

Cattle Call

Could Vaccines and Gel Caps Carry Mad Cow Disease?

By **MARC SIEGEL, M.D.**

You won't find hamburger meat from British cows on your supermarket shelf: European beef has been banned by the USDA because of possible contamination by mad cow disease. But many vaccines and pill capsules sold in this country are still made using cow products from European regions where mad cow disease is endemic.

The FDA has repeatedly recommended that manufacturers of drugs and vaccines not use bovine materials from European countries affected by mad cow disease. But, according to the FDA, a number of common vaccines still use bovine serum from these countries, including vaccines for diphtheria, tetanus, and hepatitis A and B.

Similarly, gel capsules for many over-the-counter medications use gelatin derived from cows from these areas.

The infectious agent of mad cow disease (Bovine Spongiform Encephalopathy or BSE) is believed to be a genetically determined protein known as a prion, which primarily affects the brain. Mad cow disease spread rapidly among British cows in the 1980s and early 1990s, principally because, though born vegetarians, the cows were compelled to consume meat-and-bone-meal derived from sheep and cow parts, including brains. (Sheep have long been afflicted by another brain-deteriorating prion known as scrapies.)

The British government responded to the growing epidemic among cows by banning the use of meat-and-bone meal, and the number of cattle with mad cow disease decreased dramatically.

In the mid-1990s, however, health officials became alarmed by the discovery of an apparent link between BSE and a new variant of Creutzfeldt-Jakob Disease (CJD), an existing human form of prion disease that primarily affected the elderly. The new variant of Creutzfeldt-Jakob Disease (vCJD) affected mainly people in their late teens and 20s, and appeared to occur in humans who had eaten meat from cows with mad cow disease. vCJD has an average duration to death of about 13 months, compared to six months in classic CJD (both diseases are uniformly fatal); its symptoms include emotional distress or confusion, unusual sensory experiences, and, ultimately, dementia and loss of muscle control.

To date, 134 people, mostly in Britain, have been diagnosed with vCJD. (No cases of vCJD have been reported in America.) Since the incubation period for prion diseases can be anywhere from 10 to 40 years, however, and since the disease peaked in cows in the late 1980s and early 1990s, there may be more cases still to come in humans who are harboring the prions but haven't gotten sick yet.

In response to mad cow disease, the USDA has banned the importation of cows, sheep and goats and their

products from Great Britain since 1989 and from all of Europe since 1997. But the FDA has not had similar success in banning these products from vaccines and gel caps.

According to the FDA, fetal calf serum from the United Kingdom was used in the production of viral seeds and cell banks in the mid-1980s, when the incidence of BSE in adult cattle was estimated to be about one in 200. Studies have indicated that the rate of transmission of BSE from mother to fetus is about 10%, suggesting that about one in 2,000 fetal calves would have been infected at the time, the FDA says. The FDA further reports that when calf serum is manufactured, the sera from approximately 1,500 calves is pooled together, making it theoretically possible that, if one in 2,000 calves is infected, any given serum pool is infected.

So, how likely are humans to get sick from vaccines made with potentially infected bovine serum? The FDA has stressed that the risks are remote, and so far, strictly theoretical. There have been no reports of any BSE contamination in any pharmaceutical or biological products, and no reported cases of vCJD resulting from the administration of a vaccine product. The FDA has further emphasized, in a report from July 27, 2000, that "the benefits of vaccination far outweigh any remote risks of vCJD."

Still, the FDA has recommended as a precautionary measure that vaccine manufacturers replace bovine materials from BSE-affected countries with those from unaffected countries. Prions are resistant to most of the usual heat and sterilization procedures used in vaccine production to kill bacteria and viruses.

Furthermore, capsules used in countless medications are made using gelatin ground from cow bones — including those from countries where mad cow disease is endemic. Bones in infected animals contain far fewer prions than brains do, but could contain some.

Last year at a conference, I was presented the case of Mr. F., who in the span of one year had eaten sirloin in Italy, been vaccinated for travel, and consumed numerous over-the-counter gel caps. He was admitted by New York Hospital when he became distraught, suffered memory lapses, and was overcome by muscular jerks. Soon he began to shout incoherently. A brain biopsy was performed, and though the patient was more than 40 years-old, the initial results were consistent with vCJD. Follow-up tests were inconclusive, and it was ultimately decided that he did not have the variant type of CJD. So to date there has still not been a case of vCJD in America, but Mr. F. reminded pathologists that the first case could come at any time.

Ruth Kava, Director of Nutrition at the American Council on Science and Health says, "There has been concern expressed that consumption of dietary supplements containing materials from BSE-affected animals would increase the risk of vCJD in humans. Certainly it would be important that animals used as the source of vaccine components be free from prion disease."

Ms. Kava points out that a consistent policy is necessary, especially because scientists are not entirely sure which tissues are capable of passing on prions. "It is logical to ban BSE-affected cows or their byproducts from the human food chain," Ms. Kava says.



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