



# e-Network Forum

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### ***Deferral of a whole blood donor over CJD concerns because of a bovine jaw/dental implant***

A physician wrote that his center recently deferred a prospective whole blood donor over CJD concerns because of a bovine jaw/dental implant that the prospective donor had received. The inquiring blood banker (who is quite an experienced blood banker) admits that he did not know that jaw/dental implants were made of bovine origin and he wonders if others have encountered donors who have also had bovine jaw/dental implants. He wants to know **if other centers are asking donors about such implants**, and if so, what questions are being asked? He also wants to know if other centers are **deferring** donations by individuals who have had bovine implants? Finally, the inquiring blood banker asked if there was a **list of the various types of implants that are made from bovine materials**.

The following replies were submitted in response to the above.

1. **A Rhode Island blood bank physician** responded that in her experience, dental bone grafts are made from 3 sources:

- synthetic materials
- sea coral
- cattle

She also reported that she was familiar with two companies that supplied these products, [Ceramed](#) and [Osteohealth](#) (no web link). She reported that according to Ceramed **only U.S. cattle** are currently used to make the bovine grafts.

2. **The Editor of the 6th edition of the AABB book entitled "Collected Questions and Answers"** reports that the following information can be found in an excerpt regarding xenotransplantation that appeared in his book.

- **Question:** We have had several donors who have volunteered information related to animal tissue grafts. Three donors indicated that they received pig or cow **tissue** for bone growth during dental procedures. We have the following questions related to this:
  - Is the donor acceptable? If not what is the deferral period?
  - Are prior donations (that were made after the graft, but before the donors acknowledged such a procedure) subject to recall, or market withdrawal, or recipient notification?
  - Are the sexual contacts of such donors acceptable as donors?

**Response:** The transplantation of animal **tissue** to humans is termed **xenotransplantation** ("xeno" from the Greek for foreigner). The major concern in such transplants is that there is a fear that viruses or infectious agents that may have been modified by passage through a xenotransplant recipient (who is typically immunosuppressed) may become infective to the general public. There is at least one documented case of an animal virus thought to be species specific infecting a xenotransplant recipient. In this case baboon CMV was transmitted following a baboon liver transplant to an HIV infected patient. Because of such risk of unknown infections, the Food and Drug Administration and the Centers for Disease Control and Prevention have put a **moratorium on animal-to-human transplantation**. In January of 2000 the Xenotransplant Subcommittee of the Food and Drug Administration's (FDA) Advisory Committee on Biologic Response Modifiers met to discuss the donation deferral of xenotransplant recipients. The committee made the following recommendations:

- Indefinite **deferral** from donations blood or tissue for ALL **xenotransplant recipients**.
- Indefinite deferral for all individuals who have had **intimate contact** with xenotransplant recipients. Intimate contact includes sexual contacts.

The following individuals were **not** felt to be at risk:

- Farmers, veterinarians and others who have regular contact with animals.
- Health care workers who deal with xenotransplant recipients in the clinical setting unless unusual exposure to patient's blood or tissue occurs.
- Blood and blood components from xenotransplant recipients should be **withdrawn from distribution**. At this time it is not clear if the final ruling will require that blood and blood components already donated by xenotransplant recipients be recalled and destroyed. It must be emphasized that these suggested deferrals are only recommendations of the subcommittee. At the time of this writing the FDA Blood Product Advisory Committee plans to further deliberate this issue prior to any final decision. References are provided in the book.

According to the Collected Questions and Answers book editor, there is **nothing stated regarding the deferral of donors (tissue or blood) who have been exposed to BSE/CJD-risk medical PRODUCTS (including implants or vaccines)** save for bovine-derived insulin from the UK or human-derived Growth Hormone. Despite a number of vaccines being prepared from BSE-risk cattle or from cattle of unknown countries, there are no known formal proposals for the deferral of donors having received these products. For those interested, here is a transcript from the FOOD AND DRUG ADMINISTRATION TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES ADVISORY COMMITTEE AND VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE JOINT MEETING of JULY 27, 2000 that you might find fascinating ([MS Word download](#)). Finally, according to the responding blood banker, this AABB book provides a list of vaccines that have in the past or might still contain/use bovine-derived materials derived from countries on the USDA's BSE list or from unknown countries.

3. **A blood banker near Silicon Valley in Northern California** says that it seems cow bone material is frequently used in oral surgery these days. She is aware of several sources of cow bone products including [Bio-Oss](#), and [Ceramed](#) (PepGen and OsteoGraf). She believes that all these products are currently of **American bovine source**. The responding blood banker reports that at her donor center they treat bovine grafts the way they treat bovine insulin, which is to defer the donor UNLESS they are sure that the product was derived from American cows. She has not consulted the FDA to determine their level of concern about bovine bone.
4. On a related note, **a San Diego blood bank physician** said that she recently came across a bottle of "Natural" type vitamins for "Adrenal support". Interestingly these vitamins contained bovine liver, bovine adrenal, bovine bone and bovine brain! She realizes that this observation may be opening Pandora's box, but she wants to know what do with this information, particularly in California where the taking of alternative medicines is common.

**ADDENDA** Nov. 26, 2001

5. (And response to #4) **A Los Angeles blood banker** commented on #4 above and said "We have had contact with FDA over this issue. We called our C.S.O. at the FDA (Mary Anne Denham), and she relayed us information from Dr. Jay Epstein. He indicated that any dietary supplement manufactured in the U.S. would NOT have any growth hormone of human or bovine origin. He indicated, however, that **FDA has NO CONTROL over the importation of supplements containing hGH of human or bovine origin from foreign countries**. When a donor indicates that they are taking a supplement containing 'human growth hormone' or bovine-derived material, we ask them for information about the manufacturer and actually contact the manufacturer for information about the product. We've started a file with documentation about the origin of the source material in the product, and plan to provide our donor screening staff with a list of 'cleared' supplements. (**Editor's NOTE:** Visit this FDA site to learn about their oversight of the [Dietary Supplements industry](#))
6. (And response to #4): **Another Los Angeles blood banker** also commented on #4 above and said "I don't really have an answer to the bovine products but I would like to add my voice to the possible magnitude of this problem. I decided to take a "natural" product recommended to me by a reputable source and the first thing I did was to look at the ingredients. It contained

bovine product and, as a Blood Banker, I immediately was put off. But then I read about the company making this product and they said that they have been using cattle from their Wisconsin plant for many years. So that reassured me enough to take the product. But how many people will go to the trouble of even reading the ingredients let alone checking into the source? And how many Donor Centers ask their donors about "natural" supplements that might not be thought of as drugs? Do these manufacturers go through any type of regulating body where we could check to make sure that all of the bovine products come from US cattle? I shudder to think of the massive task of contacting the many companies that may be manufacturing "natural" products. But I don't think we can afford to lose any more donors either.

**ADDENDA** Feb. 6, 2008

7. **A 54 year old female located in New Jersey** reports that she recently had **periodontal surgery**, and about two weeks later attempted to be a blood donor. As part of the pre-donation eligibility process, she was asked if she had ever received a **bone graft**. Her periodontist was consulted, and the donor center was told that the graft was made from **bovine source material**. The prospective donor was then informed that she could **NEVER be a blood donor again** because of **receiving an 'animal' graft**. She asks "What if there was documentation that the grafting product was made in the US from US cows?" She also asks "**If the cows used for the graft material were not from this country, is she at risk of contracting Mad Cow Disease?**" Finally, she asks "If there was even an inkling that this disease could be transmitted to humans via bovine grafts, would the FDA allow such a product to be on the market?"

**ADDENDA** March 11, 2008

8. **A senior medical technologist** recently sent an email inquiry to the FDA's Center for Biologics Evaluation and Research (CBER) requesting information about the eligibility of blood donors who have received bovine-derived bone grafts. A **Consumer Safety Officer** who **responded** to the medical technologist's inquiry wrote in an email ([see PDF](#)) that there **should be no objections** to a blood donation from a donor who has received a bovine-derived bone graft, **provided it has been cleared by the FDA/CDRH**. On the other hand, the Consumer Safety Officer recommends that a **donor be deferred if the bovine source of the implanted device is of unknown origin**.

**Editors' note:** The answer provided by the FDA Consumer Safety Officer **may be relevant** to the situation of the 54 year old female in New Jersey who had periodontal surgery and who received a bovine source bone graft only to be told afterwards (see [ADDENDUM #7 of Feb. 6, 2008](#)) that she could NEVER be a blood donor again because she received an 'animal' graft.

Please submit comments to the [e-Network Forum](#).

Ira A. Shulman, MD  
CBBS e-Network Forum Editor & Moderator

W. Tait Stevens, MD  
CBBS e-Network Forum Assistant Editor & Moderator



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