Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

Oversight of Tissue Banking

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EXECUTIVE SUMMARY

PURPOSE

To provide a profile of the current external oversight system for tissue banking, and to identify limitations in that system.

BACKGROUND

Human tissue is an important resource for medical treatment. For example, it is used in burn treatment, reconstructive surgery, cancer care, and heart valve replacement.

Tissue from one donor can be processed into many forms and used to treat many people. The exact number of donors is not known, but it is growing. In 1999, more than 20,000 donors provided cadaveric tissue, up from perhaps 6,000 donors in 1994. It is estimated that tissue banks distributed more than 750,000 allografts for transplantation in 1999.

Human tissue can transmit disease. In the early 1990's two events raised major concerns. First, HIV was transmitted from one infected donor to several recipients of organs and unprocessed tissues. Second, investigators from the Food and Drug Administration (FDA) found instances of domestic suppliers accepting foreign tissue that had not been tested or screened; in one case the FDA found tissue that tested positive for Hepatitis B.

These concerns led FDA to issue an interim final rule in December 1993. FDA modified this regulation and reissued it as a new rule, effective in January 1998. It requires that tissue banks screen and test donors and that they maintain the appropriate records. The rule also provides for FDA inspections of tissue banks and retention, recall, and destruction of tissue that doesn't comply with these requirements.

This report responds to a request from the Secretary of Health and Human Services, asking the Office of Inspector General to examine the oversight system for tissue banking. We analyzed available data related to tissue banking, and we reviewed regulations, laws, and standards. We interviewed staff from FDA, from 30 tissue banks, and from associations representing various sectors of the tissue banking industry.

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. Our report does not address eyes and reproductive tissue.

PROFILE OF TISSUE BANKING OVERSIGHT

Oversight of tissue banking takes place at three levels:

- **The Food and Drug Administration** focuses on preventing transmission of

communicable disease by requiring donor screening and testing. FDA has conducted 188 inspections of 118 tissue banks since 1993. The agency has proposed two regulations and is developing a third that would expand its oversight of tissue banking. These regulations would require registration of all tissue banks, expanded screening and testing, and use of good tissue practices, akin to good manufacturing practices.

- **The American Association of Tissue Banks** (AATB) conducts a voluntary accreditation program. While AATB currently accredits 58 tissue banks, we identified another 90 that are not accredited. 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.

- **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 tissue procurement processes, tracking practices, 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.

LIMITATIONS IN TISSUE BANKING OVERSIGHT

No new cases of disease transmission through human tissue have been identified since the FDA's 1993 regulation. This absence of new cases points to significant strengths and accomplishments in the current system which has focused on preventing the spread of communicable disease. Nevertheless, in the course of this limited inquiry, 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. Banks have failed to meet basic standards of the AATB and been denied accreditation. States have received notification of adverse incidents involving tissue.

The rapid development of the tissue banking field means that traditional oversight methods may not keep pace with growth and changes in the industry. Consequently, thoughtful consideration needs to be given to the nature of any oversight approach.

Below, we outline limitations and vulnerabilities in current approaches, and we offer a combination of options that, taken singularly or in combination, could provide a way of enhancing oversight of the tissue banking field.

FDA oversight

Some tissue banks have never been inspected by FDA. We found at least 36 tissue banks that have never been inspected, out of 154 tissue establishments that we were able to identify. FDA has indicated that regulation of tissue banks is an unfunded mandate, and that in order to carry out these inspections, the agency has had to borrow resources

from other programs, such as blood and plasma.

FDA lacks a prescribed cycle for reinspection of tissue banks. Of 118 tissue banks that FDA has inspected, 68 have been inspected only once. Due to limited resources, the agency has had to establish a priority list for followup inspections. The first priority is reinspection of firms whose previous inspection was classified as Official Action Indicated, the most serious level of deficiency.

The number and location of tissue banks are unknown. Information is lacking about the number of tissue banks in operation and the products they produce and distribute. FDA has proposed a regulation to require tissue banks to register and list their products. The regulation would address directly this limitation in knowledge about tissue banking.

The scope of FDA's current regulation is limited. Because the agency's current regulation focuses on donor screening and testing to prevent transmission of HIV-1 and -2 and Hepatitis B and C, other important aspects of tissue bank quality are not monitored. Until FDA's good tissue practices rule 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.

Private accreditation

Many banks do not seek AATB accreditation. AATB accredits 58 tissue banks. However, 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. For many tissue banks there is no real incentive to seek accreditation. There are a number of ways to encourage private accreditation of tissue banks. For example, FDA could provide technical advice and information that could be used in developing standards. FDA also could consider in what areas, if any, the agency could accept accreditation as showing compliance with FDA regulations. In such a case, legislation would be needed.

State oversight

Only two States inspect tissue banks. In many ways, these inspections go beyond FDA requirements; yet the inspections are limited to banks that conduct business in Florida and New York. Other States could give consideration as to whether they wish to regulate tissue banking and, if so, how they would coordinate with other entities to limit redundancy and regulatory burden.

Information on supply and availability of tissue

Concerns about shortages. There is no national system for tracking the availability of tissue. Two recent surveys by industry representatives raised concerns that skin may not be available when needed for treating burn victims. However, some shortcomings in these studies suggest that additional research is warranted to examine the extent and implications of shortages of tissues.

RECOMMENDATIONS

The Food and Drug Administration should expedite the publication of its regulatory agenda that requires registration of tissue banks, enhanced donor suitability screening and testing, and the use of good tissue practices.

At present, FDA is able to inspect only those banks that it knows about. Requiring registration of all tissue banks would ensure that the agency has a comprehensive list of tissue banks as a first step in assuring their compliance with standards.

In addition, many tissue banks are neither accredited by the AATB nor licensed and inspected by New York or Florida. Those banks that are not accredited or inspected do not have to meet any standards beyond the current FDA minimum requirements that they screen and test tissue donors for HIV and hepatitis.

FDA should set a realistic, yet aggressive, date by which it would complete an initial inspection of all tissue banks.

This could be accomplished under FDA's existing regulatory authority. Establishing a baseline of information will provide a minimum level of assurance that tissue banks are meeting basic public health and safety standards to prevent transmission of communicable diseases.

FDA should determine an appropriate minimum cycle for tissue bank inspections.

This, too, could be accomplished under FDA's existing regulatory authority. A minimum cycle for inspections would help ensure that tissue banks are meeting standards on an ongoing basis.

FDA should work with States and with professional associations that have inspection and accreditation programs to determine in what areas, if any, oversight activities could be coordinated.

FDA, the industry, and the States with regulatory programs could benefit from examining where standards are in agreement, as well as areas in which standards might conflict. Following such an examination, determination could be made of whether formal partnership or other arrangements would be appropriate to maximize the effectiveness of the oversight process. Such arrangements could require enactment of legislation.

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 B.

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.