonprofit companies to include public members on their boards of directors.

- As an extension of charitable trust doctrine and in recognition of the altruistic nature of gifts of human tissue, require payments by for-profit tissue companies for tissue received from nonprofit tissue banks to be based on the fair market value of the tissue. Require proceeds from the sale of tissue by nonprofit tissue banks to private tissue companies that are beyond the bank's costs of acquiring, storing, processing and transferring the tissue to be placed in a charitable trust, and used for charitable purposes. These could include education on the tissue donation process and/or making tissue products and procedures available for uninsured and underinsured populations.

- Require all California tissue processors and distributors to clearly specify that their products are derived from donated human tissue.

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Tom Favor, Tissue Bank Coordinator, New York State Department of Health

Melissa Honohan, Policy Manager, Association of Organ Procurement Organizations

Arthur Caplan, Chair, Department of Medical Ethics and Director of the Center for Bioethics at the University of Pennsylvania

Jim Warren, Editor and Publisher of Transplant News

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Robert Rigney, Executive Director of the American Association of Tissue Banks

Phyllis G. Weber, Executive Director of the California Transplant Donor Network

Lorrie McNeill, Director of the Division of Communication and Consumer Affairs of the Food and Drug Administration

Sarah Ockler, National Donor Family Council

In addition, an extensive set of questions was submitted to the California Department of Health Services and the answers to these questions are incorporated throughout this memorandum.