

# **Bovine Spongiform Encephalopathy and variant Creutzfeldt-Jakob Disease**

## **Questions and Answers**

9 March 2001

### **Questions and Answers about Bovine Spongiform Encephalopathy**

- 1. What is Bovine Spongiform Encephalopathy (BSE)?**
- 2. What causes BSE?**
- 3. Which countries have reported BSE?**
- 4. Which countries are on the U.S. Department of Agriculture list of countries where BSE is known to exist or where a substantial risk for BSE exists?**
- 5. How was BSE spread?**
- 6. Is BSE occurring in the United States?**
- 7. What measures has the US government taken to ensure that BSE does not occur in the US, and that people are not exposed to the BSE agent in foods?**
- 8. What are the chances of dogs and cats getting a BSE-like disease from eating pet foods with beef by-products?**
- 9. Is there any way to confirm if an animal has been infected?**

#### **1. What is Bovine Spongiform Encephalopathy (BSE)?**

BSE is a progressive, fatal neurological disorder of cattle, and has been called "mad cow disease." Cattle affected by BSE experience progressive degeneration of the nervous system. Affected animals may display changes in temperament such as nervousness or aggression; abnormal posture; poor coordination and difficulty in rising; decreased milk production; or loss of body weight despite continued appetite. There is neither any treatment nor a vaccine to prevent the disease. The incubation period (the time from when an animal becomes infected until it first shows disease signs) is from 2 to 8 years. Most cases in Great Britain have occurred in dairy cows between 3 and 6 years of age.

#### **2. What causes BSE?**

The nature of the infectious agent that causes BSE is unknown. Currently, the most accepted theory is that the agent is a modified form of a normal cell protein known as a prion. Researchers think that contact between the prion and normal protein in the brain causes the normal protein to change its shape and stop working. A prion is not a bacterium, parasite, or virus, and thus treatments usually used for treating or preventing bacterial infections (e.g. antibiotics) or viral infections are not effective against prions.

#### **3. Which countries have reported BSE?**

The vast majority of cases of BSE (more than 99% as of 1 March 2001) have been reported from the United Kingdom during the epidemic. However, cases have also originated in native cattle of other European countries including: the Republic of Ireland, Switzerland, France, Liechtenstein, Luxembourg, Netherlands, Portugal, Spain, Italy, Germany, Belgium, and Denmark

#### **4. Which countries are on the U.S. Department of Agriculture (USDA) list of countries where BSE is known to exist or where a substantial risk for BSE exists?**

Initially, the USDA list included only countries and other regions in which BSE was known to exist, such as the United Kingdom, France, Switzerland, and the Republic of Ireland. In 1998, the USDA expanded the list to include countries and other regions in which BSE had not been documented but where there might be the risk of BSE due to less restrictive controls on importation or less adequate surveillance for BSE than in the US. Thus, all European countries, even those that have had no reported cases of BSE, are currently on the USDA list, which is published in the Code of Federal Regulations, title 9, part 94 (9 CFR 94).

## **5. How was BSE spread?**

It is thought that BSE was spread via meat and bone meal fed to cattle. The practice of using this material as a source of protein in cattle feed has been common for several decades. In the late 1970s there was a change in the production (rendering) process used to make this meat and bone meal. One hypothesis is that this change permitted the infectious agent to survive the rendering process, and get transmitted to other animals, that are fed meat-and-bone meal nutritional supplements.

## **6. Is BSE occurring in the United States?**

According to the Animal and Plant Health Inspection Service of the U.S. Department of Agriculture, BSE has not been detected in the United States, despite active surveillance efforts since May 1990. As of October 31, 2000, 11,700 bovine brain specimens had been examined by an ongoing BSE surveillance system in the United States, and no evidence of BSE was seen. Regularly updated numbers of bovine brain samples tested as part of the nationwide BSE surveillance program are available at: <http://www.aphis.usda.gov/oa/bse/bseurvey.html#charts>. Further, to prevent BSE from entering the United States, severe restrictions were placed on the importation of live ruminants and certain ruminant (cattle, sheep, and goat) products from countries where BSE was known to exist. These restrictions were later extended to include importation of ruminants and certain ruminant products from all European countries.

## **7. What measures has the US government taken to ensure that BSE does not occur in the US, and that people are not exposed to the BSE agent in foods?**

The USDA is responsible for the health of US livestock and leads an interagency surveillance program for evidence of BSE in the US. No cases of BSE have been detected in the US despite 10 years of active surveillance. To prevent BSE from entering the country, the USDA Animal and Plant Health Inspection Service (APHIS) has, since 1989, prohibited the importation of live ruminants from countries where BSE is known to exist in native cattle. On December 12, 1997, APHIS stopped the importation of live ruminants and most ruminant products, including meat, meat-and-bone meal, offal, glands, etc. from all of Europe. The USDA Food Safety Inspection Service and the Food and Drug Administration (FDA) are jointly responsible for food safety in the US. In August 1997, FDA prohibited the use of most mammalian protein in the manufacture of animal feeds given to ruminants. In addition, the final regulation also requires quality control procedures to make sure that ruminant feed does not contain the prohibited mammalian tissues.

## **8. What are the chances of dogs and cats getting a BSE-like disease from eating pet foods with beef by-products?**

Dogs have not been shown to be susceptible to BSE but cats have. As of January 2001, approximately 80 cats in the UK, one in N. Ireland, one in Liechtenstein and one in Norway have been diagnosed with something similar to BSE. It is felt that they were exposed to BSE through contaminated pet food. The strain-type for the cats matched the cattle and vCJD cases. The USDA prohibits the importation of pet food from Europe into the US. There is no evidence of animal to human transmission through normal contact.

## **9. Is there any way to confirm if an animal has been infected?**

There is no test to confirm the disease in a live animal. Microscopic examination of brain tissue after death is the primary laboratory method used to confirm a diagnosis of BSE.

## Questions and Answers about variant CJD (vCJD)

1. What is the “classic” form of Creutzfeldt-Jakob disease (CJD)?
2. What is variant Creutzfeldt-Jakob disease (vCJD) and how is it different from CJD?
3. What is the evidence directly linking vCJD to BSE exposure?
4. How many cases of vCJD have occurred?
5. Of the reported vCJD fatalities, were any of them U.S. Service Members?
6. Is there any monitoring of the incidence of Creutzfeldt-Jakob disease in the United States?
7. What is the risk of contracting vCJD to service members and their families who have been stationed in Europe and consumed European beef?
8. Is there any way to confirm if a person has been infected?
9. What is the incubation period for vCJD?
10. If vCJD is linked to BSE, why have we not seen an outbreak of vCJD in humans similar to the outbreak of BSE in cows?

### 1. What is the “classic” form of Creutzfeldt-Jakob disease (CJD)?

CJD is a slow degenerative human disease of the central nervous system. CJD belongs to a group of fatal neurological diseases known as Transmissible Spongiform Encephalopathies (TSEs). CJD is classified as a TSE because of the characteristic spongy degeneration of the brain that occurs as the disease progresses. Prior to the identification of variant CJD (vCJD), classic CJD was recognized to exist in only three forms. Sporadic cases (85-90% of CJD cases) have an unknown cause and occur throughout the world at the rate of about one case per million people. Iatrogenic cases (less than 5% of CJD cases) result from the accidental transmission of the causative agent by contaminated surgical equipment or as a result of cornea or dura mater transplants or the administration of human-derived pituitary growth hormones. Familial cases (5-10% of CJD cases) are associated with a gene mutation.

### 2. What is variant Creutzfeldt-Jakob disease (vCJD) and how is it different from CJD?

Like CJD, vCJD is classified as a TSE because of characteristic spongy degeneration of the brain and its ability to be transmitted. vCJD is a new disease that was first described in March 1996. In contrast to the traditional forms of CJD, vCJD has affected younger patients (average age 29 years, as opposed to 65 years), has a relatively longer duration of illness (median of 14 months as opposed to 4.5 months) and is strongly linked to exposure, probably through food, to a TSE of cattle called BSE. There are also some differences in the way the brain tissue looks on pathologic exam in a patient with vCJD vs. classic CJD.

### 3. What is the evidence directly linking this vCJD to BSE exposure?

There is strong epidemiologic and laboratory evidence suggesting that the same infectious agent causes vCJD and BSE. For instance, there have been no confirmed cases of vCJD in geographic areas where there have been no BSE cases. In addition, the time interval or "incubation period" between the most likely period for the initial exposure of the population to potentially BSE-contaminated food (1984-1986) and onset of initial vCJD cases (1994-1996), about 10 years, is similar to the known time intervals between exposure to the classic CJD agent and the development of CJD.

### 4. How many cases of vCJD have occurred?

Cases of variant CJD are very rare, and most have occurred in the United Kingdom. The latest information (March 7, 2001) issued by the Department of Health, United Kingdom ([www.doh.gov.uk/cjd/](http://www.doh.gov.uk/cjd/)) indicates that there have been 85 confirmed cases of vCJD in the United Kingdom. These cases have all been diagnosed since 1995. France has reported two cases. The Republic of Ireland reported one case in 1999. No cases have been recognized in other European countries, or in the United States

### 5. Of the reported vCJD fatalities, were any of them U.S. Service Members?

No. There are no reported cases of vCJD in the US, including service members and their families wherever they are stationed.

**6. Is there any monitoring of the incidence of Creutzfeldt-Jakob disease in the United States?**

Yes. The Centers for Disease Control and Prevention (CDC) monitors the trends and current incidence of diseases, including CJD, in the United States by analyzing death certificate information. *There have been no cases of vCJD reported in the United States.* A summary of the CDC data was published in the Journal of the American Medical Association on November 8, 2000 (Volume 284, No. 18, pp. 2322-3; available at <http://jama.ama-assn.org/issues/v284n18/full/jlt1108-6.html>).

**7. What is the risk of contracting vCJD to service members and their families who have been stationed in Europe and consumed European beef?**

The risk cannot be precisely determined but it appears to be extremely small. The risk varies depending on the source of the beef and beef products consumed. In the UK it is *currently* estimated to be perhaps only about 1 case per 10 billion servings. In the other countries of Europe, the risk would not likely be any higher than in the UK, with the possible exception of Portugal. In the UK, France and Ireland, the rate of vCJD in the population is still very low, less than 100 cases in a total population of about 122 million people.

**8. Is there any way to confirm if a person has been infected?**

There is no test to confirm the disease in living people. Microscopic examination of brain tissue at autopsy is the primary laboratory method used to confirm a diagnosis of vCJD.

**9. What is the incubation period for vCJD?**

The incubation period is unknown but it is estimated to be 10 to 20+ years.

**10. If vCJD is linked to BSE, why have we not seen an outbreak of vCJD in humans similar to the outbreak of BSE in cows?**

The difference between BSE and vCJD may be due to the fact that in humans, recycling of infected tissue into the human food chain has not occurred, and thus the epidemic will evolve more slowly than in cattle. The small number of cases of vCJD in humans may also mean that there is a certain “dose” of infectious agent needed, and that many people who may have eaten contaminated products got too small a dose to become infected. There is also some evidence of a genetic susceptibility in the people who have been infected. Finally, it may be relatively hard for the infectious agent to infect a different species than the one in which it arose.

## Questions and Answers on BSE and Food Safety

1. What measures has DoD taken to minimize the exposure of troops and family members to the BSE agent in foods?
2. What preventive measures have been done or should be considered to reduce the risk of exposure in Europe?
3. What was the source of beef consumed by military personnel stationed in Europe?
4. What was the source of beef consumed by military personnel stationed overseas in areas other than Europe?
5. Are there risks from any other products such as pork or chicken?
6. Is there any risk from dairy products?
7. Is there a way to kill off the BSE prions in beef and beef products?

### 1. What measures has DoD taken to minimize the exposure of troops and family members to the BSE agent in foods?

- a) All beef procured by DoD in for use in the US conforms to USDA regulations and comes from USDA approved sources. This includes commissaries, exchanges, MWR facilities, operational rations, and Prime Vendor deliveries. All beef and beef products used in MRE's, T-rations, UGRs, field feeding and all other operational rations have continuously come solely from US beef.
- b) For beef procured outside of the US, the following actions have been taken: In March 1996, within days after official notification of a probable link between BSE and vCJD, DoD stopped procurement and sale of beef from the UK and other countries with confirmed cases of BSE. In March 2000, in response to the emergence of BSE in additional European countries and changes in US import laws (9CFR94.18), DoD banned procurement of all ruminant (e.g., cattle, sheep, and goat) meat and meat products of European origin.

### 2. What preventive measures have been done or should be considered to reduce the risk of exposure in Europe?

Public health control measures, such as BSE surveillance, the culling of sick animals, or banning specified risk materials, or a combination of these, have been instituted in Europe to prevent potentially BSE-infected tissues from entering the human food chain. Specified Risk Materials (SRMs) are animal products in which infective agent has been found. They include brain, spinal cord, retina, neural ganglia, bone marrow and ileum. The most stringent of these control measures have been applied in the United Kingdom and appear to have been highly effective. In June 2000, the European Union Commission on Food Safety and Animal Welfare adopted a decision requiring all member states to remove SRMs from the animal feed and human food chains as of October 1, 2000; such bans had already been instituted in most member states. To reduce the possible current risk of acquiring vCJD from food, travelers to Europe and service personnel stationed in Europe may wish to consider either:

- a) Avoiding beef and beef products altogether or
- b) Selecting beef or beef products that are solid pieces of muscle meat (steaks and roasts as opposed to burgers and sausages) that might have a reduced opportunity for contamination with tissues that might harbor the BSE agent.

### **3. What was the source of beef consumed by military personnel stationed in Europe?**

For service members stationed in Europe prior to 1996, beef sources were:

- a) Dining Facilities: U.S. beef has been served in all military dining facilities since before 1980.
- b) Operational rations: In MRE's, T rations, UGRs, field feeding and all other operational rations only US beef was used.
- c) Commissaries: Prior to 1990, commissaries in Europe procured approximately 35% of the beef from the UK and 65% from other European countries. Since 1990, commissaries in Germany, Netherlands, Belgium and the UK (excluding Edsal commissary in Scotland) received only US beef. Commissaries in Italy, Spain, Greece, and Turkey (and the Edsal commissary in Scotland) continued getting the majority of their beef from the UK until 1996 when all procurement of beef from the UK ended.
- d) Army and Air Force Exchange Service (AAFES): European beef was used up until 2000. Approximately 20% of this was from the UK until March 1996.

In March 1996, DoD stopped procurement and sale of beef from the UK and other countries with confirmed cases of BSE. Since March 2000, DoD stopped procurement and sale of ruminant (e.g., cattle, sheep, and goat) meat and meat products of European origin. The procurement of these meat items is now required to be from US and non-European approved sources.

### **4. What was the source of beef consumed by military personnel stationed overseas in areas other than Europe?**

The possibility exists for UK or other European beef to have been consumed in areas outside of Europe. For example, it may have been purchased by naval ships resupplying in the Mediterranean, or provided to service members in SW Asia following Operations Desert Shield/Desert Storm. From 1990 to March 1996, military dining facilities in Southwest Asia utilized beef originating from several countries, including the UK. DoD policy excluded UK beef after March 1996 and European beef after March 2000.

### **5. Are there risks from any other products such as pork or chicken?**

There is no known association of vCJD with pork or chicken.

### **6. Is there any risk from dairy products?**

There is no known concern/risk from dairy products. Milk from cows infected with BSE has been repeatedly tested for the ability to transmit the disease. It has never occurred.

### **7. Is there a way to kill off the BSE prions in beef and beef products?**

The prion agent is highly stable; it resists freezing, drying, and heating at normal cooking temperatures. It even resists those temperatures used for pasteurization and sterilization.

## Questions and Answers about BSE/vCJD and Blood Donation

1. What is DOD's policy regarding vCJD/BSE as it relates to blood donors?
2. Can vCJD be transmitted by transfusion?
3. Since there is a theoretical risk of transmission via transfusion, what precautionary steps have been taken to mitigate the theoretical risk?
4. Has DOD adopted the FDA's recommendations and are any additional deferrals planned?
5. If vCJD has not been transmitted by blood or blood product transfusion, why are some donors being told that they cannot donate blood because they were stationed in the United Kingdom?
6. Several newspapers have reported that the American Red Cross (ARC) has indicated a desire to defer blood donors that have spent more than six months in any part of Europe from 1980 to present. Is DOD prepared to implement such a deferral?
7. Why are only those people who lived in the United Kingdom for more than six months disqualified from donating blood? Why not one month or 10 years?
8. How long does DOD anticipate the deferral being in effect?

### 1. What is DOD's policy regarding vCJD/BSE as it relates to blood donors?

In December 1999, at the recommendation of the Food and Drug Administration (FDA), any person who spent six months or more cumulatively in the United Kingdom (UK) between 1980 and 1996 was deferred from donating blood. This action was taken to avoid the extremely remote possibility of transmitting the causative agent of variant Creutzfeldt-Jakob Disease (vCJD). This blood donation deferral policy is also the current policy of the Department of Defense to comply with the FDA policy.

### 2. Can vCJD be transmitted by transfusion?

The transmissibility of vCJD by blood or blood products is unknown, and laboratory and epidemiological studies are underway to evaluate the risk. Until such studies are complete, there remains a theoretical risk that vCJD could be transmitted via transfusion.

### 3. Since there is a theoretical risk of transmission via transfusion, what precautionary steps have been taken to mitigate the theoretical risk?

The FDA recommended that blood donors that have spent six months or more cumulatively in the United Kingdom from 1980 through 1996 be indefinitely deferred as blood donors.

### 4. Has DOD adopted the FDA's recommendations and are any additional deferrals planned?

DOD implemented indefinite deferrals for UK travel exceeding 6 months from 1980 through 1996. The FDA's Advisory Committee for Transmissible Spongiform Encephalitis recommended in January 2001 that additional donor deferrals be initiated for donors that have resided in Portugal, France, or the Republic of Ireland for more than 10 years from 1980 to present. The FDA is currently evaluating the recommendation and is expected to announce further guidance in the very near future. DoD will follow the guidance as determined and published by the FDA.

### 5. If vCJD has not been transmitted by blood or blood product transfusion, why are some donors being told that they cannot donate blood because they were stationed in the United Kingdom?

There is a theoretical risk of transmission by transfusion, which makes it necessary to be as cautious as possible until more facts are known. The vast majority of vCJD cases have been identified in the UK, which makes residence in the UK a risk factor for developing vCJD. As a precaution, FDA recommends that blood donors who have six months or more cumulative time in the UK from 1980 through 1996 be indefinitely deferred.

### 6. Several newspapers have reported that the American Red Cross (ARC) has indicated a desire to defer blood donors that have spent more than six months in any part of Europe from 1980 to present. Is DOD prepared to implement such a deferral?

Should the ARC change its deferral policy, DOD will evaluate the ARC policy and FDA guidance to determine what precautionary standard of practice will be implemented.

**7. Why are only those people who lived in the United Kingdom for more than six months disqualified from donating blood? Why not one month or 10 years?**

The FDA Advisory Committee reviewed data presented by US and international experts regarding the theoretical risks of being exposed to vCJD by eating beef and beef products in the UK versus the risk of deferring so many donors that there would be critical blood shortages in the US. The committee recommended six months as the period most likely to reduce the theoretical risk of transmitting this disease through blood transfusion and not causing serious blood shortages in the US

**8. How long does DOD anticipate the deferral being in effect?**

The deferral will remain in effect indefinitely. The FDA will continue to review the deferral guidance and provide updates as more information becomes available on the agent that causes the disease, the route of transmission and whether or not it can be transmitted through blood or blood products.

## Questions and Answers about BSE and Vaccines

- 1. Could anyone in Europe diagnosed with the newly recognized variant of CJD (vCJD) have acquired this from vaccines?**
- 2. Why are animal products used in the manufacture of vaccines, and which bovine-derived products are used?**
- 3. What position has the FDA assumed concerning the risk of transmission of BSE through vaccines?**
- 4. What is the risk of getting vCJD if a vaccine contained the BSE agent?**
- 5. My child was just immunized. Should I be worried?**
- 6. Are there vaccines licensed in the US that may have been manufactured using bovine –derived materials from countries where BSE has been found?**
- 7. The FDA has identified some vaccines manufactured with bovine-derived material. Which of these vaccines have been used to immunize DOD personnel and family members?**

### **1. Could anyone in Europe diagnosed with the newly recognized variant of CJD (vCJD) have acquired this from vaccines?**

In the UK the majority of cases of vCJD were born before 1980, and it is very unlikely that they received vaccines containing the BSE agent (Vaccine 2000 19:409-410). Surveillance of vCJD in the UK has identified three "risk factors," or characteristics common to most if not all of the people who had vCJD: 1) residence in the UK; 2) a particular genetic susceptibility; and 3) age. Epidemiological evidence to date suggests that these cases of vCJD acquired the disease from eating beef products containing the BSE agent after 1980.

### **2. Why are animal products used in the manufacture of vaccines, and which bovine-derived products are used?**

Vaccines contain either killed or weakened forms of disease-causing bacteria or viruses, or components of these that stimulate a response by the body's immune system, which then protects against the development of disease. Many bacteria and viruses can be cultured in the laboratory using growth media. Although synthetic media have been developed for growth of many medically important microorganisms, some still require additional nutrients that are easily provided by animal-derived products such as serum and blood.

Animal-derived products used in vaccine manufacture can include amino acids, glycerol, detergents, gelatin, enzymes and blood. Cow milk, tallow, bones, and skeletal muscle are used as sources for amino acids, sugars such as galactose, glycerol, and gelatin for growth media. Many difficult to grow microorganisms require the addition of serum from blood to the growth media.

### **3. What position has the FDA assumed concerning the risk of transmission of BSE through vaccines?**

The Center for Biologics Evaluation and Research (CBER), FDA regulates biological products including vaccines. For several years CBER has recommended that bovine derived components from countries where BSE has occurred or is at high risk to occur not be used for the manufacture of US-licensed biological products including vaccines. There is no evidence that any case of vCJD has resulted from use of a vaccine, and there is no evidence that any vaccines harbor the BSE agent. CBER recently determined that some vaccines were manufactured using bovine components from countries where cases of BSE have occurred or are at risk to occur. CBER believed that the chance of getting vCJD through vaccines is remote and theoretical

### **4. What is the risk of getting vCJD if a vaccine contained the BSE agent?**

There is no evidence to date that vaccines have contributed to the cases of vCJD seen in Europe. Nor is there evidence that any vaccines harbor the BSE agent. Vaccines are given a very limited number of times via the intramuscular, subcutaneous or oral route. Even in experimental studies, these routes of administration are less effective at spreading the agent than the intracerebral route usually used to assess infectivity in animal studies.

**5. My child was just immunized. Should I be worried?**

No. These are statement from the Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER) regarding BSE, vCJD and vaccines:

?? *“There is no evidence to date that vaccines have contributed to the cases of vCJD seen in Europe. Nor is there evidence that any vaccines harbor the BSE agent.”*  
(<http://www.fda.gov/cber/bse/bseqa.htm>)

?? *...”The consumption of food contaminated with the BSE agent has been linked to a fatal disease in people called new variant or variant CJD (vCJD). There is no evidence that any case of vCJD has resulted from use of a vaccine, and there is no evidence that any vaccines harbor the BSE agent.”*  
(<http://www.fda.gov/cber/bse/bseqa.htm>)

**6. Are there vaccines licensed in the US that may have been manufactured using bovine–derived materials from countries where BSE has been found?**

Yes, the FDA has released information on the following vaccines. There are two groups. The first are vaccines that may have been produced using bovine materials from countries on the USDA list, and the second group includes vaccines that may have been produced using bovine-derived materials of unknown geographical origin.

**Vaccines that use bovine-derived materials from countries from countries where BSE has been found include:**

- ?? Aventis Pasteur, S.A.’s Haemophilus influenzae type b conjugate vaccine, ActHIB® (ActHIB® is also marketed as OmniHIB™ by SmithKline Beecham Pharmaceuticals)
- ?? North American Vaccine Inc.’s diphtheria and tetanus toxoids and acellular pertussis (DTaP) vaccine, Certiva™
- ?? SmithKline Beecham Biological’s DTaP vaccine, Infanrix®
- ?? SmithKline Beecham Biological’s Hepatitis A vaccine, Havrix®.

**Vaccines that use bovine-derived materials of unknown geographical origin include:**

- ?? Aventis Pasteur, S.A.’s inactivated polio vaccine, IPOL®
- ?? BioPort’s Anthrax vaccine
- ?? Lederle Laboratories’ Pneumococcal polysaccharide vaccine, PNU-IMUNE® 23.

This information will be periodically updated to reflect the most current status.

Currently, the FDA has not recommended withdrawing any vaccines. One of FDA's main concerns is the safety of vaccines and other drugs given to consumers. In its efforts to monitor the safety of vaccines the FDA continually reviews potential risk of products in relation to new entries, including the BSE agent. The FDA and other Public Health Service agencies believe that the risk of contamination of any US licensed vaccine with BSE agent is remote and theoretical. The bottom line is there is no evidence to date that vaccines have contributed to the cases of vCJD seen in Europe. Nor is there any evidence that any vaccines harbor the BSE agent.

**7. The FDA has identified some vaccines manufactured with bovine-derived material. Which of these vaccines have been used to immunize DOD personnel and family members?**

DOD uses five FDA licensed vaccines that were identified as possibly using bovine-derived material from countries where BSE has been found:

Haemophilus influenza type b- Act HIB  
Diphtheria, tetanus toxoids and acellular pertussis (DTaP)- Infanrix  
Inactivated Polio (IPOL)-IPOL  
Hepatitis A- Havrix  
Anthrax Vaccine Adsorbed- BioPort

Currently, the FDA has not recommended withdrawing any vaccines. One of FDA's main concerns is the safety of vaccines and other drugs given to consumers. In its efforts to monitor the safety of vaccines the FDA continually reviews potential risk of products in relation to new entries, including the BSE agent. The FDA and other Public Health Service agencies believe that the risk of contamination of any US licensed vaccine with BSE agent is remote and theoretical. The bottom line is there is no evidence to date that vaccines have contributed to the cases of vCJD seen in Europe. Nor is there any evidence that any vaccines harbor the BSE agent.