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Introduction

Good morning, Madam Chairman and Members of the Committee. Thank you for inviting the Food and Drug Administration (FDA or the Agency) to participate in this hearing concerning human tissue banking. I am Dr. Kathryn C. Zoon, Director, Center for Biologics Evaluation and Research (CBER), FDA. CBER is the FDA Center responsible for regulation of many of the different types of human tissue and cells used in transplantation. I will provide background information on the regulation of human tissue for transplantation and FDA's current and future actions to help ensure the safety and availability of these products.

Transplanted human tissue products have the potential to treat or cure a wide variety of health conditions. Similar to any medical product or therapy, however, such transplants are not risk-free. FDA aims to help ensure that establishments take appropriate precautions to minimize the risks of transplanted human tissue.

The Agency's involvement in the regulation of human tissue is not new. FDA regulates tissue under the authority of the Public Health Service Act (PHS Act) and the Federal Food, Drug, and Cosmetic Act (FD&C Act). Several categories of

human tissue used for transplantation are being regulated as medical devices under the 1976 Medical Device Amendments. Many cellular and tissue products not categorized as medical devices are regulated by FDA as "biological products" under both the PHS Act and FD&C Act. Other cells, tissues, and cellular and tissue-based products are regulated solely under the communicable disease provisions of the PHS Act.

I am here today to talk about products primarily regulated by CBER and the many steps that FDA has taken in the past decade along with present and future actions to help ensure the safety of these products.

Background

FDA's goals with regard to human tissues are to prevent the spread of communicable disease; ensure that safety and efficacy is demonstrated for cellular and tissue-based drug, biological, and medical device products; enhance public confidence in these products; and, to accomplish these goals through implementing regulations in a manner that will not discourage the development of new products.

The term "tissue" covers products which have long been transplanted for widespread medical uses--such as skin

replacement after severe burns; tendons and ligaments to repair injuries; bone replacement; and, corneas to restore eyesight. Over the past decade, improved technology and techniques have expanded and enhanced the variety of potential therapeutic uses of tissue-based products. These new techniques hold the potential of providing therapies for cancer, AIDS, Parkinson's Disease, hemophilia, anemia, diabetes, and other serious conditions.

With the increased use of human tissue has come a heightened public awareness of the need for appropriate regulation to minimize the potential risks. Developments in the 1980s and 1990s prompted FDA to examine our approach to the regulation of tissue. Several incidents illustrated the risks of disease transmission when adequate precautions were not taken.

- In the 1980s, there have been multiple incidents of CJD transmission by dura mater (a brain covering) allograft due to pooling during manufacture.
- In 1991 it was discovered that seven people had been infected with Human Immunodeficiency Virus (HIV) through the transplantation of whole vascularized organs and tissue from a donor who tested negative for HIV. This led to intense discussions within the tissue bank community and the Public Health Service (PHS) on how to reduce the risk of infectious diseases from transplanted human tissues.

- There have been documented instances of distribution of tissue from donors who tested repeatedly reactive for hepatitis B (HBV).

- In October 1993, FDA learned that human tissue from foreign sources was being offered for sale in the United States with little or no documentation as to the source of the tissue. There was little, if any, information on the cause of the donor's death, the medical condition of the donor, or the results of donor screening and testing. This raised significant concerns about the safety and quality of the human tissue. The Agency quickly confirmed that the tissue had not been adequately screened and tested for infectious diseases.

- More recently, in 1999 a patient died from cardiac arrest during surgery to remove an infected corneal transplant. The probable source of the infection was contamination of the media that had been used to store the cornea.

- This year, significant bacterial contamination of patellar tendons resulted in two patients developing septic knees; one required removal of the graft. The establishment's procedures for irradiating the product to remove potential bacterial contamination were not followed.

Presently, heightened public awareness has resulted from various media articles including the Orange County Register series in April 2000 on the collection practices of local tissue banks.

FDA has prioritized the regulation of human cellular and tissue-based products, and the public should be confident that FDA is committed to regulating these products in a

manner where benefits to patients are maximized and risks to patients are minimized.

FDA's Approach to Tissue Regulation

After careful consideration of the myriad health issues and extensive public discussion, FDA published the "Proposed Approach to the Regulation of Cellular and Tissue-Based Products" on February 28, 1997. This document described FDA's planned regulatory framework for human cellular and tissue product regulation. Subsequently, FDA accomplished many of the regulatory goals described in the February 1997 document through publication of a series of proposed and final rules.

The 1997 Proposed Approach provided for a unified approach to the regulation of both traditional and new products. Additionally, the framework detailed the type of regulation necessary to protect the public health as applicable to different products. This framework provided a risk-based tiered approach to cell and tissue regulation. For human cells and tissue products with limited public health risk, FDA proposed regulation to prevent communicable disease transmission. For products that pose greater health risk,

the framework additionally provided for premarket review and approval of product applications.

FDA's Proposed Approach document focused on necessary actions needed to prevent the unwitting use of contaminated tissues with the potential for transmitting infectious diseases such as AIDS and hepatitis; preventing improper handling or processing that might contaminate or damage tissues; and, helping to ensure that clinical safety and effectiveness are demonstrated for tissues regulated as drugs, biological products and medical devices.

Tissue Action Plan

When FDA published the "Proposed Approach to the Regulation of Cellular and Tissue-based Products" in February 1997, we realized a blueprint was needed to implement the approach, including prescribed time frames for our planned actions. The Tissue Action Plan (TAP or action plan), implemented in March 1998, was the manifestation of this blueprint. The TAP contained a description of the steps FDA would take to create a tissue framework and respond to various recommendations by other organizations that are described below. TAP has been instrumental in implementing FDA's proposed framework for the regulation of human tissue.

In order to provide overall direction and coordination, a TAP Core Team was created with representation from various CBER Offices, the Center for Devices and Radiological Health (CDRH), and the Office of the Commissioner (Office of Policy, Office of Regulatory Affairs, and Office of Chief Counsel). The Core Team meets monthly to ensure progress in fulfilling TAP action steps; disseminate information externally; decide policy issues; and, finalize TAP documents.

FDA formed eleven task groups that meet on a routine basis, in accordance with set milestones. The task groups developed regulations and guidance in areas such as establishment registration, donor suitability, current good tissue practices (GTP), compliance and inspections.

As specified in the Proposed Approach document and action plan, FDA established the Tissue Reference Group (TRG), which provides a single reference point for product specific questions. The TRG considers the appropriate review criteria, responds to inquiries from the cellular and tissue product industry, identifies areas needing scientific or

policy development, and interacts with FDA's Ombudsman on product jurisdiction requests.

Rulemaking

After the tissue incidents of the 1990s, but prior to publication of the proposed approach document, FDA took actions to minimize the risk of disease transmission. On December 14, 1993, FDA issued an "Interim Rule for Human Tissue for Transplantation" (58 FR 65514) which required donor screening, infectious disease testing, and record keeping to prevent the transmission of infectious diseases through human tissue used in transplantation. The regulation applied to "conventional" human transplanted tissues (musculoskeletal, skin, ocular) but did not encompass tissue used in cellular therapies. Additionally, the regulation excluded semen and other reproductive tissue, human milk, bone marrow, and vascularized human organs, such as heart, kidney, liver, lung and pancreas. Under the regulation, FDA could conduct inspections and, when necessary, detain, recall, or destroy tissue. The Interim Rule was made final, with some modification, on July 29, 1997, now Title 21, Code of Federal Regulations (21 CFR) Part 1270.

As noted previously, FDA then created the proposed approach document. To implement the proposed approach, and in accordance with the action plan, FDA subsequently published three proposed rules that included requirements for establishment registration and product listing; donor suitability determination; and good tissue practice. Information on FDA's proposed and final rules that pertain to tissue are summarized in the chart below, and an explanation in greater detail follows:

Publication Date	Rule Type	Title of Rule	Effective Date	Numb. Of Comments
12/14/93	Interim	Human Tissue for Transplantation	12/14/93	73
07/29/97	Final	Human Tissue Intended for Transplantation	1/26/98	NA
05/14/98	Proposed	Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue Based Product	N/A	28
09/30/99	Proposed	Suitability Determination for Donors of Human Cellular and Tissue-Based Products	N/A	481
04/18/00	Proposed	Reopening of Comment Period: Suitability Determination for Donors of Human Cellular and Tissue-Based Products (Reopen for 90 Days)	N/A	77
01/08/01	Proposed	Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products: Inspection and Enforcement	N/A	34 as of 5/15/01
01/19/01	Final	Human Cells, Tissues, and Cellular and Tissue Based Products; Establishment Registration and Listing	Staggered 75 days & 2 years	NA

As referenced in the chart above, FDA finalized the first of three rules on January 19, 2001 (66 FR 5447), entitled, "Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing." This rule requires establishments to register and list with the Agency their human cell, tissues, and cellular and tissue-based products. This rule is intended to identify establishments that engage in the recovery, screening, testing, processing, storage, or distribution of human tissue intended for transplantation. Under the registration final rule, establishments engaged in these activities with conventional tissues, such as bone, skin, and corneas, are required to register and list their products by May 4, 2001. New establishments involved in the manufacturing of conventional tissue must register and list within 5 days after beginning operations. Other establishments that manufacture non-conventional or new cellular or tissue-based products, such as hematopoietic stem cells, are required to register and list beginning January 19, 2003.

In order to prevent the spread of communicable diseases, it is necessary to screen and test donors of cells and tissues.

FDA published a proposed rule "Suitability Determination for Donors of Human Cellular and Tissue-Based Products" (64 FR 52696) on September 30, 1999. Disease agents such as HIV, HBV, hepatitis C virus (HCV), syphilis and the agent of Creutzfeldt Jakob desease (CJD) have been detected in human tissue, including bone, skin, corneas, and semen. The proposed rule would expand current screening and testing requirements to include donor screening for CJD and donor testing for syphilis. In addition, donors of leukocyte-rich cells or tissues would be tested for Human T-cell Lymphotropic Virus type I and type II (HTLV-I/II) and Cytomegalovirus (CMV). A donor who tested repeatedly reactive for a particular disease agent, or who possessed clinical evidence of or risk factors for such a disease, would be considered unsuitable, and cells and tissues from that donor would not ordinarily be used. The Agency is reviewing comments on the rule, which has not yet been finalized.

Because tissue establishments perform various functions that can affect the safety and quality of tissue products, FDA published a proposed rule for "Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement" (66 FR 1508) on

January 8, 2001. With this proposed rule, FDA completed the set of proposals that, when finalized, implement the new regulatory framework. The proposed rule would require manufacturers to follow current GTP, which is critical in ensuring the quality of tissue products. GTP include practices involving the methods, facilities, and controls used in tissue manufacture, and the establishment of a quality control program. FDA is in the process of carefully reviewing all comments received in response to this proposed rule.

Implementation Costs

In Fiscal Year (FY) 2002, FDA estimates that the Agency will dedicate $4.35 million to the regulation of human tissue. This is part of the President's FY 2002 budget request for FDA, which represents a ten percent increase for the Agency over the FY 2001 level. Estimates of the implementation of the tissue regulation will be developed as part of the FY 2003 budget process and may be revised as we garner additional information from future establishment registrations. Such additional information will help us determine with greater accuracy the amount of time and resources that will be needed to conduct inspections and other compliance related activities.

Tissue Inspections

FDA conducts on-site inspections of tissue establishments to determine compliance with FDA regulations. At the conclusion of the inspection, FDA's investigator may issue a notice of inspection observations (FDA Form 483) concerning potential deficiencies from regulatory requirements. The investigator will discuss the observations with the most responsible official at the establishment. Based on those observations, FDA classifies the establishment according to the corrective action steps indicated by the inspection.

The three classifications are: Official Action Indicated (OAI), Voluntary Action Indicated (VAI), or No Action Indicated (NAI). A chart indicating the results of 380 FDA inspections of tissue establishments between October 1, 1993, and November 6, 2000, is provided below:

Fiscal	Inspection	District Decision		
Year	Count	NAI	VAI	OAI
94	41	25	6	9
95	30	9	7	12
96	4	1	3	0
97	36	16	13	3
98	111	54	47	7
99	65	26	33	4
00	93	54	29	8
Total	380	185	138	43

For various reasons, 14 of the inspections are not in the database. As a result of these 380 inspections, FDA has taken the following actions: Fifteen orders for retention or recall; six warning letters; and, nine opportunities for Voluntary Corrective Action Letters. Further, the number of voluntary recalls of banked human tissue has increased from three in FY 1994 to 24 in FY 2000. From the beginning of the current FY until April 30, 2001, there have been 12 recalls.

Pooling

FDA has concerns about the practice of pooling tissues from multiple donors during processing. In general, FDA believes that the risks associated with pooling tissues from multiple donors appear to outweigh any identified medical benefits. Risks include exposure and possible cross-contamination from one tissue to another tissue of such infectious disease agents as viruses (enveloped and non-enveloped), bacteria, fungi, and prions, including known and emerging infectious agents.

FDA's January 8, 2001, proposed rule "Current Good Tissue Practice for Manufacturing of Human Cellular Tissue-Based Products; Inspection and Enforcement," (66 FR 1508) provides that human cells and tissue shall not be pooled, that is, placed in physical contact or mixed in a single receptacle, during manufacturing because of the risk of exposure to infectious agents. FDA is currently reviewing comments to this proposed rule.

Office of the Inspector General/General Accounting Office Recommendations

In January 2001, the Department of Health and Human Services' (DHHS) Office of the Inspector General (OIG)

issued a report entitled, "Oversight of Tissue Banking." This report contained a number of observations and recommendations relevant to FDA's regulation of tissues (the report did not address eye banks), and several recommendations for other DHHS agencies. FDA is committed to taking actions to address the findings. The OIG recommendations are listed below followed by FDA's actions:

- **FDA 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.**

  All three of the proposed rules have been published; and the Establishment Registration and Listing Rule was finalized January 8, 2001.

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

  The OIG reported that 36 tissue banks had never been inspected by FDA. FDA intends to inspect these 36 and all other uninspected establishments in our inventory. Inspections of new firms identified as the result of the registration and listing rule will take priority for FY 2002 over inspections of firms previously covered by FDA and found non-violative.

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

  The Agency established a prioritized scheme several years ago for the inspection of tissue establishments. Our priorities, from highest to lowest, include: firms previously violative, firms about which we have received complaints, firms never inspected and which are known to lack accreditation by a standard setting organization such as American Association of Tissue Banks (AATB) or Eye Bank Association of America (EBAA), firms never

inspected and which are known to be accredited, and firms which were previously inspected and found not violative.

- **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 recognizes that States and professional associations have an important role in the quality of tissue available. States and professional associations, however, may have different concerns and interests than FDA's. Accrediting organizations and State-regulated programs may cover fewer types of human cells, tissues, and cellular and tissue-based products and may set standards that would not cover the entire spectrum of products. Moreover, the goals of professional organizations differ in several critical ways from regulatory oversight programs. Such accrediting organizations often work with tissue establishments to attempt to bring them into compliance with their standards, but lack enforcement authorities. FDA's goals are to protect the public from unsafe tissue products and the Agency uses a variety of enforcement tools to help ensure public health and safety.

In other product areas, FDA has entered into mutually beneficial contracts with States to perform FDA inspections. This has been successful in areas where the State law parallels the Federal law and there has been sufficient experience with the regulatory program to standardize inspections. When these elements are present, FDA plans to seek ways to establish similar partnerships with such States.

The issue of how to best implement a comprehensive, resource efficient program of on-site inspections of tissue establishments is complex. We are aware of tissue recalls and market withdrawals conducted by firms, which are accredited, so accreditation can not be seen as an absolute guarantee of safety and suitability. FDA is carefully evaluating the recommendations of the OIG concerning the overall regulatory framework for tissues, including how to best assure adequate inspectional coverage.

For now, the Agency believes that FDA biennial surveillance inspections are necessary to determine whether establishments are complying with FDA regulations. FDA can not obtain this information through accrediting bodies or State inspections at this time. We will continue to explore ways to exchange information with accrediting bodies and States.

In December 1997, the General Accounting Office (GAO) published a report entitled, "Human Tissue Banks: FDA Taking Steps to Improve Safety, But Some Concerns Remain." Some of the GAO recommendations are listed below, followed by a summary of FDA progress to date:

- **FDA should move ahead with its plan to require:**

  Tissue facilities including reproductive and stem cell facilities to register with FDA;

  Reproductive and stem cell facilities to adhere to all requirements of the current regulation

  Facilities that collect and store cord blood to provide accurate oral and written communication to consumers with regard to the State of knowledge of collection, processing, and storage techniques, as well as the likelihood of requiring cord blood transplantation, and to portray the risks and benefits relative to other therapies.

FDA has published either proposed or final rules in all three of these areas.

- **FDA should also add to its oversight plans provisions that would require:**

Tissue facilities to obtain informed consent before processing any tissues for transplantation from living donors.

GAO was specifically referring to cord blood. FDA did not agree with this recommendation. FDA believes that seeking informed consent for use of cord blood after collecting umbilical cord blood does not raise any additional safety concerns than would be raised by seeking informed consent before collecting cord blood.

The current cord blood banking protocols, operating under an FDA-accepted IND application, provide the opportunity through data collection to assess the safety and risks of obtaining informed consent after cord blood has been collected. If FDA learns that the timing of informed consent affects the safety of the tissue, the Agency will modify its position.

Tissue facilities to report serious errors and accidents and adverse events to FDA

The proposed GTP rule (§1271.350(a)) would require establishments to report adverse reactions to CBER within 15 days, using FDA Form-3500-A. In addition, the proposed rule would require establishments that become aware of biological product deviations (formerly called "errors and accidents") involving distributed products to determine if they could reasonably be expected to lead to a reportable adverse reaction, and if so, to report the product deviation to CBER's Office of Compliance and Biologics Quality (OCBQ) as soon as possible.

Facilities that collect, store, process, distribute, transplant human tissues to establish validated systems to track tissues to consignees and recipients.

The proposed GTP rule (§1271.290) would require that facilities establish and maintain a method of product tracking that enables the tracking of all products from donor to recipient and vice versa.

Tissue facilities that collect, store, process, or distribute allogeneic peripheral stem cells and any cord blood stem cells to make premarket submissions if

FDA determines that adequate safety and efficacy data are not available to such products.

The comment period for the January 20, 1998, Federal Register (FR) Notice entitled, "Request for Proposed Standards for Unrelated Allogeneic Peripheral and Placental/Umbilical Cord Blood Hematopoetic Stem/Progenitor Cell Products: Request for Comments," closed on July 17, 2000. FDA is currently reviewing the comments submitted to determine whether INDs would be required and/or whether standards could be developed for some of these products. FDA intends to publish a FR Notice when our review is complete and issue more specific guidance as appropriate.

Tissue facilities to inform FDA of the types of processing techniques used on tissues and supply information on the safety and efficacy of these techniques.

Under proposed GTP rule (§1271.220(a)), any establishment engaged in the processing of human cellular and tissue-based products would be required to develop, conduct, control, and monitor its manufacturing processes to ensure that each product: 1) conforms to its specifications, 2) is not contaminated, 3) maintains its function and integrity, and 4) is manufactured so as to prevent transmission of communicable disease by the product.

The proposed GTP rule (§1271.225) would require an establishment to develop and implement procedures for making changes to a process.

The proposed GTP rule (§1271.230(a)) would require establishments to validate their processes where verification is not feasible and validation activities must be documented and maintained at the establishment and made available for review on inspection.

For products that are regulated as drugs, biological products, and medical devices, in addition to regulation under the communicable disease provisions of the PHS Act, FDA reviews premarket applications for safety and efficacy.

Meetings/Outreach

In order to successfully implement Agency plans for the regulation of human tissues, FDA has involved tissue establishments and medical professionals in many public discussions. A list of our meetings and outreach is contained in Appendix I.

In the future, FDA intends to provide opportunity for public discussion on issues related to cellular and tissue-based products. FDA intends to use various venues to continue our dialogue with industry organizations such as the AATB, the EBAA, the American Association of Blood Banks(AABB),the American Society for Reproductive Medicine (ASRM)/Society or Assisted Reproductive Technology (SART), the Foundation for the Accreditation of Hematopoietic Cell Therapy (FAHCT) and the International Society for Hematotherapy and Graft Engineering (ISHAGE).

Conclusion

FDA can assure the Committee that we are committed to establishing a regulatory framework, which not only helps ensure the safe use of human tissue for transplantation, but also allows the development of this technology and instills public confidence. While FDA has taken many steps towards this end, we

realize that more remains to be done.

We look forward to the Committee's continued interest in this area and would be happy to answer any questions.

Appendix I

List of Tissue-Related Meetings, Workshops and Outreach Activities in which FDA participated:

General/Ongoing Interactions with Industry:

FDA presentations/participation at American Association of Tissue Banks (AATB) and Eye Bank Association of America (EBAA)) Annual and Mid-year Meetings

FDA presentations/participation at AATB Reproductive Tissue Council Meetings

FDA presentations/participation at Food and Drug Law Institute (FDLI) and Regulatory Affairs Professional Society (RAPS) meetings

FDA presentations/participation at American Society for Reproductive Medicine (ASRM) annual meetings

FDA site visits to tissue establishments

FDA consultant to the CDC/Industry Task Group developing the model certification program for embryo laboratories under the 1992 Fertility Success Rate and Certification Act

FDA liaisons to ASRM's, National Coalition for Oversight of Assisted Reproductive Technologies (NCOART)

FDA liaisons to AATB Standards and Medical Advisory Committees

Meetings with other Federal/State Agencies:

6/98	Meeting with Japan Health Science Foundation
1998	CDC - Multiple meetings on coordination of reproductive tissue issues
1997	Trilateral meeting between U.S., Canada, Mexico- Mexico City
9/97	HRSA - Discussion of regulation of pancreatic islet tissue
9/97	New York State Deptartment of Health - Meeting with Dr. J. Linden on coordination of Tissue Bank Inspections

7/97	Federal Trade Commission - Discussion of Stem Cell Promotion
Specific Events with Industry:	
5/01	Meeting with EBAA on GTP
4/16/01	FDA/ASRM meeting - Good Tissue Practice Proposed Regulation
3/28/01	Meeting between Health Canada and FDA to discuss the regulation of Human and Xeno Tissue Products.
8/14-15/00	Workshop: Unrelated Allogeneic Cord Blood Banking and Transplant Forum
8/2/00	Open Public Meeting - Human Bone Allograft: Manipulation and Homologous Use in Spine and Other Orthopedic Reconstruction and Repair
6/00	CDC Donor Suitability Workshop
2/10/00	FDA / ASRM Meeting Concerning the Donor Suitability Proposed Regulation
11/17-19/99	AATB QA Workshop, New Orleans, LA - FDA Review of Tissue Bank Inspections; Status of Required Serology Testing; Update Regarding Proposed Regulations
9/99	ASRM - Presentation - FDA Update on Regulation of Reproductive Cells and Tissue.
6/99	EBAA - Presentation on Registration Proposed Rule and Donor Suitability Proposed Rule
6/99	Institute of Science, Law and Technology (ISLAT) informational meeting with FDA to discuss ART issues
4/8/99	Human Tissue Industry Seminar hosted by ASQ and Los Angeles District, Los Angeles, CA

4/99	RESOLVE consumer association informational meeting with FDA to discuss ART issues
3/99	AATB - Presentation on Donor Suitability Proposed Rule
2/9-11/99	FDA Central Region Human Tissue Course for FDA Investigators
12/98	FDA Science Forum on Proposed Approach
11/98	EBAA - Compliance with Final Rule
10/98	ASRM - FDA update on Regulation of Reproductive Cells and Tissue
9/10/98	Workshop: Hematopoietic Stem/Progenitor Cell Products: Discussion of Unrelated Allogeneic/Umbilical Cord Blood and Peripheral Blood Cell Banking and Transplantation
8/98	AATB Annual Meeting - FDA Update and Implications of FDA Regulation of Reproductive Tissue
7/98	AATB Informational meeting with FDA concerning establishment certification and standard development
6/98	EBAA Annual Meeting - Establishment Registration and Listing - proposed rule
5/98	AATB mid-year meeting - FDA - What's Ahead/ CJD and Dura Mater
4/20/98	FDA/AATB Meeting Concerning Summary of Records
4/9/98	Video Conference arranged by FDA Southwest Region and Dallas District on the Regulation of Human Tissue Intended for Transplantation presented to EBAA members located in the Southwestern U.S.
3/98	Training and Review - Regulatory Issues in Tissue Banking

2/98	FDA presentation at CDC and RESOLVE (a federation of infertility patient associations) sponsored meeting "Approaches to A.R.T. Oversight: what's Best in the U.S.".
12/23/97	Workshop: Ethical Issues in Cord Blood Banking
11/97	Meeting with Society of *InVitro* Biology - Proposed Approach
7/11/97	FDA/AATB - Discussion of Regulation of Demineralized Bone Matrix
6/97	Discussion of Regulation of Eye Tissue with EBAA
3/17/97	FDA Open Public Meeting for comments on the "Proposed Approach"
3/12/97	Training provided to Baltimore District Biologics Cadre, regarding Inspection of Human Tissue Establishments.
12/96	FDA invited to discuss Good Tissue Practices with AATB, EBAA and ASRM
10/96	Heart valve industry - Discussion of regulation of heart valve allografts
12/13/95	Workshop: Cord Blood Stem Cells - Procedures for Collection and Storage
10/95 and 3/96	FDA invited to discuss reproductive tissue donor testing, screening and establishment registration with ASRM and AATB
6/20-21/95	Tissue Workshop: Tissue for Transplantation and Reproductive Tissue: Scientific and Regulatory Issues and Perspectives
3/95	Workshop on Human Tissue Intended for Transplantation and Human Reproductive Tissue: Donor Screening and Infectious Disease Testing

2/1-3/95	FDA Mid-Atlantic Region Tissue Bank Training for FDA Investigators, Baltimore, MD
6/94	Workshop on Human Tissue Intended for Transplantation