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## 5 Drug Makers Use Material With Possible Mad Cow Link

By MELODY PETERSEN AND GREG WINTER  
Published: February 8, 2001

For the last 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 that they found the F.D.A.'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 Persian 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

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one is known to have contracted the disease this way.

"Any risk is very remote," said Dr. Karen Midthune, director of the F.D.A.'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 nation's vaccine supply -- and that the F.D.A. 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 F.D.A. 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. The F.D.A. is not even sure how many supplement makers there are.

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

All five vaccine makers, which include GlaxoSmithKline, Aventis and American Home Products, 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 many months to grow cultures used in making vaccines. Both the companies and the F.D.A. say that the current products are safe and should remain on pharmacy shelves.

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 F.D.A. first asked the vaccine makers in a 1993 letter to stop using materials from cattle raised in Britain and other countries where there was a threat of mad cow disease. Regulators followed up with another letter in 1996 in which the agency "strongly" recommended that drug companies take "immediate and concrete steps" to make sure they were not using the materials.

In interviews, regulators said it was not until last year that they learned that some vaccine makers were not complying. During a routine review of a company's application for a license, the F.D.A. discovered that the company, which it will not identify, was using cattle parts from a high-risk country.

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Regulators immediately demanded that all vaccine makers identify where their biologic ingredients were coming from. That review found the nine vaccines.

Dr. Murray M. Lumpkin, a senior medical adviser at the F.D.A., said his agency's investigative resources were limited.






"You have to prioritize where the greater risk is," Dr. Lumpkin said. For example, the F.D.A. now has inspectors visiting animal feed companies, he said, after it found that many of them were not following regulations adopted in 1997. Those rules, in part, prohibit using beef parts to make cattle feed. Scientists contend that cattle in Britain were infected after eating feed that contained parts of other infected cows.

"That is where we think the greatest risk for Americans is at this time," Dr. Lumpkin said.

But critics including doctors, scientists and consumer advocates say that the F.D.A. should have acted more aggressively by ordering, rather than asking, companies to follow the agency's recommendations.

"The companies acted recklessly because, in part, the F.D.A. failed to regulate them," said Dr. Peter G. Lurie, another member of the F.D.A's advisory committee on the disease.

Dr. Lurie, a researcher at Public Citizen, the consumer group, said he agreed that the vaccines should stay on pharmacy shelves. But he faulted both the companies and the F.D.A. for possibly undermining public confidence in the safety of vaccines.

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In their defense, F.D.A. officials said they expected companies to heed their requests.

"The expectation," Dr. Lumpkin said, "is that people will behave responsibly."

Mad cow disease, which is always fatal, is believed to be caused by an infectious protein called a prion. In sick animals or humans, the prion twists into an abnormal shape, often in the brain. These misfolded prions accumulate in toxic clumps, eventually destroying normal brain tissue and creating spongelike holes.

Cattle ingredients are used in a myriad of drugs other than vaccines. But the F.D.A. says it cannot release a list of these drugs because many details of how a product is manufactured are proprietary corporate information.

But regulators say, for instance, that many drugs contain gelatin, made from the bones or hooves of cattle. And calf lungs are used to make surfactants, which help premature infants breathe.

As for dietary supplements, the industry's trade groups say that hundreds of products use an array of cow tissues, from ground prostate glands and testicles in pills that supposedly bolster sexual vitality to thymus extract for healthy skin.

Many organs that scientists consider particularly risky for the transmission of mad cow disease are also used, including freeze-dried brain and pituitary glands in supplements that manufacturers say stimulate memory, adrenal extract for energy, even powdered spleen to help clear the sinuses.

As with vaccines, the F.D.A. has urged supplement makers not to use cow tissue from certain countries. But the F.D.A., which has no specific manufacturing rules for supplements, cannot say whether products sold in the United States are free of such ingredients.

"The F.D.A. is toothless," Dr. Brown said. "Their purview over dietary supplements is infinitesimally small."

Without comprehensive federal guidelines, the Natural Nutritional Foods Association, the largest trade group, started a voluntary program in 1999 to test whether its members' products are free of contaminants, including mad cow disease. But of about 500 companies eligible, only 20 have gone through the review.

For its part, the F.D.A. inspects only about 60 of the more than 1,000 supplement manufacturers each year. "We rely on the industry to do the right thing," said Dr. Christine Lewis, director of the F.D.A.'s dietary supplement division.

In 1995, the F.D.A. told its border agents to detain any imports of suspect cattle parts or products made from them. Regulators say they have not found any supplements sold in the United States that contain the materials.

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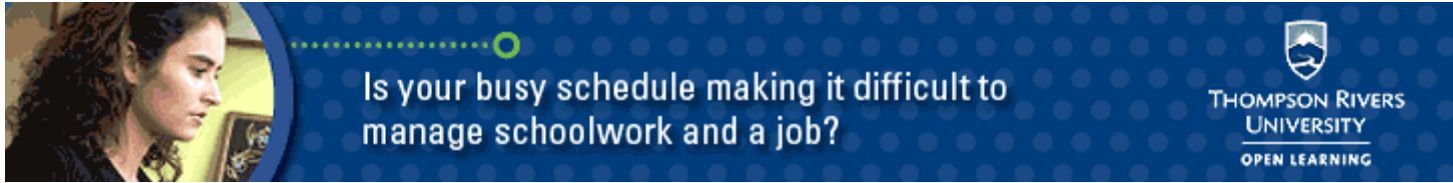
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And one industry executive said there was little incentive to even try to import such materials. "These glands are not very expensive," said Matt Schueller, vice president at Enzymatic Therapy, a supplement maker in Green Bay, Wis.






Even so, Dr. Brown and others say that the border controls are not enough.

Every year, more than \$1 billion of supplements are imported from high-risk countries, according to a 1999 F.D.A. study. Only about 7 percent of these products say on their labels that they contain animal parts, but there could be more, Dr. Brown said. Foreign labeling laws vary widely, he said, making it hard to know what some imports contain.

The companies that make the nine vaccines say they have tried to comply with the F.D.A.'s requests and, over the years, have provided regulators with any information they asked for.

They say that in most of the vaccines, the ingredients that regulators have questioned are in the cultures used to start each batch. They say that some of these cultures, which are used year after year, were created in the 1980's, before the F.D.A. told them to stop using material from certain countries.

American Home Products has been working for five years to change the material used in bacterial seed cultures for its vaccine, Pnu-Immune 23, which prevents pneumonia, said Dr. Peter R. Paradiso, a top researcher in the company's Lederle Vaccine subsidiary. The 23 cultures making up the vaccine must be modified one at a time, he said, with regulators approving each one.

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"The risk is very, very minuscule," Dr. Paradiso said. He calculates the risk of Pnu-Imune passing on the disease, in a worst case situation, at one in 2.4 trillion doses.

At Aventis, Len Lavenda, a spokesman, said that the company had believed that IPOL, its polio vaccine, complied with the F.D.A.'s request. But last year, regulators disagreed, he said, because the company cannot trace the origin of some ingredients purchased in the 1980's.

In ActHIB, Aventis's vaccine to protect against haemophilus influenzae Type B bacterium, the company used small amounts of hemin, a blood derivative, from cattle in the Netherlands. Material from the Netherlands was banned in 1997, but Aventis decided not to change its supplier, he said, because its scientists believed that infectious material could not survive the production process.

"That was probably a mistake," Mr. Lavenda said. The vaccines are safe, he said, but the company fears its decision could weaken the public's confidence in the vaccines.

BioPort, which makes vaccines against rabies and anthrax, said that it did not understand until last year that the F.D.A. wanted the companies to change seed cultures created before 1993.

GlaxoSmithKline, the British pharmaceutical giant that sells three of the vaccines cited by the F.D.A., declined to answer specific questions. Carmel M. Hogan, a company spokeswoman, said the company had been trying since 1990 "to move away from using bovine materials from infected countries."

The F.D.A. said the problem with Infanrix, one of GlaxoSmithKline's vaccines, which prevents diphtheria, tetanus and pertussis, stems from an ingredient made for it by Chiron Behring in Germany. Chiron stopped using material from German cows in September, said Thomas Schick, a Chiron spokesman, after American regulators visited its factory.

The final vaccine, Certiva, also for children, was made by North American Vaccines until 1999 when there were production problems. Baxter International, which purchased North American last year, said the company did not intend to sell Certiva again.

### The Vaccines In Question

An outside committee of health experts and federal regulators has reviewed the risk of contracting the human equivalent of mad cow disease from several vaccines and has concluded that the risk is remote and only theoretical. No one is known to have been infected by a vaccine. The United States Public Health Service said in December that all people should continue to be vaccinated. The service said there was no need to select one vaccine over another.

The Food and Drug Administration calculates that at the worst the risk of contracting

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the disease from one dose of a bacterial vaccine, such as a vaccine to protect against tetanus, is one in 40 million.

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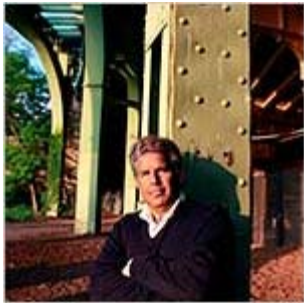
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And with viral vaccines, like the one against polio, the F.D.A. estimates that the risk is far lower -- no more than one in 40 billion.

More information is available on the Web at [www.fda.gov/cber/bse/bse.htm](http://www.fda.gov/cber/bse/bse.htm).

Here is the list of vaccines that use cattle materials from countries where the government says there is a risk of mad cow disease:

- \*ActHIB, sold by Aventis Pasteur, to prevent infection by the haemophilus influenzae Type B bacterium.
- \*OmniHIB, sold by GlaxoSmithKline, to protect against haemophilus influenzae Type B.
- \*Infanrix, sold by Glaxo SmithKline, to prevent diphtheria, tetanus and pertussis.
- \*Havrix, sold by GlaxoSmithKline, to prevent hepatitis A.
- \*Certiva, sold by North American Vaccine, now a unit of Baxter International, to prevent diphtheria, tetanus and pertussis.

Vaccines that use cattle materials of unknown geographic origin are:

- \*IPOL, sold by Aventis Pasteur, to prevent polio.
- \*Pnu-Imune 23, sold by American Home Products' Lederle Laboratories, to prevent pneumococcal diseases.
- \*Anthrax vaccine, sold by BioPort.

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\*Rabies vaccine, sold by BioPort.

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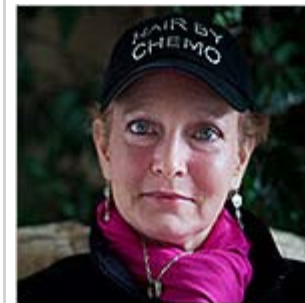
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