Carol Grayson

From: Terry S. Singeltary Sr. <flounder@ GRO-C
To: Bovine Spongiform Encephalopathy <BSE-L@ GRO-C
Cc: <cjdvoice@ GRO-C
Sent: 14 October 2004 15:20
Subject: [CJDVoice] U.K. woman concerned mad cow in U.S. blood

U.K. woman concerned mad cow in U.S. blood

By Steve Mitchell
Medical Correspondent

Published 10/13/2004 6:51 PM

WASHINGTON, Oct. 13 (UPI) -- A federal advisory panel Thursday may consider concerns raised by a British woman that the U.S. blood and plasma supply could be contaminated with the human version of mad cow disease, United Press International has learned.

Carol Grayson, of Newcastle, England, told the U.S. Food and Drug Administration she knows of cases in which European and U.K. nationals who could be harboring the human form of mad cow disease -- formally known as variant Creutzfeldt Jakob disease -- have donated blood and plasma in the United States while here as students or tourists.

VCJD is an incurable, fatal brain illness that can be contracted from eating beef products contaminated with mad cow disease, also known as bovine spongiform encephalopathy or BSE.

"I am aware that over the years citizens from European countries with cases of BSE/vCJD have sold their blood in the United States and been accepted as donors," Grayson wrote in a document obtained by UPI. FDA officials said the letter will be included in material presented to the agency's Transmissible Spongiform Advisory Committee when it meets Thursday in Silver Spring, Md.

"Even if this practice has now stopped, if vCJD is transmittable via blood products, is there not a risk that vCJD could already have been in the blood supply and that American recipients may be incubating vCJD?" Grayson asked.

There has been one confirmed case of vCJD in the United States and health authorities suspect the person, who was a British citizen, contracted the disease while growing up in England.

The TSE advisory committee, which is composed of experts from academia, government and industry, will discuss whether current FDA deferral policies for blood donors are adequate to ensure safety of the U.S. blood supply. This is in light of two recent cases of people who were infected with vCJD in the United Kingdom -- apparently by blood transfusions. These cases, which were reported last December and August, are the first known vCJD infections tied to blood transfusions.

Grayson, who is affiliated with Haemophilia Action UK, an advocacy group for hemophiliacs,

told UPI she is concerned, not only about U.S. citizens, but also about British citizens. England has been importing U.S. plasma for several years due to concerns its domestic supply could be contaminated with vCJD.

Dave Cavenaugh, of the Committee for Ten Thousand, a U.S. hemophilia advocacy group, said hemophiliacs are very concerned about this issue, because they are at increased risk if vCJD is in the blood supply.

"We take (blood products) weekly," Cavenaugh told UPI. "It's very scary."

He added that members of the general population also could be at risk if they receive a blood transfusion for surgery or use other blood products.

Concerns about widespread vCJD infection among U.K. citizens recently were heightened by a study that indicated as many as 3,800 people unknowingly could be carrying the deadly disease, but not yet displaying symptoms. Last month, the U.K. Department of Health warned 6,000 hemophiliacs and others with blood disorders they may have been exposed to plasma infected with vCJD, because some of the initial donors subsequently developed the disease. The potentially exposed patients were advised not to donate blood, tissues or other organs.

Grayson's husband, Peter Longstaff, 43, who is a hemophiliac, was one of those warned about possible exposure. Grayson, who is a former nurse, said she thinks he is now showing signs of the fatal disease.

The Plasma Protein Therapeutics Association said in a statement issued Monday that safeguards currently in place should "provide appropriate assurance of safety for consumers of plasma-derived therapies."

In addition to deferring high-risk donors, available data indicate that processing plasma products reduces infectivity if it is present, PPTA said. Also, there has never been a single case of vCJD transmission tied to plasma products, the association said.

Cavenaugh said assertions that processing procedures reduce infectivity in plasma are not reassuring to him, because it may not completely eliminate infectivity.

Dr. Louis Katz, president of America's Blood Centers, a network of non-profit blood centers based in Washington, told UPI the fact that there have been only two cases tied to blood transfusions suggests the risk from blood is very small.

"Does that mean it's zero? No it doesn't," Katz said.

He noted, however, that because there currently are no screening tests or inactivation procedures for vCJD in blood, deferral of the high-risk donors "is about as good as we can do."

FDA recommends residents of, or those who have spent considerable time in, the United Kingdom or France not be permitted to donate blood or plasma in the United States. However, Grayson asserted in her letter to the agency she is aware of two specific instances when this ban was not enforced.

In one case, "My friend's son who has lived in the United Kingdom for the first 20 years of his life ... went to study in the United States in 1999" and sold his blood on several occasions, her letter said. "He wrote telling me that he had been economical with the truth, as he had smoked dope on the way to donate and was afraid he would be barred from donating," she added.

Another example, Grayson wrote, occurred in 1999 when "a French film crew, filming a documentary ... on blood safety around the world ... stepped off a plane and headed for the nearest plasma center on the U.S./Mexican border to sell their blood, and were accepted as plasma donors." France has had cases of both mad cow and vCJD. The film, "The Blood Scandal," was made by Emmanuel Amara.

Both France and the United Kingdom are of particular concern to the FDA regarding blood safety. Of the more than 150 cases of vCJD worldwide, 149 have occurred in the United Kingdom, where mad cow disease was first seen in the 1980s, and six cases have been reported in France.

Although the agency recommends allowing plasma to be collected from people who have spent significant time in European countries with known cases of mad cow disease because the processing procedures should reduce infectivity, it specifically advises against collecting plasma from those who have resided in the United Kingdom or France for extensive amounts of time. This is "in consideration of the relatively greater risk of vCJD" in those countries," according to FDA's current recommendations.

The agency's William Freas, who serves as executive secretary of the TSE advisory committee, confirmed he received Grayson's remarks, but said it was up to the committee members whether her concerns would be discussed at the meeting.

"They're going to receive her concerns," but the individual members are independent from the FDA and only they can decide whether to discuss the issues raised by Grayson, Freas told UPI. He said he could not say anything more, due to FDA's "very tight restrictions on what we can say" before advisory committee meetings.

Grayson said in her letter she is concerned that if any of the foreign nationals who donated blood or plasma in the United States do subsequently develop vCJD, U.S. patients who received the blood or blood products derived from their donation may never be notified.

U.K. authorities "informed me that if a U.K. citizen dies from vCJD, they ask the family if they have donated blood in the United Kingdom, but they don't ask if they have donated in any other country," Grayson wrote. "If my friend's son were to be incubating vCJD when he donated in the United States, and then died of the ... disease, how would recipients of his blood products be traced in the United States? How many citizens from European countries with BSE/vCJD have donated blood in the United States?"

Jennifer Garfinkel, spokeswoman for AABB -- formerly known as the American Association of Blood Banks -- in Bethesda, Md., told UPI the questionnaire given to donors to screen out those who are high-risk for vCJD urges them to be honest and accurate about their answers.

Asked if AABB had concerns about the possibility vCJD was in the U.S. blood supply or blood products, Garfinkel said. "We're always trying to make the blood supply more safe."

E-mail

TSS