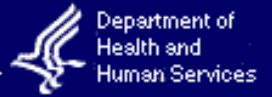




U.S. Food and Drug Administration



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FDA Public Health Notification*: Update of Information about BioMedical Tissue Services

March 2, 2006

FDA is issuing an update to its October 26, 2005, information paper on BioMedical Tissue Services (BTS) (<http://www.fda.gov/bbs/topics/NEWS/2005/NEW01249.html>) to strongly recommend that health care providers inform their patients who received tissue implants prepared from BTS donors that they may be at increased risk of communicable disease transmission and to offer them testing. As part of its ongoing investigation, FDA has become aware of additional information regarding the reliability of donor blood samples that is important for health care providers to consider.

Background

On October 26, 2005, FDA issued an information paper regarding its investigation of BTS (<http://www.fda.gov/bbs/topics/NEWS/2005/NEW01249.html>). FDA expressed concern that BTS had supplied tissue from donors that had not been subject to an adequate donor eligibility determination. FDA and CDC recommended that health care providers inform their patients of this potential risk and offer to provide access to appropriate infectious disease testing.

Donor eligibility is determined through donor screening and donor testing. Donor screening involves reviewing all relevant medical records, physically assessing the donor and questioning the donor's next-of-kin to determine whether risk factors for or clinical evidence of relevant communicable diseases exist. Donor testing involves testing samples of the donor's blood taken pre- or post-mortem. Relevant communicable diseases for which the donor is tested are HIV-1 and 2, hepatitis B virus, hepatitis C virus and syphilis. A donor is determined eligible to donate tissues only if the results of donor screening and donor testing indicate freedom from communicable diseases or communicable disease risks.

On January 31, 2006, FDA issued an Order to Cease Manufacturing and to Retain Human Cells, Tissues and Cellular and Tissue Based Products (HCT/PS) to BTS and its Chief Executive Officer and Executive Director of Operations (<http://www.fda.gov/bbs/topics/news/2006/NEW01309.html>). The order was issued after FDA's inspection of BTS uncovered serious violations of the regulations governing donor screening and record keeping practices. Despite records maintaining otherwise, the firm had inadequately screened donors for risk factors for, or clinical evidence of, relevant communicable disease agents and diseases. In addition, FDA found numerous instances where death certificates maintained in BTS' files were at variance with the death certificates FDA obtained from the state where the death occurred, on important information such as cause, place, and time of death, and the identity of the next of kin. Therefore, the donor screening performed cannot

be relied on to exclude donors with risk factors for or clinical evidence of infectious disease.

FDA regulations require that, before tissues are released for distribution, blood samples from each donor be provided to the testing laboratory for donor testing. Each sample must be clearly linked to an individual donor, and each tissue clearly linked to that donor. FDA and the affected processors now have additional information that calls into question the reliability of some of these donor blood samples submitted for communicable disease testing from BTS tissue donors. In some instances, blood samples did not come from the same donor as the linked tissues. Therefore, the results of communicable disease tests obtained from the blood sample may not correctly reflect the status of the donor.

Recommendations

FDA and CDC strongly recommend that health care providers offer testing to their patients or refer them to other health care providers who can provide such testing. While we still believe the risks from these tissues are low because the tissues were routinely processed using methods to help to reduce the risk of infectious disease, the actual infectious risk is unknown. As mentioned previously, the relevant communicable diseases for which tissue donors are required to be tested are: HIV-1 and 2, hepatitis B virus, hepatitis C virus and syphilis, and health care providers should consider testing their patients for these same disease agents. If you have questions about the tissues you received for implantation and the methods by which they were processed to minimize the risk of communicable disease transmission, you should contact the processor from which you received the tissues.

Reporting Adverse Reactions to FDA

Patients and health care providers should report any adverse reaction possibly related to a tissue transplant to the appropriate processing firm. FDA requires tissue establishments to investigate any adverse reaction involving a communicable disease for which there is a reasonable possibility that the transplanted HCT/P, distributed by them, caused the reaction, and to report fatalities and/or serious injuries to FDA. Information on reporting of such reactions may be found on the web at <http://www.fda.gov/cber/tissue/hctadverse.htm>.

We also encourage health care providers to report all adverse reactions related to HCT/Ps directly to FDA. You can report any adverse reaction to MedWatch, FDA's voluntary reporting program. You may submit reports to MedWatch by phone at 1-800-FDA-1088; by fax at 1-800-FDA-0178; by mail to MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857-9787; or online at <http://www.fda.gov/medwatch/report.htm>. Consumers can also report any adverse reaction directly to MedWatch.

Getting More Information

Additional questions may be directed to FDA's Center for Biologics Evaluation and Research at 1-800-835-4709 or by e-mail at octma@cber.fda.gov.

**This public health notification by the Center for Biologics Evaluation and Research is intended to quickly share safety information with health care providers when the information available and our understanding of an issue are still evolving. We will revise this notice as new information merits and so encourage you to check this site for updates.*

Updated March 2, 2006

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