



TO: Vermont Health Care Providers

FROM: Susan Schoenfeld, Deputy State Epidemiologist

DATE: March 17, 2006

RE: **BioMedical Tissue Services Tissue Implant Recall Update**

Summary: The Vermont Department of Health (VDH) is working to confirm that all facilities/clinicians who performed tissue implants with tissue that originated from BioMedical Tissue Services (BTS) are aware of the FDA recall (October 2005) and of the recommendations listed below. Though risk of infection to these patients is low, we support the recommendations to notify patients and offer testing.

Recommendation: FDA and CDC strongly recommend that health care providers offer testing to their patients who received the implants in question, or refer them to other health care providers who can provide such testing. While the FDA believes 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. 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. Because of the problems identified (see below) 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.

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. The FDA provided updated information on March 2, 2006 (<http://www.fda.gov/cber/safety/bts030206.htm>).

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.

Adverse reactions possibly related to a tissue transplant should be reported to the appropriate processing firm. The FDA encourages facilities and physicians to also report directly to the FDA to MedWatch, FDA's voluntary reporting program, by phone at 1-800-FDA-1088; by FAX at 1-800-FDA-0178.

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

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