

U.S. Request on Vaccines Ignored by Drug Firms

For eight years, the Food and Drug Administration has repeatedly asked pharmaceutical companies not to use materials from cattle raised in countries where there is a risk of mad cow disease.

But regulators discovered last year that five companies, including some of the world's largest drug concerns, were still using ingredients from those countries to make nine widely used vaccines.

Some of the companies say they found the agency's request unclear and do not believe they did anything wrong. Others say they could not keep up with the government's expanding list of countries where cattle could be infected. One, however, acknowledged that it could have moved more quickly.

The nine vaccines include some regularly given to millions of American children, including common vaccines to prevent polio, diphtheria and tetanus. They also include the anthrax vaccine, which the government requires for soldiers serving in the Gulf.

Federal health officials stress that the vaccines are still considered safe. They calculate that the odds of these vaccines passing on the disease, in the worst eventualities, are between one in 40 million and one in 40 billion doses.

The officials say that the very slight chance that someone could be infected is far outweighed by the benefits that these vaccines bring in fighting disease and preventing death.

Indeed, it is now only a scientific theory that a vaccine could infect someone with the human form of mad cow disease - called new variant Creutzfeldt-Jakob disease. No one is known to have contracted the disease this way.

"Any risk is very remote," said Dr. Karen Midthune, director of the agency's Office of Vaccine Research and Review. "But if we have the ability to bring this remote risk to zero, that is something we want to do."

Nonetheless, the fact that these suspect materials slipped into the country's vaccine supply - and that the agency did not discover it for seven years - raises questions about the agency's ability to ensure that all medicines are free of the infectious proteins that can cause mad cow disease.

The Food and Drug Administration so far has only investigated the vaccine makers and has not looked to see whether other medicine is free of possible mad cow contaminants.

Some experts say they worry more about dietary supplements. Unlike drugs, supplements are largely unregulated.

"It's just insane not to have greater safeguards" for supplements, said Dr. Paul Brown, chairman of the agency's advisory committee on mad cow disease. "The potential exists for abuse."

The five vaccine makers are GlaxoSmithKline, Aventis, American Home Products, Bioport and North American Vaccines (which was acquired by Baxter International last year).

The five vaccine makers have now agreed to stop using the suspect materials, which include blood, fetal calf serum and meat broth.

But it will take a year or more to replace existing supplies with reformulated products because it can take months to grow cultures used in making vaccines. Both the companies and the agency say the current products are safe.

They point out that the suspect ingredients, for the most part, are used only in the early stages of manufacturing, when cultures are grown. Blood, for instance, may be used to feed the bacteria and viruses in these cultures. The cultures are then significantly diluted in the final vaccine.

The Food and Drug Administration first asked the vaccine makers in 1993 to stop using materials from cattle raised in Britain and other countries where there was a threat of mad cow disease.~folo~Florence Has Protest Barbecue~/folo~Italian agricultural and tourist associations organized free beef barbecues Thursday in restaurants and piazzas in Florence to protest new mad cow restrictions imposed by the European Union, The Associated Press reported from Florence.

About 250 kilograms (550 pounds) of fiorentina, a T-bone steak that is Tuscany's culinary pride, were prepared to be cooked up in a central piazza in Florence, said Gilberto Bacci, a spokesman for Confesercenti, an association of restaurants, hotels and other tourist services.

At least 40 restaurants around Florence said they would also offer a free taste of the steak.

Elsewhere in Europe on Thursday, German officials said the country would create a government agency for food safety.

In Dublin, Irish officials said banned nerve tissues had been found in a shipment of beef from Germany.

The officials said they were raising the discovery "as a matter of urgency" with German officials.