Patient Safety Advisory

Veterans Health Administration Warning System
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Item: **Shutdown of Donor Referral Services (DRS) Tissue Harvesting Co by FDA**

General Information: FDA issued an order to Donor Referral Services (DRS) of Raleigh, North Carolina, to "cease manufacturing and to retain human cells, tissues, and cellular and tissue-based products (HCT/Ps)", due to violations of Good Manufacturing Practices (GMP).

At this time it has been determined that tissue from DRS was sold or distributed to:

- Alamo Tissue Services of San Antonio, Texas
- Bonebank Allographs, San Antonio, TX
- DCI, Nashville, TN
- Global Orthopedic, Ellisville, MS
- Lost Mountain Bank of Kennesaw, Georgia
- Neuro Tec, Marietta, GA
- US Tissue (AlloSource) of Cincinnati, Ohio and Salt Lake City, Utah
- Tissue Management Solutions, Scottsdale, AZ
- Tissue Net of Orlando, Florida (may have received from US Tissue (AlloSource) of Cincinnati)
- West Coast Medical, Seattle, WA

Recommendations: a) Verify if your facility has purchased the human cells, tissue, and cellular and tissue-based products from DRS or any of their direct or indirect distributors.
b) Check with your supplier to determine if any products that they sent to your facility are the HCT/Ps that are included in the action of the FDA against DRS.
c) Sequester the affected products if they have not been implanted yet and obtain alternative sources to replace the affected products.
d) If alternative sources are not immediately available, the physicians should assess the impact of denying use of this product against the patient's medical outcome.
e) Individuals who have received this material will likely need notification and patient call back for testing once it is determined that they have received the recalled material. Refer to VHA Directive 2005-049 "Disclosure of Adverse Events to Patients."

Addl. Information:	We are continuing to investigate and will provide additional information, including patient notification guidance, to impacted VA facilities as they are identified.
Source:	FDA News http://www.fda.gov/bbs/topics/NEWS/2006/NEW01433.html
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