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MAD COW DISEASE: ARE OUR PRECAUTIONS ADEQUATE?

HEARING

BEFORE THE

SUBCOMMITTEE ON CONSUMER AFFAIRS, FOREIGN COMMERCE AND TOURISM

OF THE

COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

UNITED STATES SENATE

ONE HUNDRED SEVENTH CONGRESS

FIRST SESSION

APRIL 4, 2001

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C O N T E N T S

MAD COW DISEASE: ARE OUR PRECAUTIONS ADEQUATE?

WEDNESDAY, APRIL 4, 2001

U.S. SENATE,
SUBCOMMITTEE ON CONSUMER AFFAIRS,
FOREIGN COMMERCE AND TOURISM,
COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION,
Washington, DC.

The Subcommittee met, pursuant to notice, at 9:31 a.m. in room SR–253, Russell Senate Office Building, Hon. Peter G. Fitzgerald, Chairman of the Subcommittee, presiding.

OPENING STATEMENT OF HON. PETER G. FITZGERALD, U.S. SENATOR FROM ILLINOIS

Senator FITZGERALD. Good morning, everyone. I open this hearing of the Subcommittee on Consumer Affairs, Foreign Commerce and Tourism. I am going to give my opening statement and then we will go to Senator Campbell, and then we will go to opening statements of other Senators if they have one. I believe Senator Durbin is also on his way to testify as well. The two Senators will testify first and then we will have two panels of expert witnesses.

Mad cow disease is back in the news. Although reports of bovine spongiform encephalopathy, or BSE, are down significantly in Great Britain, where the disease peaked in 1993 with an estimated 1,000 cases per week, other European countries once thought immune to the disease are now reporting cases of BSE.

The spread of the disease throughout Europe invites our re-examination of the measures in place in the United States to prevent transmissible animal diseases. Additionally, we have recently witnessed graphic images of the mass slaughter of the animals in Britain to control the latest outbreak of foot and mouth disease, a blight unrelated to BSE. Some consumers apparently did not distinguish between foot and mouth disease and mad cow disease and other questions are arising as well.

Beginning in 1988, our government, through the United States Department of Agriculture, the Food and Drug Administration, and various other agencies, has employed a number of different measures to safeguard the American public from BSE. As *Newsweek* reported earlier this month, "the United States, to its credit, has shown foresight. Not a single mad cow has been reported in this country." Let me repeat that again: *Newsweek* recently reported that "not a single mad cow has been reported in this country."

In addition to the preventative measures adopted by regulation and the vast ocean that separates us from Europe, initiatives with-

in industry and differences between the way the U.S. and Europe traditionally feed and slaughter cattle may help the United States remain BSE-free. We hope to examine some of these initiatives and differences today.

But while the risks may be low, we cannot be complacent. The recent focus on BSE has invited examination of our defenses. By 1988, researchers in Britain knew that their cattle faced a deadly epidemic. They had identified BSE as a neurological disease, thought that it was probably transmitted through cattle feed derived from animals such as cattle, sheep, and goats, and knew that thousands of cattle may have consumed contaminated feed.

To date there have been over 170,000 cases of BSE reported in Europe, the vast majority of them in Great Britain. At the hearing today, this Subcommittee will examine the nature of the disease as well as the measures taken in this country to prevent the disease's establishment and spread in the United States.

Concerns have also been raised about our primary efforts to keep the infection out of the country. The effectiveness of our import prohibitions is also an issue we will explore. The Subcommittee would like answered some very basic questions, such as what is BSE, how much do we know, who are the experts in the field, how do they assess the risk, should consumers be concerned, what are we doing to prevent BSE, should we be doing more?

By examining these issues publicly, it is our hope to help answer questions posed by consumers. As former Secretary of Agriculture Dan Glickman wrote in response to a recent magazine article on BSE, "The American public is far more likely to be affected by salmonella, E. coli, or listeria than by BSE." I look forward to hearing from our witnesses today about whether they agree with that statement, whether our defenses are in place, and whether there is anything further we need to do.

With that, I would like to welcome Senator Campbell and invite him to make his remarks.

[The prepared statement of Senator Fitzgerald follows:]

PREPARED STATEMENT OF HON. PETER G. FITZGERALD,
U.S. SENATOR FROM ILLINOIS

Mad cow disease is back in the news. Although reports of Bovine Spongiform Encephalopathy, or BSE, are down significantly in Great Britain—where the disease peaked in 1993 with an estimated 1,000 cases per week—other European countries once thought immune to the disease are now reporting cases of BSE. The spread of the disease throughout Europe invites our reexamination of the measures in place in the United States to prevent transmissible animal diseases. Additionally, we have recently witnessed graphic images of the mass slaughter of animals in Britain to control the latest outbreak of foot and mouth disease—a blight unrelated to BSE. Some consumers apparently do not distinguish between foot and mouth disease and mad cow disease, and other questions are arising as well.

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But while the risks may be low, we cannot be complacent. The recent focus on BSE has invited examination of our defenses.

By 1988, researchers in Britain knew that their cattle faced a deadly epidemic. They had identified BSE as a neurological disease, thought that it was probably transmitted through cattle feed derived from animals such as cattle, sheep, and goats, and knew that thousands of cattle may have consumed contaminated feed. To date, there have been over 170,000 cases of BSE reported in Europe, the vast majority of them in Great Britain.

At the hearing today, this subcommittee will examine the nature of the disease, as well as the measures taken in this country to prevent the disease's establishment and spread in the United States.

Concerns have also been raised about our primary efforts to keep the infection out of the country. The effectiveness of our import prohibitions is also an issue we will explore.

This subcommittee would like answers to some very basic questions: (A) What is BSE?; (B) How much do we know?; (C) Who are the experts in the field?; (D) How do they assess the risk?; (E) Should consumers be concerned?; (F) What are we doing to prevent BSE?; (G) Should we be doing more?

By examining these issues publicly, it is our hope to help answer questions posed by consumers. As former Secretary of Agriculture Dan Glickman wrote in response to a recent magazine article on BSE, the American public is far more likely to be affected by salmonella, E. coli, or listeria than by BSE. I look forward to hearing from our witnesses today about whether they agree with that statement, whether our defenses are in place, and whether there is anything further we need to do.

STATEMENT OF HON. BEN NIGHTHORSE CAMPBELL, U.S. SENATOR FROM COLORADO

Senator CAMPBELL. Thank you, Mr. Chairman, for calling this hearing and allowing me the opportunity to testify on an issue that has certainly a direct impact on our state of Colorado and the rest of the nation as a whole.

Let me state, perhaps repeat what you have already alluded to, and that is that the purpose of this hearing should not be to whip up people's fears so they go off pell-mell into some kind of a stampede of hysteria. Frankly, the media is doing that quite well without government help. I was looking at the *Newsweek Magazine* that you spoke about and in reading the article, you were right, they say that not one single case has been reported of mad cow disease. But holy smokes, if you just look at the cover of that magazine, "Mad Cow Disease" in big print, the slow deadly spread of it and how it could become an epidemic, that cover really instills needless fears in people, I think.

The day does not go by now that we are not reading about mad cow disease or related diseases like hoof and mouth. It seems to me that we need as elected officials here in Washington to proceed in a prudent, cautious way to do everything we can to prevent the spread of any cattle disease or any livestock disease, but certainly only then can we continue to elicit confidence in the consumers in the American food supply.

History has certainly taught us that inaccurate or insufficient information leads to destructive rumors. It has also taught us that the public perception of inadequate government responses to their concerns can also lead to groundless fears.

But the genie is out of the bottle and certainly the mainstream press is carrying stories almost daily, as I mention. But it is neither wise nor prudent to scare people, but it is not wise nor prudent to totally avoid it, as some have suggested.

Regrettably, there are some people in this country already who are whipping it up, and while we are working here today to try to make sure that people know that the American food supply is safe, I was reading with great interest the comments made by the head of PETA, the People for the Ethical Treatment of Animals, in stating her hopes that foot and mouth disease does spread to the United States. The lady, Ingrid Newkirk, the president of PETA, said in an interview: "If that hideousness comes here, it would not be any more hideous for the animals. They are bound to a ghastly death anyway. But it would wake up consumers. I openly hope that it comes here. It will bring economic harm only for those who profit from giving people heart attacks and giving animals a concentration-like existence. It would be good for the animals, good for human health, and good for the environment."

That is why this hearing is important, because of some of the irresponsible, destructive rumors that increase the fears with inaccurate information.

The American people have already expressed their concern about mad cow disease. According to an *ABC News-Washington Post* poll conducted in January, 44 percent of the respondents said they had heard of the disease and they were very concerned or moderately concerned that it would become a problem in the United States. That percentage increased to 65 percent in those responding to a similar question in the Gallop Poll, so clearly it is out there.

Those poll numbers make it clear that Congress cannot simply stick its head in the sand like an ostrich and pretend that the public is not aware or not concerned or simply refuse to talk about it because it might hurt sales.

As a rancher myself and having heard from fellow cattlemen, I have personal as well as policy concerns about this disease, as well as other related diseases. Colorado is the home of 12,000 beef producers and 3,150,000, head of cattle. I repeat that number because it is more than the human population of 22 states. Nationwide, Colorado ranks fourth in cattle on feed and tenth in overall cattle numbers. Nearly one-third of our counties in Colorado are classified as either economically dependent on the cattle industry or the industry plays a vital role in their economies. Many counties across the country are also dependent on the cattle industry.

Therefore, it is critical that we in Congress do everything we can to protect this industry with careful contingency planning.

What we are seeing overseas is a rapid spread of three categories of diseases. This hearing deals primarily with the first, but I would like to mention a little bit about all three. That first category that you spoke about is mad cow disease. It is a disease formed by a mutated protein in the brain. Even if the infected animal is destroyed, the disease can spread through the distribution of cattle feed.

Animals which are inflicted with the mad cow disease are basically cloven-foot animals: cows, sheep, and goats. The symptoms which the infected animals exhibit include drooling, arching the back, shedding weight, losing balance, waving their heads, weaving, and threatening other animals.

A particularly disturbing aspect of this disease is that it can be found to spread to humans, as you know. A recent news program

included footage of a patient in Europe inflicted with mad cow disease and it is certainly a heart-wrenching and disturbing sight. But as you also said, so far mad cow disease has not been found in the United States ever, not ever.

But we have had some recent scares that have been portrayed pretty graphically in the newsprint and over television, too. Just 2 weeks ago, a herd of quarantined sheep in Vermont was feared to be infected with that disease. The sheep had come from Belgium 3 years ago and might have been fed contaminated feed. The USDA seized that herd, as you know, and killed the sheep and tested them and they were tested negative. There was not any disease in that herd.

The second herd of quarantined sheep in Vermont was seized and also killed and tested. They were also tested negative. Then a week ago a herd of cattle in Texas, there was some fear that it might have been infected with the same disease. They were imported from Germany in 1996, before the 1997 ban was placed on the importation of European livestock.

In all three of those herds, not one animal was found infected. There is now, of course, as you know, a ban on animals, imported feeds, and products and so on.

The second category I would like to just mention is just a little bit outside the scope of this hearing, but I think important, is foot and mouth disease. This disease is known to cause blisters and lesions on an animal's tongue, lips, mouth, and hoofs. The animals infected show signs of lameness and anorexia. The ones that are infected with foot and mouth disease are generally the same—cows, sheep, goats, pigs, cloven-footed animals—and wild animals such as elk and deer can also become infected.

It does not affect humans, but humans can be carriers simply by walking through a contaminated pasture and then walking through a fresh pasture where animals are grazing. There is no cure for it, but it can run its course in a short 2 or 3 weeks, and the ones that do survive take about 6 months to fully recover. But during that time, if they are dairy herds, milk production is affected very significantly and that certainly could affect the dairy industry.

It is just about out of control in England and on the European continent, too. The first outbreak of foot and mouth disease in England was about 6 weeks ago and today the entire country is under quarantine. In the past 3 weeks there have been confirmed cases in France, Ireland, and Northern Ireland.

Fortunately, in the United States the last incident of foot and mouth disease was in 1929. But with the ease and speed of how viruses travel with all the modern transportation systems, a recurrence in the United States certainly is in the realm of possibility. In fact, just a few days ago a hog was suspected in North Carolina of having foot and mouth disease. It turned up negative, as the other tests have turned up, too.

The third category includes livestock-related disease, such as the chronic wasting disease. We are seeing that disease more often in Colorado and many of the western states among our herds of elk and deer, but it certainly does affect domestic livestock, too. It affects the brain and central nervous system and causes these animals to lose massive amounts of weight, which in turn leads to

death. Just 2 days ago, wildlife officials in Colorado began killing 300 deer in northeastern Colorado to try to control spread of that wasting disease.

So certainly I believe, as I think you do, that Congress must do everything we can to protect the supply of food without causing any kind of a panic. I might mention that last Friday at the Chicago Board of Trade the markets for livestock and grains did drop because of some of these potentially damaging rumors—and I mention the word again, "rumors"—about the livestock-related disease in North Carolina. That is I think what we should try to avoid.

We can see this need at the state level and in the private sector. Some states are not going to wait for the Federal Government to do more to prevent the influx of any of these diseases, including mad cow. Colorado, along with North Dakota and Montana, have issued emergency directives that impose their own restrictions, such as increasing the kinds of animals banned or requiring disinfectant baths for certain animals.

My state, Colorado, went further by broadening the ban to include horses and companion animals such as cats and dogs, which are not covered by the Federal ban. The Colorado restriction will stay in effect until the country from which the animals originated are free from that disease for 6 months.

The private sector is also taking important steps. Recent news reports indicate that both Burger King and McDonald's are requiring meatpackers the prove that the cattle they buy have not been fed with feed containing animal byproducts. Hopefully that will assure their customers that their food is safe in those chains and I certainly commend them for that.

I recently introduced Senate Bill 534 on March the 14th of this year, which establishes a Federal Inter-Agency Task Force, to be chaired by the Secretary of Agriculture, for the purpose of coordinating actions to prevent the outbreak of the 3 categories I mentioned earlier. The agencies in the task force will include Agriculture, Commerce, Health and Human Services, Treasury, Food and Drug Administration, the National Institutes of Health, the Centers for Disease Control, and Customs, and other agencies that the President deems appropriate.

Currently APHIS, the Animal and Plant Health Inspection Service, is already working with Federal agencies like Customs and a number of others to try to do that. This bill that I introduced would expand this Federal effort, formalize the creation of a task force, and increase the impact of Federal efforts through better cooperation. I think that this bill would also require that no less than 60 days after the enactment that the task force would submit to Congress a report that would describe the actions the agencies are taking and a plan to prevent the spread of these diseases and make recommendations for the future that we can deal with.

I certainly look forward to working with this Subcommittee in hopes that that bill will get a hearing and it will be passed. But clearly, if we fail to take action in some kind of swift and timely and prudent manner, we certainly will be accused to being a party to how the West was lost.

With that, Mr. Chairman, I thank you for the time and look forward to working with you.

Senator FITZGERALD. Without objection. We thank you very much for coming, Senator, and we will put those materials in the record. Can we keep the map here during the rest of the hearing?

Senator CAMPBELL. I am going to stay as long as I can, yes, sir.

Senator FITZGERALD. That is great.

Senator Burns, you were here first, and then we will go to Senator Dorgan.

STATEMENT OF HON. CONRAD BURNS,
U.S. SENATOR FROM MONTANA

Senator BURNS. Thank you very much, Mr. Chairman.

I get a big kick in this town. You know, we usually call the disease on the farm and ranch "hoof and mouth," but here in Washington it is "foot and mouth." There is a little bit of a difference, but not much. I will tell you that.

Mr. Chairman, thank you for this hearing. It is important, I think, that we recognize one thing as we hear from our witnesses today. When the first instance of mad cow disease in 1985 broke out, many states, and especially our Department of Agriculture, took note of that and reacted immediately. I want to congratulate those folks in the livestock business, who did not let one instance go by without us taking precautions to protect our own herds and our own consumers in this country. We started to put things into motion right away, and in fact it was just 4 years later in 1989 when we banned all imports from the countries where BSE was known to have been. Of course, with 95 percent of that disease being in the U.K., it was fairly easy to localize and to prevent that from spreading in the United States.

The European Community did not take the precautions at the same time that we did and naturally it did spread into Germany and into France. But they still do not have the problem that the U.K. has.

So I am here this morning to say congratulations on our agencies, who reacted immediately, as they always do. I realize that coming back from overseas, some of our international travelers have to spend a little more time getting through Customs, dealing with the Agriculture Department and filling out those questions and going through some procedures if they were known to hike or to participate in activities where you were in contact with the agricultural areas of the U.K. or in Europe. But it was a necessary thing, and we are very, very aware of just how important it is that we react now to these type of things.

So this hearing should be very enlightening. We do not have one single case in the United States, due to the action and the reaction of our agencies right away whenever the situation broke out in the U.K.

Thank you for having this hearing this morning. I look forward to hearing from the witnesses.

Senator FITZGERALD. Thank you, Senator Burns.

The Ranking Member, Senator Dorgan.

STATEMENT OF HON. BYRON DORGAN,
U.S. SENATOR FROM NORTH DAKOTA

Senator DORGAN. Mr. Chairman, thank you very much.

Senator Campbell, thank you for your testimony. The point that you made is an important one: There is no mad cow disease in this country. We have had surveillance for some 10 years, and it seems to me that only by aggressive steps we can make sure that we prevent the spread of mad cow disease into the United States and protect the interests of both livestock producers and also consumers.

All of us represent consumers. Some of us represent livestock producers. So there is a kind of a natural tension in hearings like this, only because some are worried that if you hold a hearing of this type you sort of spread the alarm. Yet at the same time, all of us recognize, including those in the livestock industry, that we must take aggressive steps always to be sure that we prevent the spread of diseases like this and we protect both the livestock industry and consumers.

The livestock industry, of course, would be devastated in this country, as it has been in some parts of Europe, by the spread of this disease. But much more important in many ways, it puts many consumers at risk. Senator Campbell, you held up *Newsweek* and I brought it over as well: "Mad Cow Disease, the Slow Deadly Spread." One would conclude from this that mad cow disease is rampant in the United States. Of course, it is not. There is not one case reported of mad cow disease in this country.

But it is paramount that we have a safe food supply. To do that in a global economy is becoming more and more difficult. Senator Campbell, you have taken the lead on legislation and I also have joined you, both on legislation and in a letter to President Bush suggesting that he create an inter-agency task force to coordinate all the steps that we need to be taking, both with respect to mad cow disease and also foot and mouth disease, and to help prevent the spread of that to our shores. I appreciate your leadership on that.

But we also should think through the proposition of the need for additional resources for food inspection. When you understand that we have a global economy and we have shut off the shipment of cattle from England, for example, since 1985 dealing with this issue, it is reasonable to ask the question, however, if we are moving cattle in from Canada and Mexico, how are those cattle being fed?

We say to our producers, for example, that they must sign affidavits and go through a regimen, which I support, with respect to their cattle. Yet in a global economy we have cattle coming across our border in several different directions, and the legitimate question is how are those cattle being fed, with approved feeds or with feeds that include organ material from dead cattle?

I just think that we need to do a lot in a lot of areas. I would encourage the President to form an inter-agency task force. I support the leadership of Senator Campbell and many others here in the Senate and am pleased to work with them, and hope that this hearing will provide a substantial amount of information for the American people and for the Congress, and I hope it provides us some additional avenues in which we can produce more dollars for research and also for testing and ensuring food safety in this country.

It is my hope that we can look back in a rear view mirror 10 and 20 years from now and say that mad cow disease did not spread to this country because we took the right and aggressive steps, on behalf of the American consumer and on behalf of our livestock industry to prevent its spread to this country.

Senator FITZGERALD. Senator Dorgan, thank you.

Senator Brownback, if you have an opening statement.

STATEMENT OF HON. SAM BROWNBACK,
U.S. SENATOR FROM KANSAS

Senator BROWNBACK. Yes, I do. Thank you very much, Mr. Chairman and thank you for calling the hearing.

I first want to congratulate and thank my colleague Senator Campbell for putting forth this bill. I am a co-sponsor of it. I think it is a good measure for us to put forward. And Senator Durbin, for your participation and work on this.

This is a big issue in my state, as you might guess, with the number of cattle that we have on feed and the beef processing industry. I was Secretary of Agriculture in the state for 6 years. My family farms. I talked to my brother last night about the cattle that he runs and he is deeply concerned.

I want to make sure, though, that we know that this is not taking place in this country, that our food supply is safe, as Senator Dorgan noted, because what tends to take place is as these get on the front page of magazines and newspapers here is people think, "Well, this is in America." It is not in America. If we take the right steps, aggressive steps, it is not going to come to America. We are going to keep it out of this country, so that the food supply, the meat supply in America, is safe. It is very safe. It is a high quality, well maintained, high produced food supply that is in this nation.

So I think these are important things for us to do to be at the very outset quite aggressive on making sure that BSE does not ever hit our shores. I was recently in Dodge City, Kansas. In their feed yards, 50,000-70,000 head of cattle, people are deeply concerned and taking every precautionary step to make sure that nothing like this gets anywhere close.

I am glad to see Customs Service stepping up. USDA is stepping up. So I hope this hearing, Mr. Chairman, actually can be used to do two things. One is to make sure we are doing everything we possibly can as a government in supporting the Campbell bill to do that.

The second, Mr. Chairman, is to tell the consumers of America this is not in America. The meat supply in this country is safe, and we are going to do everything we possibly can to maintain the safety of the meat supply, and it is going to be maintained. We could do both, I think, service to both areas if we emphasize what needs to continue to be done and recognize what is being done and also tell the country that the meat supply in this nation is safe.

Mr. Chairman I would ask as well unanimous consent that my full opening statement be submitted to the record as if read.

[The prepared statement of Senator Brownback follows:]

PREPARED STATEMENT OF HON. SAM BROWNBACK,
U.S. SENATOR FROM KANSAS

Mr. Chairman, thank you for holding this hearing on such an important topic. The recent European outbreak of Bovine Spongiform Encephalopathy—a disease affecting the brain and nervous system in livestock, has stirred concerns at home about efforts to protect our food supply. This is a serious issue since the disease can fatally affect humans who eat contaminated meat. The fact that the U.S. has not suffered the fate of Europe thus far, is not luck—too often we take for granted the strong safety precautions put into place by USDA, FDA and other Federal agencies to ensure we have the safest food supply in the world.

That being said, we can never be too safe. When the stakes are as high as they are with this disease—possible contamination of our food supply and loss of consumer confidence in our food safety process—we cannot afford to rest on our laurels. This is particularly true because an outbreak in the U.S., where livestock production is concentrated in the middle of the country, would cause significantly more damage than it has in Europe. This is why I joined with Sen. Campbell in co-sponsoring legislation to coordinate across different government agencies to make sure we are taking all possible precaution. I am specifically interested in making sure that Customs is doing all it can to more closely inspect travelers from Europe given the circumstances. I am also curious to hear from FDA regarding the role they currently play in this issue and the additional measures that you have identified as necessary safeguards.

It is important that we examine this issue carefully, and stick to the facts. There is a tendency to sensationalize stories like this—but that does not bring us closer to the solution. BSE is something we should take seriously and continue to strive to prevent its spread. However, it is wrong to give the American public the impression that our meat supply is in immediate danger from this disease, that American meat is in any way unsafe—or that our government is not taking the threat seriously. Farmers, food processors, inspectors and consumers are all on the same side on this issue: we all want to maintain the safest food supply in the world. I hope this hearing will help us continue to reach for this goal.

I applaud USDA for taking the precautionary measures which have helped keep these diseases out of the U.S. so far. Your current practice of banning meat imports from countries dealing with this disease is an important first step. I would also encourage you to make any recommendations to us that you feel will assist you in tackling this disease.

If there are any additional resources you need to tackle this issue, we ask that you identify them and respond to us promptly. Again, I support the action that USDA has already taken and I encourage even more aggressive steps to prevent and prepare for the continued protection of our food supply.

Thank you for coming and I look forward to the information you will provide for us.

Senator FITZGERALD. Without objection. Thank you, Senator Brownback.

Senator BROWNBACK. Thank you.

Senator FITZGERALD. Senator Durbin, thank you very much for coming and we welcome your remarks.

STATEMENT OF HON. RICHARD J. DURBIN, U.S. SENATOR FROM ILLINOIS

Senator DURBIN. Thank you very much, Mr. Chairman. I appreciate the opportunity to join this morning in this important hearing.

Mad cow disease, more properly known as BSE, has really grabbed the attention of the whole world, as Senator Dorgan, you and others have noted. We have seen these awful scenes in Europe, video clips of trembling cows barely able to move or even feed themselves, images of teenagers wasting away from a mysterious illness linked to eating contaminated beef, pictures of millions of head of cattle destroyed in hopes of stopping the spread of this terrible disease.

My message here today, my reminder to the American people, as the panel as said: These are European scenes. Europe is afflicted with BSE. We are not. Europe is suffering from hoof and mouth disease. We are not. Europe has cases of vCJD, the human illness related to BSE. We do not.

The United States has long had the safest food supply in the world. We owe this to the expertise of our farmers and to the safety consciousness of the food industry and to the Federal Government in its regulatory capacity. We owe it as well to having the world's best system of regulation and oversight for food safety.

Hoof and mouth was eradicated in the United States in 1929 and has not been seen since. BSE, first identified in Britain in 1986; 15 years later, neither the animal nor the human version of this has ever occurred to our knowledge in the United States. Our vigilance has paid off and will continue to provide us an unparalleled degree of protection.

At the same time, though, we have to acknowledge how dramatically the food system has changed. The globalization of commerce has affected our food supply as radically as any other commodity. Automobiles or clothes or computers purchased here in the United States are put together with components from all over the world. So are our food products. We have become used to buying fresh grapes in the middle of winter. It is easy to forget those grapes have crossed thousands of miles and several national borders before coming to rest in our supermarkets. Animals are shipped worldwide, as are animal products and animal feeds.

As the complexity of international trade in food and feed products has multiplied, so too have the demands on our food safety system. Federal agencies have not always responded as fully as they might.

Last year, in response to my request, the General Accounting Office reported widespread noncompliance with many of the measures put in place the protect our country from BSE. Noncompliance rates as high as 28 percent were reported in some segments of the industry, with virtually no enforcement response from the Food and Drug Administration. Although the compliance picture has improved somewhat, there is still need for additional safety measures.

I will be introducing soon the National Food Security and Safety Act to better fortify our nation's defenses against BSE and other related animal diseases. This legislation will strengthen our three primary firewalls against BSE: First, our national borders. The National Food Security and Safety Act will update information requirements on imported foods and feeds so that Federal agents at the border will not have to play a guessing game as to whether a product does or does not contain meat and, if it does, whether that meat is from a cow or from a country where BSE is known to occur.

This information, which is not currently required, limits the ability of inspectors at the border to keep out unsafe foods. Governor Perry of Texas has called for intensified inspections at our border to ensure the safety of our livestock and our food supply. More than 3 billion pounds of meat products enter our country every year. The provisions of my bill will allow for much more focused and effective inspections of these imports.

No. 2, protection of food and feed supplies. BSE and similar diseases are known to concentrate in the central nervous system of ruminant animals such as cows and sheep. So why do we continue to feed these tissues to animals or, for that matter, to people? My bill eliminates ruminant nerve tissue from both the human food and animal feed supply. It also prohibits the use of material from any animal with symptoms of neurological disease.

I am also proposing to expand the current feed ban so that at the very least ruminant animals are not eating feed that contains any material—blood, bone, or fat—anything from other ruminants. The bill would put in place a certification program that makes use of the best in class certification programs already in place. I am also evaluating a further extension to the feed ban so that ruminant feed does not contain an animal-derived materials.

Third, surveillance. My bill calls for the creation of a national task force, as others on the panel have suggested, to report back to Congress on priorities for conducting the best possible surveillance program for detecting BSE and related diseases as a means of further ensuring that these diseases are not present in the U.S. in either livestock or in humans.

The fourth is non-food products, and I think we often overlook this. In addition to better protecting the food supply, we need to remember that animal products are used in many non-food items, including supplements, cosmetics, and medicines. For instance, pharmaceutical companies sometimes use blood or fetal calf material in the production of vaccines. My bill would make mandatory several strategies that are widely recognized to provide an appropriate measure of safety, but not always practiced.

A colleague of mine recently visited a major drug company in his district and came to learn that one of their miracle drugs depended on the intestine of sheep that were being raised in Scotland. These sheep now are being protected with a mile-and-a-half quarantine around the farm, for if they are ultimately destroyed it will have devastating impact, not only on this pharmaceutical company, but also on the people who depend on this important drug.

Science is central to our food safety system and we have got to make sure that the best scientific information available to industry and to Federal agencies is there. It has been the best, most trustworthy guide to keeping our food supplies safe. The National Food Security and Safety Act empowers agencies to make changes or exemptions to the bill's requirements when such an action is justified by sound science.

Let me conclude by saying that I have one other issue that I think frankly relates directly to what we are discussing at this hearing. That is the fact that because of a number of factors, we have perhaps the safest food in the country, the safest food system, I should say, in protecting the food in our country, but we also have an incredible proliferation of Federal agencies that are responsible. Some 12 different Federal agencies have jurisdiction over the safety of food in America, some 35 different laws.

Senator Charles Percy of Illinois had a hearing in the 1960s asking that we finally consolidate all of our food safety inspection into one scientifically driven agency. I have legislation to accomplish that, and I am trying to encourage my colleagues, when they step

back from food safety issues, to realize that unless we can put aside the competition of Federal agencies, of committees of jurisdiction, and of special interests downtown, and finally come up with one agency that makes sense, we will continue to have this piecemeal approach.

The American people expect a lot more. To suggest that if a pizza has pepperoni on it it is the U.S. Department of Agriculture's responsibility, but if it is a cheese pizza it is the Food and Drug Administration's responsibility, is a little hard to explain in Illinois or anywhere in this country.

So I hope that as part of this conversation about food safety we will look at mad cow disease, the imminent problem, but also realize we have a larger problem that should be addressed with bipartisan cooperation.

Thank you, Mr. Chairman.

[The prepared statement of Senator Durbin follows:]

PREPARED STATEMENT OF HON. RICHARD J. DURBIN,
U.S. SENATOR FROM ILLINOIS

Mr. Chairman, thank you very much for the opportunity to speak here this morning.

Mad cow disease—more properly known as BSE—has grabbed the attention of the whole world. We've all seen the awful scenes in Europe. Video clips of trembling cows, barely able to move, or even feed themselves. Images of teenagers wasting away from a mysterious illness linked to eating beef. Pictures of millions of head of cattle destroyed, in hopes of stopping the spread of a terrible disease.

My message here today—my reminder to the American people—is that these are *European* scenes. Europe is afflicted with BSE. We are not. Europe is suffering from foot and mouth disease. We are not. Europe has cases of vCJD—the human illness related to BSE. We do not.

The United States has long had the safest food supply in world. We owe this to the expertise of our farmers and to the safety-consciousness of the food industry. We owe it, as well, to having the world's best system of regulation and oversight for food safety.

Foot and mouth was eradicated in the U.S. in 1929 and has not been seen since. BSE was first identified in Britain in 1986. Fifteen years later, neither the animal nor the human version of this disease has ever occurred in the U.S. Our vigilance has paid off, and will continue to provide us an unparalleled degree of protection.

At the same time, we need to acknowledge how dramatically the food system has changed. The globalization of commerce has affected our food supply as radically as any other commodity. Automobiles or clothes or computers purchased here in the U.S. are put together with components from all over the world. So are our food products.

We've become so used to buying fresh grapes in the middle of winter, that it's easy to forget those grapes may have crossed thousands of miles—and several national borders—before coming to rest on the supermarket shelves. Animals are shipped worldwide, as are animal products and animal feeds.

As the complexity of international trade in food and feed products has multiplied, so too, have the demands on our food safety system. Federal agencies have not always responded as fully as they might.

Last year, in response to my request, the General Accounting Office reported widespread non-compliance with many of the measures put in place to protect our country from BSE. Non-compliance rates as high as 28 percent were reported in some segments of the industry, with virtually no enforcement response from FDA. Although the compliance picture has improved somewhat, there is need for additional safety measures.

For that reason, I will soon be introducing the National Food Security and Safety Act to better fortify our nation's defenses against the introduction of BSE and related animal diseases. This legislation will strengthen our three primary firewalls against BSE.

ONE: NATIONAL BORDERS

The National Food Security and Safety Act will update information requirements on imported foods and feeds so that Federal agents at the border will not have to play a guessing game as to whether a product does or does not contain meat, and if it does, whether that meat is from a cow or from a country where BSE is known to occur.

This information, which is not currently required, limits the ability of inspectors at the border to keep out unsafe foods. Governor Perry of Texas has called for intensified inspections at our borders to insure the safety of our livestock and food supply. More than three billion pounds of meat products enter our country every year. The provisions in my bill will allow for much more focused and effective inspections of these imports.

TWO: PROTECTING FOOD AND FEED SUPPLIES

BSE and similar diseases are known to concentrate in the central nervous system of ruminant animals such as cows or sheep. So why do we continue to feed these tissues to animals, or for that matter, to people? My bill eliminates ruminant nerve tissue from both the human food and animal feed supply. It also prohibits the use of material from *any* animal with symptoms of a neurological disease.

I am also proposing to expand the current feed ban so that, at the very least, ruminant animals are not eating feed that contains any material—blood, bone, fat—*anything* from other ruminants. The bill would put in place a certification program that makes use of the best-in-class certification programs already in place.

I am also evaluating a further extension of the feed ban so that ruminant feed does not contain any animal-derived materials.

THREE: SURVEILLANCE

My bill calls for the creation of a national task force to report back to Congress on priorities for conducting the best possible surveillance program for detecting BSE and related diseases, as a means of further insuring that these diseases are not present in the U.S. in either livestock or in humans.

NON-FOOD PRODUCTS

In addition to better protecting the food supply, we need to remember that animal products are used in many non-food items, including supplements, cosmetics, and medicines. For instance, pharmaceutical companies sometimes use blood or fetal calf material in the production of vaccines. My bill would make mandatory several strategies that are widely recognized to provide an appropriate measure of safety, but are not always practiced.

SCIENCE

Central to our food safety system has been the application of the best scientific information available to industry and to Federal agencies. Science has been the best, most trustworthy guide to keeping our food supply safe. The National Food Security and Safety Act empowers agencies to make changes or exemptions to the bill's requirements when such an action is justified by sound science.

By updating and expanding our food safety system, the U.S. food supply will continue to be the safest in the world.

Senator FITZGERALD. Thank you, Senator Durbin and Senator Campbell. Thank you both for coming.

We will go to our first panel of expert witnesses. We have Dr. Richard Johnson, who is a Special Advisor at the National Institute of Neurological Disorders and Stroke at the National Institutes of Health; Dr. Alfonso Torres, Deputy Administrator for Veterinary Services at the USDA; Dr. Stephen Sundlof, Director of the Center for Veterinary Medicine at the FDA; and also Dr. Will Hueston, a Doctor of Veterinary Medicine, University of Maryland, the Virginia-Maryland Regional College of Veterinary Medicine.

So we have a panel made up exclusively of doctors.

Doctors, welcome. Thank you all for coming.

Dr. Johnson, if you would like to begin. We are going to limit each of you to 5 minutes. We ask if you could not read prepared

remarks, but instead summarize as best you can your testimony within the 5 minutes allotted. Thank you.

Dr. Johnson.

STATEMENT OF RICHARD T. JOHNSON, M.D., SPECIAL ADVISOR, NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE, NATIONAL INSTITUTES OF HEALTH

Dr. JOHNSON. Thank you, Mr. Chairman. Good morning. I want to thank you for asking me to talk on the transmissible spongiform encephalopathies or, as I will call them from now on, TSEs. My name is Richard T. Johnson. I am a board-certified Neurologist and a Professor of Neurology, Microbiology, and Neuroscience at Johns Hopkins University School of Medicine and at the School of Public Health and Hygiene. I am also a special consultant to the National Institutes of Health on TSEs.

The diseases are a series of fatal neurodegenerative diseases, uniformly fatal, that show distinct brain pathology of spongiform changes. Hence the name, the title. They are transmissible to other species, the same species, and at times across species. They have long incubation periods, sometimes over decades. And they are due to an unusual agent which has been termed a prion. This is probably an abnormal folded protein, as was mentioned by Senator Campbell.

The animal TSEs include bovine spongiform encephalopathy—that is BSE or mad cow disease—scrapie in sheep, which has been recognized for hundreds of years, and varying recent forms which have been identified in cats, mink, elk, deer, exotic zoo animals.

In humans, the Creutzfeldt-Jakob disease is the most important, and there is the recent distinct variant of this disease called variant Creutzfeldt-Jakob disease, which seems to have a common origin with BSE and has been limited to England and several cases in France. Creutzfeldt-Jakob disease as we know it here in the United States is a rare disease. It occurs about one million per population per year, and therefore we have about 200 cases per year in the country. 90 percent of these occur sporadically, without any known exposure or any known origin. 10 percent are genetic diseases and are inherited, usually as a dominant gene.

In the early stage of the disease there is loss of cognition, there are a variety of motor abnormalities that occur, characteristically monotonic jerking, a rapid progressive descent without remission, usually leading to death in a period on average of about 4 to 5 months. 90 percent are dead within 12 months. So it is a rapidly progressive pre-senile dementia. The average age death is 67 in this country.

Now, the variant CJD is a very different disease, what has been seen in England. It is a disease that is clinically and pathologically distinct and the more it is studied the more distinct it appears. The average age of death is 29. The average from the beginning of the disease—the average survival, median survival, is 14 months instead of 4 or 5.

Pathologically, the symptomatology is different and pathologically there is far different deposition of this abnormal protein in the brain in very characteristic patterns.

Now, as of April the 2nd the United Kingdom had reported 97 probable or confirmed cases of deaths from variant CJD. There have been two or three in France. There have been none in the United States. The timing of the cases in England make them appear to relate to the BSE epidemic and, furthermore, the nature of the agents transmitted to mice from the cattle in the BSE epidemic and from the patients with variant Creutzfeldt disease appear to be the same. So there seems to be an identity of the agents.

BSE is not restricted, of course, to the U.K. since it has now been reported in France, Portugal, Germany, Spain, the Republic of Ireland, but there have been no cases of BSE in the United States.

Where did it come from? One theory is that it came from scrapie, the sheep disease, which has not been shown to be transmissible to humans, and the practice of feeding rendered carcasses to livestock—including sheep—to cattle, as a protein-rich supplement. There were changes in the rendering industry in about 1980 which may have led to the removal of solvents, change in the composition of the bone meal, which may have led to this movement of the agent across the species.

It may also be that cattle spontaneously develop the disease and that hypothesis is out there and unproven.

If variant VD is related to the consumption of meat, why have not more people come down? Why have there been only 97? The difference is probably exposure to dosage, what one has been exposed to, and the species barriers which we know these diseases have, such as scrapie, which has never been transmitted to humans, and there are also genetic factors that are now becoming clear that predispose people. There is one particular gene—there is one particular area in the prion genome which has been found to be consistent in those 97 in England that have come down.

I know you have a keen interest in measures being taken to prevent it. An essential part of that are efforts for the detection and diagnosis. There are ongoing studies on the biology of prions being carried on, supported by the National Institutes of Health, and there is recently a major effort to develop contracts to develop presymptomatic testing so that animals going to market or people before getting ill can be tested for the disease.

This concludes my testimony. I would be pleased to answer any questions.

[The prepared statement of Dr. Johnson follows:]

PREPARED STATEMENT OF RICHARD T. JOHNSON, M.D., SPECIAL ADVISOR, NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE, NATIONAL INSTITUTES OF HEALTH

Mr. Chairman and members of the subcommittee, good morning, and thank you for inviting me to speak to you about the transmissible spongiform encephalopathies, referred to as TSEs. My name is Dr. Richard T. Johnson. I am a board-certified neurologist with appointments in the Departments of Neurology, Molecular Biology and Genetics, and Neuroscience at The Johns Hopkins University School of Medicine. I also hold a joint appointment in the Department of Molecular Microbiology and Immunology at The Johns Hopkins University School of Hygiene and Public Health. My professional expertise is primarily in the fields of neurology, neuroimmunology, and neuropathology, and in 1986-87, I served as the primary neurology consultant for a Public Health Service interagency epidemiological study of human growth hormone and Creutzfeldt-Jakob Disease. I am currently serving as an expert consultant to the National Institute of Neurological Disorders and Stroke and to the National Institutes of Health on the TSEs.

The TSEs are fatal neurodegenerative diseases of humans and animals. They share a characteristic brain pathology which has the appearance of "spongy" holes in the brain; a long incubation period—sometimes decades long; and the probable causative agent—proteinaceous infectious particles—known as "prions." Prions are transmissible particles that are devoid of nucleic acid and seem to be composed exclusively of a modified protein. According to the prion hypothesis, an abnormal conformation, or folding, of the normal protein carries the disease, and recruits normal prion proteins to the harmful conformation. The notion of an infectious agent that lacks the nucleic acids—the molecules which carry hereditary traits from one generation to the next and trigger the production of specific proteins—is revolutionary, but the preponderance of scientific evidence supports this hypothesis.

Animal TSEs include bovine spongiform encephalopathy, known as BSE or "mad cow disease," scrapie in sheep, and varying forms which occur in cats, mink, elk, deer, and exotic zoo animals. Creutzfeldt-Jakob disease, known as CJD, is the most common human TSE; other lesser known and rarer human forms include Fatal Familial Insomnia and Kuru. A distinct new variant form of CJD—vCJD—has been recognized only since 1996, the onset of illness in the first case having occurred in early 1994. I will briefly discuss the symptoms, incidence, and likely routes of transmission of classic CJD first, and then discuss variant CJD and its link with BSE.

In the early stages of the disease, CJD patients may have failing memory, behavior changes, impaired coordination and visual disturbances. As the illness progresses, mental deterioration becomes pronounced, and involuntary movements, blindness, weakness of extremities, and, ultimately, coma may occur. CJD usually becomes apparent in later life, and the disease typically leads to death within 1 year following the onset of symptoms—in the United States, the mean age of death is 67 years.

CJD, while the most common human TSE, is still very rare; it afflicts only about one in a million people each year. About 90 percent of these cases are sporadic—meaning they appear to occur spontaneously, about another 10 percent are an inherited genetic disorder, and less than 1 percent are transmitted. The failure to find increased incidence of CJD in persons who have come into even close and regular contact with CJD patients suggests the disease is not contagious through normal routes. However, inadvertent human-to-human transmission has been reported from corneal transplantation; direct contact with contaminated medical and surgical instruments; inoculation of growth hormone prepared from contaminated cadaver pituitary glands; and grafts of dura mater—the tough fibrous membrane covering the brain and the spinal cord and lining the inner surface of the skull—obtained from cadaveric donors who had unsuspected CJD.

Variant CJD is also fatal, but is clinically and pathologically distinct from classic CJD. Clinically, vCJD patients have an earlier age of onset—mean age at death is 29 years compared to 67 years in CJD. They usually present with behavioral changes, loss of the ability to coordinate muscular movements, and peripheral sensory disturbances such as loss of sensation, rather than changes in mental activity and thinking ability, and do not show the usual brain wave activity changes of CJD. Variant CJD patients have a longer duration of illness from onset of symptoms to death—median survival is 14 months in vCJD compared to 4 months in CJD. Pathologically, an unusual form of plaque is present in the brains of people with vCJD: a florid or "daisy" plaque in which an amyloid core—a hard, waxy deposit that results from the degeneration of tissue—is surrounded by "petals" of spongiform change.

As of April 2, 2001, the UK has reported 97 probable or confirmed cases of deaths from vCJD since 1995, and a few more have been reported in continental Europe. No cases of vCJD have been reported in the United States. Because of the timing of the appearance of vCJD in the UK in relation to the BSE epidemic, a link between the two diseases was deemed likely. So, I will briefly discuss BSE and the evidence in support of this link, as well as the concerns it raises.

We do not know exactly how BSE, or "mad cow disease" as it frequently referred to in media reports, originated, but we do know with some certainty how it spread and reached epidemic proportions in the UK. As explored in an article by Dr. Paul Brown and others in the January-February 2001 volume of the journal, *Emerging Infectious Diseases*, one theory for the origin of BSE is that it originated from scrapie, an endemic TSE of sheep and goats that has been recognized in Europe since the mid-18th century, and has since spread to most sheep-breeding countries. Until 1988 in the UK, the rendered carcasses of livestock, including sheep, were fed to ruminants, such as cattle, and other animals as a protein-rich nutritional supplement. Although not proven, it appears likely that changes in the UK's rendering process around 1980 allowed the causative agent in infected carcasses to survive, contaminate the protein supplement, and infect cattle. Cattle carcasses and carcass

wastes were then recycled through the rendering plants, increasing the levels of the now cattle-adapted pathogen in the protein supplement and eventually causing a full-scale BSE epidemic. An alternative explanation, proposed in the recent UK "Report of the BSE Inquiry" which investigated the emergence and identification of BSE and vCJD, is that a spontaneous disease-causing mutation occurred in cattle in the 1970s. Either of these hypotheses satisfies the need for a causative agent to survive the altered rendering process, and to escalate through recycling of an ever-larger number of infected carcasses.

BSE is not restricted to the UK; cases have been reported in France, Portugal, Germany, Spain, and the Republic of Ireland, among others, probably as a result of imported live animals or livestock food supplements. However, no documented case of BSE has occurred in the United States or other countries that have historically imported little or no live cattle, beef products, or livestock nutritional supplements from the UK, even though rendering procedures in other countries underwent changes similar to those in the UK during the late 1970s.

While there were concerns about human infection resulting from the BSE epidemic, these were generally allayed by the presumption that BSE originated from scrapie, and scrapie was not a human pathogen. UK surveillance and epidemiological studies further muted these concerns. During the 10 years after the first case of BSE was identified, cases of CJD in the UK did not increase in groups at high risk, and continued to occur in the general population at the same rate and with the same spectrum of clinical and neuropathologic features as before the appearance of BSE. However, then the onset of the variant form started to appear in 1994, and the suspected link between BSE and vCJD has now been convincingly established. Laboratory studies have shown the distinctive biological and molecular features of the pathologic agent isolated from BSE-infected cattle and human cases of vCJD to be identical. The source of transmission appears to have been beef, with infection most probably resulting from consumption of beef products contaminated by nervous system tissue.

Although the amount of infectious tissue ingested is probably a critical factor in the transmission of BSE to humans in the form of vCJD, a human genetic susceptibility in the prion protein gene—PRNP—appears to play an important role in infection. It is possible that a very specific genetic constitution, or genotype, is necessary for BSE to be able to replicate in a human as vCJD. It is also possible that certain variations of this susceptible genotype are comparatively resistant to the disease, and only become ill after longer incubation periods. As noted in Dr. Brown's recent article cited above, the difference between the incidence of BSE and vCJD may be due to limited exposure to very small infectious doses that, except in genetically susceptible persons, cannot surmount the combined effects of a species barrier—from cattle to human—and a comparatively inefficient route of infection—the digestive tract as opposed to direct central nervous system contact. On the other hand, the ultimate extent of the vCJD outbreak is unknown largely because the incubation period for vCJD is unknown.

Mr. Chairman, I know that you have an appropriately keen interest in measures being taken to prevent the occurrence and propagation of BSE in the United States. An essential aspect of any such preventive efforts is detection and diagnosis, the precision of which can only extend as far as our understanding of the nature of the disease. The NIH has a long history of research on the TSEs. This is reflected in the awarding of the 1976 Nobel Prize for intramural work begun in the 1950s that established the transmissibility of these diseases, and of the 1997 Nobel Prize for extramural work on the prion theory. Recent and ongoing studies address many aspects of TSEs and prion biology including the normal functions of the prion protein, animal models of TSEs, the molecular mechanisms of prion diseases, the role of genetics, and exploratory studies of therapeutic strategies. Finally, a major contract effort is working to develop presymptomatic tests.

This concludes my testimony. I would be pleased to respond to any questions you might have.

Perspectives

Bovine Spongiform Encephalopathy and Variant Creutzfeldt-Jakob Disease: Background, Evolution, and Current Concerns

Paul Brown,* Robert G. Will,† Raymond Bradley,‡ David M. Asher,§ and Linda Detwiler¶

*National Institute of Neurological Disorders and Stroke, National Institutes of Health, Bethesda, Maryland, USA; †National Creutzfeldt-Jakob Disease Surveillance Unit, Western General Hospital, Edinburgh, Scotland; ‡Central Veterinary Laboratory, New Haw, Addlestone, UK; §Center for Biologics Evaluation and Research, Food and Drug Administration, Rockville, Maryland, USA; ¶Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Robbinsville, New Jersey, USA

The epidemic of bovine spongiform encephalopathy (BSE) in the United Kingdom, which began in 1986 and has affected nearly 200,000 cattle, is waning to a conclusion, but leaves in its wake an outbreak of human Creutzfeldt-Jakob disease, most probably resulting from the consumption of beef products contaminated by central nervous system tissue. Although averaging only 10-15 cases a year since its first appearance in 1994, its future magnitude and geographic distribution (in countries that have imported infected British cattle or cattle products, or have endogenous BSE) cannot yet be predicted. The possibility that large numbers of apparently healthy persons might be incubating the disease raises concerns about iatrogenic transmissions through instrumentation (surgery and medical diagnostic procedures) and blood and organ donations. Government agencies in many countries continue to implement new measures to minimize this risk.

Bovine Spongiform Encephalopathy

> "The hungry Sheep look up, and are not fed,
> But swoln with wind, and the rank mist they draw
> Rot inwardly, and foul contagion spread..."
> John Milton, *Lycidas* (1637)

Bovine spongiform encephalopathy (BSE) or "mad cow disease" appears to have originated from scrapie, an endemic spongiform encephalopathy of sheep and goats that has been recognized in Europe since the mid-18th century (1). It has since spread to most sheep-breeding countries and is widespread in the United Kingdom (UK), where until 1988 the rendered carcasses of livestock (including sheep) were fed to ruminants and other animals as a protein-rich nutritional supplement.

During rendering, carcasses from which all consumable parts had been removed were milled and then decomposed in large vats by boiling at atmospheric or higher pressures, producing an aqueous slurry of protein under a layer of fat (tallow). After the fat was removed, the slurry was desiccated into a meat and bone meal product that was packaged by the animal food industry and distributed to owners of livestock and other captive animals (e.g., zoo and laboratory animals, breeding species, pets).

Although elements of the ensuing story are still disputed (including its origin from scrapie, rather than from unrecognized endemic BSE), it appears likely that changes in the rendering process that had taken place around 1980 allowed the etiologic agent in infected carcasses to survive, contaminate the protein supplement, and infect

Address for correspondence: Paul Brown, Building 36, Room 4A-05, National Institutes of Health, 36 Convent Drive, MSC 4122 Bethesda, MD 20892-4122; fax: 301-496-8275; e-mail: brownp@ninds.nih.gov.

cattle. Cattle carcasses and carcass wastes were then recycled through the rendering plants, increasing the levels of the now cattle-adapted pathogen in the protein supplement and eventually causing a full-scale BSE epidemic (2-5).

Recognition of this source of infection has led to a series of countermeasures taken by the UK and other countries to break the cycle of cattle reinfection, restrict the geographic spread of disease, and eliminate potential sources of new infections (Figure, Appendix). Probably the single most important measure in the UK was the imposition in 1988 of a ruminant protein feed ban that by 1992 began to bring the epidemic under control. However, the loss of nearly 200,000 diseased cattle, followed by preemptive slaughter and destruction of nearly four and a half million asymptomatic cattle >30 months of age, has crippled the British livestock industry and also affected the tallow, gelatin, and pharmaceutical industries, all of which make bovine-derived products.

BSE is not restricted to the UK. Cases have occurred in many other countries as a result of imported live animals or livestock food supplements (Table 1). In some countries, including the UK, the incidence of new cases is decreasing, but in other countries–France, Portugal, Germany, Spain, and the Republic of Ireland–the incidence appears to be increasing, or initial cases have only recently appeared. The explanation for this phenomenon is most probably improved case ascertainment (supported by active surveillance and immunologic methods), but new infections from contaminated feed intended for other species (e.g., pigs and poultry) may also be a contributing factor. Although in many countries, BSE has been identified in native-born cattle, no indigenous index case has been reported outside the UK (i.e., no case originating de novo or from cow-to-cow transmission). Whatever the origin of these cases, recycling of their contaminated tissues through livestock feed supplements could have occurred in the same way as in the UK.

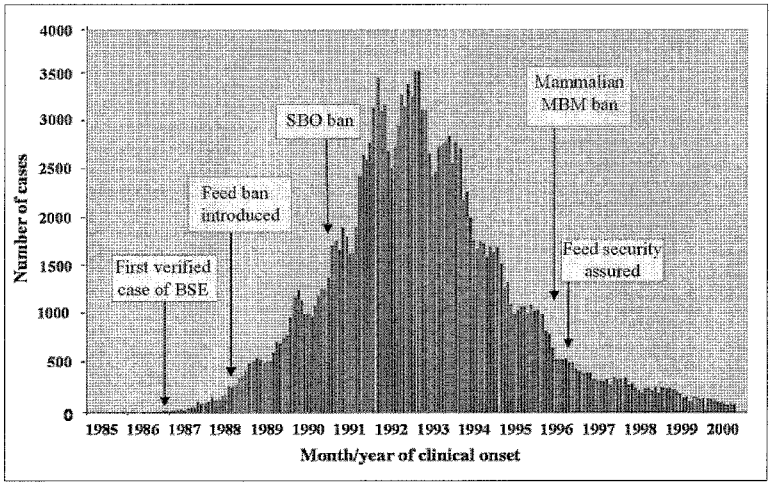

Figure. Time course of epidemic bovine spongiform encephalopathy in the United Kingdom, 1986-2000, with dates of major precautionary interventions. The mammalian ban on meat and bone meal in March 1996 extended a 1994 ban for farmed food animal species to include all mammalian species.
SBO = specified bovine offals (brain, spinal cord, thymus, tonsil, spleen, and intestines from cattle >6 months of age); MBM = meat and bone meal (protein residue produced by rendering).

Table 1. Reported cases of bovine spongiform encephalopathy in the United Kingdom and other countries (as of December 2000)

Country	Native cases	Imported cases	Total cases
United Kingdom	180,376[a]	-	180,376
Republic of Ireland	487	12	499
Portugal	446	6	452
Switzerland[b]	363	-	363
France[b]	150	1	151
Belgium	18	-	18
Netherlands	6	-	6
Liechtenstein	2	-	2
Denmark	1	1	2
Luxembourg	1	-	1
Germany	3	6	9
Oman	-	2	2
Italy	-	2	2
Spain[c]	-	2	2
Canada	-	1	1
Falklands (UK)	-	1	1
Azores (Portugal)[d]	-	1	1

Data from Organization of International Epizootics (Paris) and Ministry of Agriculture, Fisheries, and Food (UK).
[a]Includes 1,287 cases in offshore British islands
[b]Includes cases detected by active surveillance with immunologic methods
[c]Origin and dates of imported cases are under investigation.
[d]Case imported from Germany.

BSE has not occurred in the United States or other countries that have historically imported little or no live cattle, beef products, or livestock nutritional supplements from the UK. Even though rendering procedures in other countries underwent changes similar to those in the UK during the late 1970s, BSE has apparently emerged solely within the UK. The most plausible explanation is that the proportion of sheep in the mix of rendered animal carcasses and the proportion of scrapie infections in such sheep were probably higher in the UK than elsewhere. These proportions were apparently sufficient to bring very low levels of the etiologic agent in batches of rendered carcasses over the threshold of transmission in the UK but not in other countries (5). An alternative explanation proposed in the recent Report of the BSE Inquiry (6) is that a pathogenic mutation occurred in cattle in the 1970s.

Either of these two hypotheses satisfies the need for an etiologic "seed" to survive the altered rendering process and escalate through recycling of an ever-larger number of infected carcasses. However, the bovine origin hypothesis assumes that a mutation occurred only in the UK and not in other countries where similar rendering processes would also have led to epidemic BSE if mutations were occurring. In humans, mutations have occurred all over the world, not just in the UK, and there is no reason to suppose that humans differ in this respect from other mammalian species. It would therefore be peculiar if the UK had the misfortune to host the cattle world's only mutation.

Variant Creutzfeldt-Jakob Disease (vCJD)

> How soon hath Time, the subtle thief of youth,
> Stol'n on his wing my three and twentieth year!
> John Milton, *Sonnet* (1632)

Within weeks of identification of the first case of BSE, concern was expressed about human risk (7-13), and as the epidemic unfolded, a series of measures was taken to eradicate BSE and prevent potentially infected tissues from reaching the human food chain (Appendix). A surveillance unit to monitor CJD was established in the UK in May 1990, and 3 years later, surveillance was extended to several other European countries, coordinated through the European Union. By this means it was hoped that any change in the epidemiology of CJD in the UK could be detected quickly and that the significance of the change could be assessed by comparison with the epidemiology of CJD in continental Europe.

Concern was heightened by the discovery that some exotic zoo ungulates, as well as domestic and captive wild cats, were becoming infected (14-18). The ungulates and domestic cats had also been fed diets supplemented by meat and bone meal, and the wild cats had been fed uncooked tissues, including cattle heads and spines. The possibility could therefore not be ignored that the disease might also cross the species barrier to humans from the consumption of beef or dairy products, or perhaps from occupational contact with cattle by ranchers, dairymen, or slaughterhouse workers.

What muted concerns about human infection was the presumption that BSE originated from scrapie, and scrapie was not a human pathogen. Nevertheless, even those who considered human risk to be remote acknowledged that scrapie might unpredictably show an altered host range

after passage through cattle. Experimental precedents for such behavior were well known: passage of mouse-adapted strains of scrapie through hamsters altered their transmissibility on back passage to rodents (19,20); human strains of kuru or CJD did not transmit to ferrets or goats until passaged through primates or cats (21); and a bovine strain of BSE did not transmit to hamsters until passaged through mice (22). Alternatively, if BSE originated from a spontaneous mutation in cattle, experimental studies of species susceptibility to this new strain of transmissible spongiform encephalopathy (TSE) had not sufficiently advanced to predict that humans would not be susceptible. Nevertheless, during the 10 years after the first case of BSE was identified, cases of CJD did not increase in groups at high risk and continued to occur in the general population with the same spectrum of clinical and neuropathologic features as before the appearance of BSE.

Then, from May to October 1995, the CJD Surveillance Unit was notified of three cases of CJD in patients 16, 19, and 29 years of age (23,24). On neuropathologic examination, all three patients had amyloid plaques, which was unexpected in view of their occurrence in only 5%-10% of sporadic cases of CJD. The comparative youth of the patients and this unusual neuropathologic finding prompted a search for similar features in patients whose deaths might have been attributed to other diagnoses. In particular, cases of subacute sclerosing panencephalitis (SSPE) were scrutinized in view of a report from Poland that cases of CJD in three young patients had been identified by SSPE surveillance (25). No such cases were found in a review of the UK SSPE register.

If CJD in young patients was not being obscured by misdiagnosis, perhaps it reflected increased physician awareness through publicity surrounding BSE and iatrogenic CJD in recipients of contaminated growth hormone, or the active CJD surveillance program instituted in the UK, or the availability of genetic and proteinase-resistant protein (PrP) immunocytochemistry. Although all these factors may have contributed to ascertainment bias, most of the excess cases were in older age groups, in which CJD was now being diagnosed more often than in earlier decades.

By December 1995, the Surveillance Unit had been informed of 10 suspected cases of CJD in persons <50 years of age. Some were found to have sporadic or familial CJD or some other disease; however, two of the patients, ages 29 and 30 years, were later confirmed neuropathologically to have CJD and, like the previous three CJD patients, had extensive plaque deposition. As of January 1, 1996, the relationship between these cases and BSE began to excite suspicion but remained tentative because critical information judged necessary to establish a probable connection was still missing (Table 2).

During January, two additional cases of CJD in young patients were neuropathologically confirmed, and a distinctive clinical syndrome associated with plaque formation was beginning to emerge: young age at onset, early psychiatric symptoms, prominent ataxia, absence of periodic electroencephalographic activity, and a comparatively prolonged illness. However, each of these features, alone or in combination, may also be seen in classic sporadic or familial CJD. Caution was further justified by a review of the records of pre-1980 CJD patients in the UK, which identified three young patients who shared some of these features, and by the results of an inquiry about young patients with CJD in other European countries, which showed an age distribution similar to that in the UK. A major concern was that these seven apparently similar cases might represent a heterogeneous group of patients with sporadic and familial forms of CJD.

Table 2. Evolving assessment of criteria used to link bovine spongiform encephalopathy and variant Creutzfeldt-Jakob disease.

	Assessment through early 1996				
Criteria	Jan 1	Feb 1	Mar 1	Mar 8	Mar 20
Novel clinical phenotype	Uncertain	Possible	**Probable**	Probable	Probable
Novel neuropathologic phenotype	Uncertain	Possible	**Probable**	Probable	Probable
Distinct from pre-1980 cases in UK	Unknown	Possible	**Probable**	Probable	Probable
No association with PRNP mutations	Uncertain	Uncertain	Uncertain	**Probable**	Probable
Distinct from cases outside UK	Unknown	Unknown	Unknown	Possible	**Probable**

Full comparative neuropathologic examination of both pre- and post-1980 cases of CJD in young persons was needed, along with *PRNP* gene sequence analysis of as many cases as possible.

During February 1996, an additional case was referred to the Surveillance Unit with a clinical evolution similar to that of the previous seven patients, and neuropathologic examination of recent and historical cases confirmed that the recent cases were indeed distinctive. In particular, a morphologically unusual form of plaque was present in all cases: the florid or "daisy" plaque in which an amyloid core was surrounded by "petals" of spongiform change. As of March 1, despite the likelihood that this group of patients had a "new variant" of CJD, it was still unclear whether mutations were involved and whether such a syndrome was also occurring outside the UK–both points essential to confirming the association of this variant disease with exposure to BSE.

On March 4, genetic analysis was completed for six of the cases, and no pathogenic mutation was identified. These results effectively ruled out a genetic cause for the syndrome (although they did not rule out a genetic predisposition) and left the only remaining uncertainty–the geographic distribution of the variant phenotype–to be resolved by the European CJD surveillance system. The answer came by March 20: none of the young CJD patients in other European countries had the clinical and neuropathologic features of the UK cases. In the preceding week, two more variant cases had been neuropathologically confirmed, and a report on the entire group of 10 cases concluded that an unrecognized variant of CJD occurring only in persons <45 years of age was probably due to exposure to BSE (26).

This link has now been convincingly established in laboratory studies showing identical, distinctive biological and molecular biological features of the pathologic agent isolated from BSE-infected cattle and human cases of vCJD (27-29). The source of contamination appears to have been beef. However, muscle has never been reproducibly shown to contain the infectious agent in any form of spongiform encephalopathy, whatever the affected species, and thus, infection most probably resulted from beef products contaminated by nervous system tissue. Contamination could have occurred in any of the following ways: cerebral vascular emboli from cranial stunning instruments used to immobilize cattle before killing by exsanguination; contact of muscle with brain or spinal cord tissue by saws or other tools used during slaughter; inclusion of paraspinal ganglia in cuts of meat containing vertebral tissue (e.g., T-bone steaks); and perhaps most importantly, the presence of residual spinal cord and paraspinal ganglia tissue in the paste of "mechanically recovered meat" (a carcass compression extract) that could legally be added to cooked meat products such as meat pies, beef sausages, and various canned meat preparations. Measures have since been taken to eliminate these sources of potential contamination and limit the consequences of any contamination that may already have occurred (Appendix).

Although the amount of infectious tissue ingested must be a critical determinant for the transmission of BSE to humans in the form of vCJD, the human genotype at polymorphic codon 129 of the PRNP gene appears to play an important role in susceptibility to infection. The encoding alternatives, methionine (Met) and valine (Val), are distributed in the general Caucasian population in the approximate proportions of 50% Met/Val, 40% Met/Met, and 10% Val/Val. All 76 vCJD patients tested have been homozygous for methionine, and the apparently single infecting strain of BSE may not be able to replicate in any other human genotype. However, it is also possible that (as in the analogous oral infection of kuru and in peripheral iatrogenic CJD infections) heterozygotes are comparatively resistant to disease and become ill after longer incubation periods than those of homozygotes (30-33).

Predictions about the vCJD Outbreak

> Think not but that I know these things; or think
> I know them not: not therefore am I short
> Of knowing what I ought.
>
> John Milton, *Paradise Regained* (1671)

The onset of illness in the first case of vCJD occurred in early 1994, nearly a decade after the first case of BSE was recognized in cattle. Assuming that the earliest appearance of vCJD reflects the earliest exposure to BSE, this incubation period is consistent with those following peripheral infections in experimental animals and in cases of iatrogenic CJD in

humans. Through the end of November 2000, the overall tally was 87 definite or probable cases of vCJD in the UK, 2 confirmed and 1 probable case in France, and a single confirmed case in the Republic of Ireland (Table 3). The Irish patient had lived for some years in England; however, none of the French patients had lived in or visited the UK, so their infection must have come either from beef or beef products imported from the UK (approximately 5%-10% of the beef consumed in France) or from BSE-affected cattle in France. From a European standpoint, it would be much more troubling if imported beef were the source, as most European countries also imported beef or beef products from the UK, although in smaller quantities.

Unlike the BSE epidemic, the vCJD outbreak has shown only a modest increase during its first 6 years, and the number of cases with onsets in 2000 remains well below the previous year's total, although additional cases will certainly be identified in coming months. The difference between BSE and vCJD may be due to the fact that, in humans, recycling of infected tissue has not occurred, and thus the epidemic will evolve much more slowly than in cattle, or the difference may indicate a limited outbreak in humans due to very small infectious doses that, except in genetically susceptible persons, cannot surmount the combined effects of a species barrier and comparatively inefficient route of infection.

Much of the lingering uncertainty about the extent of the vCJD outbreak is attributable to the fact that the incubation period of vCJD is unknown. If the average incubation period is 10 to 15 years, the earliest patients with vCJD would have been infected in the early 1980s, when BSE was still silently incubating in small but increasing numbers of cattle. In this case, the large increase in human exposure to contaminated tissues during the late 1980s could lead to a parallel increase in cases of vCJD during the next few years. If, however, the average incubation period of vCJD is 5 to 10 years, the earliest human infections would have begun in the mid- to late 1980s, when exposure to BSE was maximal. In this case, the outbreak of vCJD should remain small because of measures to eliminate both animal and human exposure to BSE instituted from 1987 to 1997. Depending on assumptions about the incubation period and other variables, mathematical modeling predicts that the total extent of the outbreak could range from fewer than one hundred to hundreds of thousands of cases (34-37).

Table 3. Chronology of variant Creutzfeld-Jakob disease (vCJD) in the United Kingdom and other European countries, as of December 2000

Year of onset	United Kingdom	France	Ireland
1994	8	1	
1995	10		
1996	11		
1997	14		
1998	17		
1999[a]	20 (+4)	1 (+1)	1
2000[a]	1 (+2)		

[a]Parentheses indicate still-living persons with probable vCJD or deceased persons whose diagnoses have not yet been confirmed by neuropathologic examination. In 2000, additional cases have been identified that do not yet meet the minimum clinical criteria for a premortem diagnosis of "probable" vCJD. Dates are for year of onset of illness, not year of death.

If large numbers of infected persons are silently incubating the disease, the potential for human-to-human iatrogenic spread of vCJD is very real. Such apparently healthy persons would be subject to the same kinds of medical and surgical procedures experienced by the general population, including endoscopies, vascular catheterizations, operations for trauma or illness, and blood and organ donations. If, as suspected, the amount and distribution of the infectious agent in tissues of persons with vCJD is greater than in other forms of CJD, the exposure of medical and surgical instruments to possibly infectious internal tissues and the transfer of tissues as grafts and transplants become a matter of much greater concern than the nearly negligible risk currently posed by cases of sporadic CJD.

Recent and Future Policy Decisions

> A little onward lend thy guiding hand
> To these dark steps, a little further on...
> John Milton, *Samson Agonistes* (1671)

Several governments have implemented policies to minimize the risk for human-to-human disease transmission through blood donations from apparently healthy persons who may be in the incubation phase of vCJD. In the

UK, where whole blood or blood products from some persons who later died of vCJD have been administered to others, all plasma is imported and all blood from UK donors is filtered to eliminate leukocytes, which are the most likely carriers of infectivity in blood (38-40). In the United States, a blood donor policy excludes donations from anyone who has lived in or visited the UK for a cumulative period of 6 months or more during 1980 to 1996. The 6-month period was based on the fact that >80% of total US person-years in the UK would be excluded and that the 2%-3% deficit of blood donors resulting from the deferral could be absorbed by the blood banking industry without undue shortages. Several countries (Canada, Australia, New Zealand, Switzerland, Japan, and Germany) have since applied these criteria and formulated similar policies.

Because of the possibility of widespread infection in the UK, concern extends beyond blood and organ donors to the safe use of medical and surgical instruments, particularly those used in neurosurgery and ophthalmic surgery. In the absence of a screening test, a zero-risk policy is untenable because it would require termination of the national organ donor program. A compromise might be the temporary deferral of organ donors–or perhaps only corneal donors younger than 30 or 40 years of age. However, this measure might so diminish (and panic) the donor population as to be inadvisable. Similar considerations apply to invasive medical and surgical procedures: sound medical practice cannot be suspended on the basis of a theoretical risk for vCJD, and it would be unethical to deny needed procedures to persons suspected of having CJD. Under the circumstances, disposable instruments should be used whenever possible, and a standard sterilization protocol for reusable instruments should be implemented that includes the most stringent possible disinfectants (e.g., the combined use of 1 N sodium hydroxide and autoclaving at 134°C, as recommended in the recent World Health Organization guidelines on infection control for CJD [41]). No effective sterilization procedure yet exists for instruments or instrument parts too delicate to withstand these harsh measures. Each such instrument must be disinfected to the maximum extent possible, for example by washing repeatedly with detergent/proteinase solutions and exposing the washed instruments to less harsh chemicals (e.g., 6 M urea or 4 M guanidinium thiocyanate) that have shown moderate to good disinfection of TSE tissue extracts (42-44).

An equally important issue is whether the bovine-adapted scrapie agent has recrossed the species barrier to sheep, carrying its newly acquired ability to infect humans. The only reliable method to distinguish strains of TSE is a time-consuming comparison of incubation periods and topographic features of brain lesions after injection into different strains of inbred mice (28). Glycotyping of PrP strains extracted from diseased brain tissue is much faster but has not been convincingly shown to discriminate reliably between BSE and scrapie. Moreover, neither method has been used to test a sheep-adapted strain of BSE (that is, after multiple passages through sheep), which might have lost the distinguishing characteristics found on primary passage from cow to sheep.

If BSE did back-cross to sheep fed the same contaminated meat and bone meal that infected cattle, the consequences for humans will remain limited to the same period of risk as BSE–roughly 1980 through 1996–unless sheep BSE, like sheep scrapie, can be horizontally or maternally transmitted. Without a test to discriminate between the two diseases, there would be no defense against the development of endemic BSE in sheep and the consequent risk for human infection from sheep as well as cows. Therefore, global elimination of animal TSEs must seriously be considered.

Such a goal is more practical than it was even a few years ago. National programs to eliminate scrapie have historically relied on selective slaughter of blood lines or in some cases entire flocks in which scrapie was identified, and all such attempts have failed. Molecular genetic tools are now available to guide scrapie-resistance breeding programs that until recently depended on field observation and classical genetics, and immunologic tools can detect preclinical scrapie infection in tonsils, third eyelids, and possibly blood (45-48). The environmental durability of TSE pathogens will make their eradication difficult (49,50); however, the global elimination of TSE in sheep and other animals is a goal worth the expense, effort, and patience that will be needed for its achievement.

Dr. Brown is Senior Research Scientist in the Laboratory of Central Nervous System Studies at the National Institutes of Health. His most recent research focuses on the problem of iatrogenic Creutzfeldt-Jakob disease and on the potential for disease transmission through the administration of blood or blood products. He serves as consultant to the European CJD surveillance program and as Chair of TSEAC, the transmissible spongiform encephalopathy advisory committee of the United States Food and Drug Administration.

References

1. Brown P, Bradley R. 1755 and all that: a historical primer of transmissible spongiform encephalopathy. Br Med J 1998; 317:1688-92.
2. Wells GAH, Scott AC, Johnson CT, Gunning RF, Hancock RD, Jeffrey M, et al. A novel progressive spongiform encephalopathy in cattle. Vet Rec 1987;121:419-20.
3. Collee JG, Bradley R. BSE: a decade on-Part 1. Lancet 1997; 349:636-42.
4. Collee JG, Bradley R. BSE: a decade on-Part 2. Lancet 1997; 349:715-21.
5. Brown P. The risk of bovine spongiform encephalopathy ("mad cow disease") to human health. JAMA 1997;278:1008-11.
6. The BSE inquiry: report, evidence and supporting papers of the inquiry into the emergence and identification of Bovine Spongiform Encephalopathy (BSE) and variant Creutzfeldt-Jakob Disease (vCJD) and the action taken in response to it up to 20 March 1996. Lord Phillips of Worth Matravers, Chairman. London: The Stationery Office. October 26, 2000.
7. Holt TA, Phillips J. Bovine spongiform encephalopathy. Br Med J 1988;296:1581-2.
8. BSE and scrapie: agents for change [editorial]. Lancet 1988;ii:607-8.
9. Taylor DM. Bovine spongiform encephalopathy and human health. Vet Rec 1989;125:413-5.
10. Dealer SF, Lacey RW. Transmissible spongiform encephalopathies: the threat of BSE to man. Food Microbiol 1990;7:253-79.
11. Kimberlin RH. Bovine spongiform encephalopathy: taking stock of the issues. Nature 1990;345:763-4.
12. Will RG. Is there a potential risk of transmission of BSE to the human population and how may this be assessed? In: Bradley R, Savey M, Marchant B, editors. Sub-acute spongiform encephalopathies. Dordrecht: Kluwer Academic Publishers; 1991. p. 179-86.
13. Brown P. The clinical epidemiology of Creutzfeldt-Jakob disease in the context of bovine spongiform encephalopathy. In: Bradley R, Savey M, Marchant B, editors. Subacute spongiform encephalopathies. Dordrecht: Kluwer Academic Publishers; 1991. p. 195-202.
14. Jeffrey M, Wells GAH. Spongiform encephalopathy in a Nyala (*Tragelaphus angasi*). Vet Pathol 1988;25:398-9.
15. Fleetwood AJ, Furley CW. Spongiform enecphalopathy in an eland. Vet Rec 1990;126:408-9.
16. Wyatt JM, Pearson GR, Smerdon T, Gruffydd-Jones TJ, Wells GAH. Spongiform encephalopathy in a cat. Vet Rec 1990;126:513.
17. Kirkwood JK, Wells GAH, Wilesmith JW, Cunningham AA, Jackson SI. Spongiform encephalopathy in an Arabian oryx (*Oryx leucoryx*) and a greater kudu (*Tragelaphus strepsiceros*). Vet Rec 1990;127:418-20.
18. Willoughby K, Kelly DF, Lyon DG, Wells GAH. Spongiform encephalopathy in a captive puma (*Felis concolor*). Vet Rec 1992;131:431-4.
19. Kimberlin RH, Cole S, Walker CA. Temporary and permanent modifications to a single strain of mouse scrapie on transmission to rats and hamsters. J Gen Virol 1987;68: 1875-81.
20. Kimberlin RH, Walker CA, Fraser H. The genomic identity of different strains of mouse scrapie is expressed in hamsters and preserved on reisolation in mice. J Gen Virol 1989;70: 2017-25.
21. Gibbs CJ Jr, Gajdusek DC, Amyx H. Strain variation in the viruses of Creutzfeldt-Jakob disease and kuru. In: Prusiner SB, Hadlow WJ, editors. Slow transmissible diseases of the nervous system. Volume 2. New York: Academic Press; 1979. p. 87-110.
22. Foster JD, Hope J, McConnell I, Bruce M, Fraser H. Transmission of bovine spongiform encephalopathy to sheep, goats, and mice. Ann NY Acad Sci 1994;724:300-3.
23. Britton TC, Al-Sarraj S, Shaw C, Campbell T, Collinge J. Sporadic Creutzfeldt-Jakob disease in a 16-year-old in the UK. Lancet 1995;346:1155.
24. Bateman D, Hilton D, Love S, Zeidler M, Beck J, Collinge J. Sporadic Creutzfeldt-Jakob disease in a 18-year-old in the UK. Lancet 1995;346:1155-6.
25. Kulczycki J, Jedrzejowska H, Gajkowski K, Tarnowska-Dziduszko E, Lojkowska W. Creutzfeldt-Jakob disease in young people. Eur J Epidemiol 1991;5:501-4.
26. Will RG, Ironside, JW, Zeidler M, Cousens SN, Estibeiro K, Alperovitch A, et al. A new variant of Creutzfeldt-Jakob disease in the UK. Lancet 1996;347:921-5.
27. Collinge J, Sidle KC, Heads J, Ironside J, Hill AF. Molecular analysis of prion strain variation and the aetiology of 'new variant' CJD. Nature 1996;383:685-90.
28. Bruce ME, Will RG, Ironside JW, McConnell I, Drummond D, Suttie A, et al. Transmissions to mice indicate that 'new variant' CJD is caused by the BSE agent. Nature 1997;389:498-501.
29. Scott MR, Will R, Ironside J, Nguyen HB, Tremblay P, DeArmond SJ, et al. Compelling transgenetic evidence for transmission of bovine spongiform encephalopathy prions to humans. Proc Natl Acad Sci U S A 1999;96:15137-42.
30. Cervenáková L, Goldfarb LG, Garruto R, Lee H-E, Gajdusek DC, Brown P. Phenotype-genotype studies in kuru: implications for new variant Creutzfeldt-Jakob disease. Proc Nat Acad Sci U S A 1998;95:13239-41.
31. Lee H-S, Brown P, Cervenáková L, Garruto RM, Alpers MP, Gajdusek DC, et al. Evidence for susceptibility of the 129MM PRNP genotype in epidemic kuru. J Infect Dis 2000, in press.
32. d'Aignaux JH, Costagliola D, Maccario J, Billette de Villemeur T, Brandel J-P, Deslys JP, et al. Incubation period of Creutzfeldt-Jakob disease in human growth hormone recipients in France. Neurology 1999;53:1197-201.

33. Brown P, Preece M, Brandel J-P, Sato T, McShane L, Zerr I, et al. Iatrogenic Creutzfeldt-Jakob disease at the millennium. Neurology 2000;55:1075-81.
34. Cousens SN, Vynnycky E, Zeidler M, Will RG, Smith PG. Predicting the CJD epidemic in humans. Nature 1997;385:197-8.
35. Ghani AC, Ferguson NM, Donnelly CA Hagenaars TJ, Anderson RM. Epidemiological determinants of the pattern and magnitude of the vCJD epidemic in Great Britain. Proc R Soc London (Series B) 1998;265:2443-52.
36. Donnelly CA, Ferguson NM. Predictions and scenario analysis for vCJD. In: Statistical aspects of BSE and vCJD: models for an epidemic. Boca Raton (FL): CRC Press LLC 1999:163-94.
37. Ghani AC, Ferguson NM, Donnelly CA, Anderson RM. Predicted vCJD mortality in Great Britain. Nature 2000;406:583-4.
38. Brown P. Can Creutzfeldt-Jakob disease be transmitted by transfusion? Curr Opin Hematol 1995;76:472-7.
39. Brown P, Cervenáková L, McShane LM, Barber P, Rubenstein R, Drohan WN. Further studies of blood infectivity in an experimental model of tranmissible spongiform encephalopathy, with an explanation of why blood components do not transmit disease in humans. Transfusion 1999;39: 1169-78.
40. Brown P, Cervenáková L. Reply to a letter to the editor. Transfusion 2000;40:754-5.
41. WHO infection control guidelines for transmissible spongiform encephalopathies: report of a WHO Consultation. WHO/CDS/CSR/APH/2000.3. Geneva: March 23-26, 1999.
42. Kimberlin RH, Walker CA. Competition between strains of scrapie depends on the blocking agent being infectious. Intervirology 1985;23:74-81.
43. Manuelidis L. Decontamination of Creutzfeldt-Jakob disease and other transmissible agents. J Neurovirol 1997;3:62-5.
44. Pocchiari M, Peano S, Conz A, Eshkol A, Maillard, Brown P, et al. Combination ultrafiltration and 6 M urea treatment of human growth hormone effectively minimizes risk from potential Creutzfeldt-Jakob disease virus contamination. Horm Res 1991;35:161-6.
45. Roels S, Vanopdenbosch E, Langeveld JP, Schreuder BE. Immunohistochemical evaluation of tonsillar tissue for preclinical screening of scrapie based on surveillance in Belgium. Vet Rec 1999;145:524-5.
46. O'Rourke KI, Baszler TV, Besser TE, Miller JM, Cutlip RC, Wells GA, et al. Preclinical diagnosis of scrapie by immunohistochemistry of third eyelid lymphoid tissue. J Clin Microbiol 2000;38:3254-9.
47. Schmerr MJ, Jenny AL, Bulgin MS, Miller JM, Hamir AN, Cutlip RC, et al. Use of capillary electrophoresis and fluorescent labeled peptides to detect the abnormal prion protein in the blood of animals that are infected with a transmissible spongiform encephalopathy. J Chromatog A 1999;853:207-14.
48. Brown P, Cervenáková L, Diringer H. Blood infectivity and the prospects for a diagnostic screening test in Creutzfeldt-Jakob disease. J Lab Clin Med. In press 2001.
49. Palsson PA. Rida (scrapie) in Iceland and its epidemiology. In: Prusiner SB, Hadlow WJ, editors. Slow transmissible diseases of the nervous system. Volume 1. New York: Academic Press; 1979. p. 357-66.
50. Brown P, Gadjusek DC. Survival of scrapie virus after 3 years' interment. Lancet 1991;337:269-70.

Appendix

Table A. Measures taken to prevent the spread of bovine spongiform encephalopathy to animals

Precautions	Great Britain[a]	European Union[a]	United States
BSE made a notifiable disease	June 1988	Apr 1990	Nov 1987
BSE surveillance, with histologic examination of brains	June 1988	May 1990	May 1990
Ban on ruminant protein in ruminant feed	July 1988		
Ban on export of UK cattle born before July 1988 feed ban		July 1989	
Ban on import of live ruminants and most ruminant products from all BSE countries			July/Nov 1989
Ban on export of UK cattle >6 months of age		Mar 1990	
Ban on SBO for use in animal nutrition; ban on export of SBO and feed containing SBO to EU countries	Sept 1990		
High-risk waste to be rendered at 133°C/3 bar/20 min (or other approved procedure)		Nov 1990	
Ban on export of SBO and feed containing SBO to non-EU countries	July 1991		
Ban on MBM from SBO in fertilizer	Nov 1991		
After Jan 1, 1995, rendering methods must sterilize BSE		June 1994	
Ban on mammalian MBM in ruminant feed		July 1994	
BSE surveillance includes immunohistologic features of brains			Oct 1993
Ban on mammalian protein in ruminant feed[b]	Nov 1994		Aug 1997
Ban on import of live ruminants and most ruminant products (including meat products) from all countries of Europe			Dec 1997
Immunologic testing for ruminant protein in animal feed		July 1995	
Mammalian MBM prohibited from all animal feed/fertilizer	Mar/Apr 1996		
Slaughtered cattle >30 months old (except certain beef cattle >42 months old) ruled unfit for animal use (hides for leather excluded)	Mar 1996		
Mammalian MBM and MBM-containing feed recalled	June 1996		
All mammalian waste to be rendered at 133°C/3 bar/20 min (or other approved procedure)		July 1996	
Cattle tracing system improved	Sept 1998		
Quarantine of 3 sheep flocks imported from Europe with possible exposure to BSE (4 animals die with atypical TSE)			Oct 1998
BSE surveillance of fallen stock (downer cows) is intensified			Oct 1998
Proposal to eradicate scrapie is rejuvenated			Nov 1999
Allow export of deboned beef from cattle >30 months old born after July 1996	Aug 1999		
Prohibit use of animal protein, including MBM and blood meal (but excluding milk, or fish meal for nonruminants) in feed for any farmed animal species (effective January 1, 2001)		Dec 2000	
Prohibit importation of rendered protein and rendering wastes originating or processed in Europe			Dec 2000

[a]In Northern Ireland and Scotland, dates of implementation sometimes differed from those shown for England and Wales; in addition, individual European Union countries often adopted different measures on different dates.
[b]Some exemptions, e.g., milk, blood, and gelatin.
BSE: bovine spongiform encephalopathy; EU = European Union; MBM = meat and bone meal (protein residue produced by rendering); SBO = specified bovine offals (brain, spinal cord, thymus, tonsil, spleen, and intestines from cattle >6 months of age); TSE = transmissible spongiform encephalopathy.

Table B. Measures taken to prevent the spread of bovine spongiform encephalopathy to humans

Precautions	Great Britain[a]	European Union[a]	United States
Compulsory slaughter of BSE-affected cattle	Aug 1988		
Destroy milk from affected cattle (except for milk fed to cows' own calves)	Dec 1988		
Ban on import of UK cattle born after July 1988 feed ban		July 1989	
Ban on SBO for domestic consumption	Nov 1989		
Ban on export to EU of SBO and certain other tissues, including lymph nodes, pituitaries, and serum	Apr 1990	Apr 1990	
Ban on export of live UK cattle (except calves <6 months old)	June 1990	June 1990	
Ban on use of head meat after skull opened	Mar 1992		
FDA recommends use of BSE/scrapie-free sources for materials used in dietary supplements; request for safety plans			Nov 1992
Cell lines used for biologicals should be BSE agent-free			May 1993
FDA requests that bovine source materials (except gelatin) used in manufacture of regulated products be restricted to BSE-free countries			Dec 1993
Bone-in beef only from farms with no BSE for 6 years; if not BSE-free, must be deboned with visible nervous and lymphatic tissue removed		July 1994	
FDA requests that bovine-derived materials for animal use or for cosmetics and dietary supplements not be sourced from BSE countries			Aug 1994
Thymus and intestines from calves <6 months old made SBO	Nov 1994		
Import of beef only from UK cattle 1) >30 months, or 2) from herds BSE-free for 6 years, or 3) if not BSE-free, deboned with visible nervous tissue and specified lymph nodes removed		July 1995	
SBO ban broadened to include whole skull (SBM)	Aug 1995		
MRM from bovine vertebral column banned and export prohibited	Dec 1995		
Removal of lymph nodes and visible nervous tissue from bovine meat >30 months exported to EU	Jan 1996		
Ban on export of all UK cattle and cattle products except milk		Mar 1996	
SBM ban broadened to include entire head (excluding uncontaminated tongue)	Mar 1996		
Slaughtered cattle >30 months (or certain beef cattle >42 months) ruled unfit for animal or human use (hides excepted)	Mar 1996		
FDA urges manufacturers of FDA-regulated human products to take steps to assure freedom from BSE agent		May 1996	
Partial lifting of export ban on tallow and gelatin		June 1996	
SBM ban broadened to include certain sheep and goat heads, spleens, and spinal cords (SRM)	Sept 1996		
FDA recommends withdrawal of plasma and plasma products made from pools to which persons who later died of CJD had contributed			Dec 1996
CNS tissues excluded from cosmetic products for use in EU		Jan 1997	
BSE cohort cattle in UK ordered slaughtered and destroyed	Jan 1997		
Proposed ban on SRM in cosmetics for use in EU (effective October 2000)		July 1997	
SBM controls for cosmetics and medicinal products	Mar 1997		
FDA request to manufacturers that no bovine gelatin from BSE countries be used in injectable, implantable, or ophthalmic products; and that special precautions be applied to gelatin for oral and topical use			Sept/Dec 1997
Ban on marketing cosmetic products containing SRM prepared before April 1, 1998		Mar 1998	
Allow export of beef and beef products from cattle >30 months in certified BSE-free herds from Northern Ireland		Mar 1998	
Importation of all plasma and plasma products for use in UK	Aug 1998		
FDA limits plasma product withdrawals to pools at risk for contamination by vCJD donors			Sept 1998
Slaughter and destruction of offspring born to BSE-affected cattle after July 1996	Jan 1999		
FDA guidance to defer blood donors with >6 months cumulative residence in UK during 1980-1996			Nov 1999
Leukodepletion of whole blood donations from UK residents	Jul/Nov 1999		
Public FDA discussion about possible risk associated with vaccines produced with bovine-derived materials from BSE countries			July 2000
Withdrawal and destruction of a potentially tainted 1989 lot of polio vaccine from one manufacturer	Oct 2000		
SRM ban implemented (effective October 2000)		July 2000	
Ban on slaughter techniques that could contaminate cattle carcasses with brain emboli (e.g., pithing or pneumatic stun guns), effective Jan 2001		July 2000	
All cattle >30 months old must have brain examinations for proteinase-resistant protein (PrP) before entering the food chain (effective Jan-Jun 2001)		Dec 2000	

[a]In Northern Ireland and Scotland, dates of implementation sometimes differed from those shown for England and Wales; in addition, individual EU countries often adopted different measures on different dates.
CNS = central nervous system; EU = European Union; MRM = mechanically recovered meat; SBM = specified bovine materials (SBO plus entire head, including eyes but excluding tongue); SBO = Specified bovine offals (brain, spinal cord, thymus, tonsils, spleen, and intestines from cattle >6 months old); SRM = specified risk materials (SBM plus sheep and goat heads and spleens from animals of any age, and spinal cords from animals >1 year old).

Senator FITZGERALD. Well, Dr. Johnson, thank you very much.

We will go through all the panelists and then we will go to the question portion of this hearing.

Dr. Torres.

STATEMENT OF ALFONSO TORRES, DEPUTY ADMINISTRATOR FOR VETERINARY SERVICES, U.S. DEPARTMENT OF AGRICULTURE; ACCOMPANIED BY: LINDA DETWILER, SENIOR STAFF VETERINARIAN, ANIMAL AND PLANT HEALTH INSPECTION SERVICE, USDA

Dr. TORRES. Good morning, Mr. Chairman and Members of the Subcommittee. Thank you for the opportunity to speak on behalf of the U.S. Department of Agriculture and my agency, the Animal and Plant Health Inspection Service, on the activities that we conduct in prevention of BSE coming into the United States.

My name is Alfonso Torres. I am the Deputy Administrator for Veterinary Services. I also serve as the Chief Veterinary Officer of the United States before the International Office of Epizootics, which is the WTO unit that provides the international standard-setting for——

Senator FITZGERALD. Dr. Torres, could you pull the microphone more directly in front. That is better, thank you.

Dr. TORRES. Sorry, Senator.

As has been mentioned before, BSE is now affecting 13 additional European countries in addition to the United Kingdom. APHIS has taken comprehensive and stringent measures for prevention, education, surveillance, and response in cooperation with USDA's Food Safety and Inspection Service, FSIS, and the FDA.

To prevent BSE from entering the United States, APHIS has prohibited the importation of live ruminants from countries where BSE is known to exist in native cattle, starting in 1989. Other products derived from ruminants, such as fetal bovine serum, meat and bone meal, or offal, fats, and glands, are also prohibited from entry.

In December 1997, APHIS extended these restrictions to include all of the countries in Europe due to concerns, widespread risk factors, and inadequate surveillance for BSE in those countries. As of December 2000, USDA prohibited all imports of rendered animal protein products, regardless of species, from Europe to prevent potentially cross-contaminated products from entering the United States.

USDA also works very closely with other Federal agencies involved in the prevention of BSE introduction. For the past 5 years, USDA agencies including APHIS, FSIS, the Agricultural Research Service, and the Cooperative State Research, Education and Extension Service have worked closely with CDC and the FDA on technical issues regarding TSEs. In addition, APHIS officials work with representatives from these agencies and our Canadian and Mexican counterparts on a tripartite TSE working group.

As part of USDA's surveillance program for BSEs, we have examined the brains of cattle with neurological or ambulatory signs for the possibility of BSE. As of February 28th this year, brains from 12,212 high-risk animals in the United States have been examined, with no evidence of TSE detected.

APHIS, in cooperation with FSIS, has also prepared an emergency response plan to use in the event that BSE is identified in the United States. This plan details comprehensive instructions for USDA staff as to who is going to do what, when, where, and how in case of such an emergency. USDA, HHS, and other Federal and state partners are now integrating this plan into a governmentwide plan including actions to be taken by FDA and the CDC.

While BSE has never been diagnosed in the United States, other TSEs do occur in our country. Scrapie has been reported in the United States, primarily in the Suffolk breed. It is important to note, as Dr. Johnson has mentioned, that there is no scientific evidence to indicate that scrapie poses a risk to human health or can be transmitted to humans. Attempts to control scrapie are carried out through scrapie flock certification programs that have been in place since October 1992.

Chronic wasting disease, CWD, is a TSE of deer and elk that has occurred in limited areas in the western United States. First recognized in 1967, it is typified by chronic weight loss leading to death. To date there is no known relationship between CWD and any other naturally occurring spongiform encephalopathies of animals or people.

As in the past, Mr. Chairman, APHIS in cooperation with other Federal agencies and state authorities remains committed to preventing the introduction, establishment, and spread of foreign animal diseases such as BSE. USDA will continue to take every action possible to safeguard domestic livestock and the U.S. food supply from this serious disease.

Thanks, Mr. Chairman and Members of the Subcommittee, for granting me this opportunity. I will be glad to answer any questions at an appropriate time.

[The prepared statement of Dr. Torres follows:]

PREPARED STATEMENT OF ALFONSO TORRES, DEPUTY ADMINISTRATOR FOR VETERINARY SERVICES, U.S. DEPARTMENT OF AGRICULTURE

Mr. Chairman and Members of the Subcommittee, I thank you for this opportunity to testify on behalf of the U.S. Department of Agriculture (USDA) and my Agency, the Animal and Plant Health Inspection Service (APHIS), on the activities that USDA conducts to prevent the introduction of bovine spongiform encephalopathy (BSE) into the United States.

BSE, widely referred to as "mad cow disease," is a chronic degenerative disease affecting the central nervous system of cattle. The disease was first diagnosed in 1986 in Great Britain. As you know, BSE has had a substantial impact on the livestock industry in the United Kingdom. The disease also has been confirmed in native-born cattle in Belgium, Denmark, France, Germany, Ireland, Italy, Liechtenstein, Luxembourg, the Netherlands, Northern Ireland, Portugal, Spain, and Switzerland. APHIS is enforcing import restrictions and is conducting surveillance for BSE to ensure that this serious disease does not become established in the United States.

BSE is classified as a transmissible spongiform encephalopathy (TSE). The agent responsible for BSE and other TSEs has not been completely characterized. Other TSEs include scrapie (which affects sheep and goats), transmissible mink encephalopathy, feline spongiform encephalopathy, and chronic wasting disease of deer and elk. In humans, TSEs include kuru, Creutzfeldt-Jakob disease (CJD), GerstmannStraussler-Scheinker syndrome, fatal familial insomnia, and variant CJD, which has been linked to BSE.

In cooperation with USDA's Food Safety and Inspection Service (FSIS) and the Food and Drug Administration (FDA), APHIS has taken comprehensive and stringent measures for prevention, education, surveillance, and response. To prevent BSE from entering the country, APHIS has prohibited the importation of live

ruminants from countries where BSE is known to exist in native cattle since 1989. Other products derived from ruminants, such as fetal bovine serum, bone meal, meat-and-bone meal, blood meal, offal, fats, and glands, are also prohibited from entry, except under special conditions or under USDA permit for scientific or research purposes.

On December 12, 1997, APHIS extended these restrictions to include all of the countries in Europe due to concerns about widespread risk factors and inadequate surveillance for BSE. As of December 7, 2000, USDA prohibited all imports of rendered animal protein products, regardless of species, from Europe. This decision followed the determination by the European Union that feed of nonruminant origin was potentially cross-contaminated with the BSE agent. The restriction applies to products originating, rendered, processed or otherwise associated with European products. USDA took this emergency action to prevent potentially cross-contaminated products from entering the United States. The same type of rendered product from ruminant origin has been prohibited from BSE-infected countries since 1989.

USDA also works very closely with other Federal agencies involved in the prevention of BSE introduction. For example, for the past 5 years, USDA agencies—APHIS, FSIS, the Agricultural Research Service (ARS), and the Cooperative State Research Education, and Extension Service (CSREES)—have worked closely with the U.S. Department of Health and Human Services' Centers for Disease Control and Prevention, National Institutes of Health, and Food and Drug Administration on technical issues regarding TSEs. In addition, APHIS officials work with representatives from these other Federal agencies and our Canadian and Mexican counterparts on the Tripartite TSE Working Group.

As part of USDA's surveillance program for BSE in the United States, pathologists at APHIS' National Veterinary Services Laboratories (NVSL) in Ames, Iowa, histopathologically examine the brains of these suspect animals for signs of BSE. Specifically, samples are tested using a technique called immunohistochemistry, which tests for the presence of the protease-resistant prion protein, an indication marker for BSE. NVSL also examines samples from neurologically ill cattle and nonambulatory (downer) cattle identified on the farm or at slaughter and from cattle submitted to veterinary diagnostic laboratories and teaching hospitals that tested negative for rabies.

In addition, veterinary field pathologists and field investigators from APHIS and FSIS have received training from their British counterparts in diagnosing BSE. FSIS officials inspect cattle before they go to slaughter; the inspection procedures include identifying animals with central nervous system conditions. Animals with such conditions are considered suspect for BSE, prohibited from slaughter, and referred to APHIS for examination. As of February 28, 2001, the brains from 12,212 animals in the United States and Puerto Rico had been examined with no evidence of BSE or other TSEs detected.

APHIS also monitors the remaining cattle imported from Great Britain, Belgium, and other European countries before the bans on imports from those countries went into effect. As of December 31, 2000, of the 496 cattle imported from Great Britain and Ireland between 1981 and 1989, four animals were still alive. The animals are quarantined and observed regularly. APHIS continues to attempt to purchase the four live animals for diagnostic research purposes. The 24 European cattle imported in 1996-97 that are still alive are currently under quarantine, and APHIS is attempting to buy these animals as well.

There were also two flocks of sheep imported from Belgium and the Netherlands in 1996 that were under state quarantine in Vermont since October 1998 due to probable TSE exposure. Four sheep from one of the flocks have tested positive for an atypical TSE of foreign origin. There is no simple test to determine whether the sheep are infected with BSE or another TSE, such as a European strain of scrapie—a TSE that affects sheep and goats. Nevertheless, it is highly likely that the animals were exposed to feed contaminated with the agent that causes BSE before they left Europe.

The owner of an additional flock that contained female progeny from these imported sheep sold his entire herd to USDA in July 2000. On July 21, 2000, then-Secretary of Agriculture Dan Glickman issued a Declaration of Extraordinary Emergency authorizing the seizure of the two imported flocks. However, the owners of these flocks contested the decision and sought to have the seizure blocked through the legal system. On February 6, 2001, the U.S. District Court for the District of Vermont ruled that the owners of the flocks must comply with the Declaration of Extraordinary Emergency and surrender the sheep to USDA. The owners subsequently filed an appeal with the 2nd Circuit Court of Appeals in which the original decision was upheld. USDA took the first flock on March 21, 2001, and the second

flock on March 23, 2001. The sheep have been euthanized, samples for further diagnostic tests were taken, and the carcasses were disposed of in a safe manner.

APHIS, in cooperation with FSIS, has also drafted an emergency response plan to be used in the event that BSE is identified in United States. The plan details comprehensive instructions for USDA staff as to who is to do what, when, where, and how in the case of such an emergency. USDA, HHS, and other Federal and state partners are now integrating this plan into a governmentwide plan, including actions to be taken by FDA and the Centers for Disease Control (CDC).

In 1998, USDA entered into a cooperative agreement with Harvard University's School of Public Health to analyze and evaluate the Department's measures to prevent an introduction of BSE. The Harvard study, which is expected to be completed in the next few months, reviews current scientific information, assesses the pathways that BSE could potentially enter the United States, and identifies any additional measures that could be taken to protect human and animal health.

APHIS' TSE Working Group monitors and assesses all ongoing events and research findings regarding TSEs. APHIS continually revises and adjusts prevention and diagnostic measures as it receives new information and knowledge.

As an additional preventative measure, APHIS supports the FDA regulation (effective August 4, 1997) prohibiting the use of most mammalian protein in the manufacture of animal feeds given to ruminants. The final regulation also requires process and control systems to ensure that ruminant feed does not contain the prohibited mammalian tissues.

While BSE has never been diagnosed in the United States, other TSEs do occur in this country. For example, scrapie has been reported in the United States primarily in the Suffolk breed. It is important to note that there is no scientific evidence to indicate that scrapie poses a risk to human health or can be transmitted to humans.

In 1952, the Secretary of Agriculture declared a state of emergency in an attempt to eradicate scrapie in the United States. Although that goal has not yet been achieved, USDA continues to identify the disease and attempt to eradicate it through the Scrapie Flock Certification Program that was implemented on October 1, 1992.

This voluntary program is a cooperative effort among producers, allied industry representatives, accredited veterinarians, state animal health officials, and APHIS officials. The program provides participating producers with the opportunity to protect their sheep from scrapie and enhance the marketability of their animals through certifying their origin in scrapie-free flocks. In addition, APHIS regulations restrict the interstate movement of sheep from scrapie-infected and source flocks.

Chronic wasting disease (CWD) is a TSE of deer and elk that has occurred only in limited areas in the Western United States. First recognized as a clinical syndrome in 1967, it is typified by chronic weight loss leading to death. To date, there is no known relationship between CWD and any other naturally occurring spongiform encephalopathy of animals or people. Further research continues in this area.

Surveillance for CWD in Colorado and Wyoming has been ongoing since 1983 and, to date, has confirmed the limits of the endemic areas in those states. An extensive nationwide surveillance effort was started in 1997-98 to better define the geographic distribution of CWD. This ongoing surveillance effort is a two-pronged approach consisting of hunter-harvest cervid surveys conducted in Arizona, Colorado, Idaho, Kansas, Maine, Michigan, Montana, Nebraska, Nevada, New Jersey, Oklahoma, South Dakota, Utah, and Wyoming, as well as surveillance throughout the entire country targeting deer and elk exhibiting clinical signs suggestive of CWD.

As in the past, APHIS remains committed to preventing the introduction, establishment, and spread of foreign animal diseases such as BSE. APHIS, in cooperation with FDA and other agencies, is enforcing stringent import restrictions and is conducting a comprehensive surveillance program to ensure that BSE does not become established in the United States. USDA will continue to take every action possible, including prevention, preparedness, response, and recovery measures, to safeguard domestic livestock and the U.S. food supply from this serious disease. Again, I would like to thank the Chairman and Members of the Subcommittee for granting me this opportunity to explain APHIS' key role in addressing issues involving BSE.

Senator FITZGERALD. Thank you very much, Dr. Torres.

Dr. Sundlof.

STATEMENT OF STEPHEN SUNDLOF, D.V.M., PH.D., DIRECTOR, CENTER FOR VETERINARY MEDICINE, FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. SUNDLOF. Thank you, Mr. Chairman. Thank you for the opportunity to participate in today's hearing on the Federal Government's efforts to prevent BSE from occurring in the United States.

I am Stephen Sundlof. I am a veterinarian and a toxicologist and I serve as the Director of the FDA's Center for Veterinary Medicine.

Many FDA-regulated products contain bovine ingredients, including food, animal feed, drugs, vaccines, tissues, dietary supplements, cosmetics, and medical devices. Also there are theoretical concerns about transmitting CJD and variant CJD through donated human blood.

While NIH's focus is on research, the FDA and its Federal and state partners focus on prevention. In August 1997, the FDA issued a regulation that prohibits the use of most mammalian protein in animal feeds for ruminants. Even though there is no evidence of BSE in the U.S., FDA prohibited these feeding practices in order to prevent the spread of this disease should the disease get into the United States.

To ensure compliance with this rule, FDA launched a rigorous inspection program, including an extensive educational component. We enlisted the assistance of the states, and since January 1998, state regulators and Federal regulators have conducted over 10,000 inspections of renderers, feed mills, ruminant feeders, feed-haulers, and distributors.

Now FDA is re-inspecting noncompliant facilities. In January FDA field offices were directed to re-inspect all those firms that were not in full compliance with the rules. Re-inspections are being conducted to date and show that only one firm is out of compliance when re-inspected.

Education has been an important part of the compliance program. FDA sponsored workshops attended by state veterinarians and feed control officials from all 50 states, Puerto Rico, the Virgin Islands, and Canada, and FDA held briefing sessions with trade associations and consumer groups and developed supplemental guidances to the industries.

FDA currently has two import alerts in force. One calls for the detention of bulk shipments of high-risk bovine tissues from BSE countries. The second instructs FDA field personnel to detain animal feed and other products for animal use that contain ingredients of animal origin from any animal in those countries in which BSE is present.

Assuring the compliance with FDA's feed ban and having strong protections at our borders are the key strategies in preventing the occurrence and spread of BSE within the United States. Let me briefly mention some other activities that the agency has taken to protect the consumers of dietary supplements and medical-related products, such as drugs, blood, vaccines, and medical devices.

Since 1993, FDA has sent a number of letters of guidance to manufacturers on the use of bovine materials from countries affected by BSE. In 1993 and again in 1996, FDA requested that

manufacturers of FDA-regulated products intended for human use not use bovine-derived materials from BSE countries. Again in 2000, FDA re-issued advisory letters to dietary supplement manufacturers and to vaccine and other biological product manufacturers.

In September 1997, FDA released guidance for industry on the sourcing and processing of gelatin products for human use so that consumers of gelatin products such as candy or capsules can be confident of their safety. In November 1999, FDA issued guidance to blood centers to reduce the theoretical risk of transmission of variant CJD to recipients of blood products. This precautionary measure recommended procedures for deferring potential donors who may have been exposed to BSE due to travel or residence in the United Kingdom. Further revision to this guidance may be forthcoming as new information becomes available.

In July 2000, our Vaccines and Related Biological Advisory Committee and our TSE Advisory Committee jointly concluded that for licensed products the risk to recipients, if any, was theoretical and remote and was outweighed by the benefits of vaccines. The committee nonetheless recommended that if bovine materials were found to be used in vaccine production that manufacturers change the sources of vaccines of those products to non-BSE countries.

Let me close by reiterating that currently there is no evidence that BSE or variant CJD exists in the United States. Nonetheless, we are alert to the threat and FDA will continue to aggressively protect the health of the American public and our animal population by minimizing the risk of BSE introduction or spread into the United States.

Thank you again, Mr. Chairman, for the opportunity to testify.

[The prepared statement of Dr. Sundlof follows:]

PREPARED STATEMENT OF STEPHEN SUNDLOF, D.V.M., PH.D., DIRECTOR, CENTER FOR VETERINARY MEDICINE, FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. Chairman, Members of the Committee, thank you for the opportunity to participate in today's hearing on measures by the Federal Government to prevent bovine spongiform encephalopathy (BSE) or "Mad Cow Disease," from occurring in the United States (U.S.). I am Dr. Stephen Sundlof, Director, Center for Veterinary Medicine, Food and Drug Administration (FDA or the Agency).

Let me state at the outset that currently we have no evidence of BSE in the U.S. and FDA and other Federal agencies are working diligently to keep it out of the U.S. FDA has been actively involved nationally and internationally in efforts to understand and prevent the spread of BSE. FDA collaborates extensively with its sister Public Health Service agencies, the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH), relevant agencies within the U.S. Department of Agriculture (USDA), the Customs Service, and many other Federal and state agencies, as well as with affected industries and consumer groups.

BACKGROUND ON BSE AND VARIANT CREUTZFELDT-JAKOB DISEASE (VCJD)

BSE belongs to the family of transmissible spongiform encephalopathies (TSEs) diseases. TSEs are a group of transmissible, slowly progressive, degenerative diseases of the central nervous systems of humans and several species of animals. Animal TSEs include, for example, bovine BSE in cattle, "scrapie" in sheep and goats, "chronic wasting disease" (CWD) in deer and elk, feline spongiform encephalopathy in cats, and mink spongiform encephalopathy in mink. Scrapie and CWD are found in the U.S. to a small extent in certain herds of these animals.

Human TSEs include kuru, a disease of the South Pacific Fore people and Creutzfeldt-Jakob disease (CJD or "classical" CJD), which occurs throughout the world, including the U.S. (where it occurs at a stable rate of about one per million

population per year) and new variant CJD (vCJD), which was first reported in the United Kingdom (U.K.) in 1996. It is believed that vCJD may be acquired from eating food products containing the BSE agent, and there is strong epidemiological and laboratory evidence for a causal association between vCJD and BSE. The onset of illness in the first case of vCJD, occurred in early 1994. As of April 2, 2001, 97 probable or confirmed human cases of vCJD were reported in the U.K., three in France and one in Ireland. The absence of confirmed cases of vCJD in geographic areas free of BSE supports a causal association. There is no evidence to date of vCJD in the U.S. There is no known treatment for any TSE, and they are all fatal.

BSE has a prolonged incubation period in cattle, ranging from 3 to 8 years; for vCJD in humans, the incubation period is unknown, but is at least 5 years and could extend up to 20 years or longer. BSE was first discovered in the U.K. in November 1986. Epidemiological evidence established that the wide-spread amplification of BSE throughout many of the British cattle herds was related to the production and use over many years of BSE-contaminated meat-and-bone meal that was fed primarily to young calves. The original source of the BSE outbreak is uncertain.

The vast majority of BSE cases have been reported in the U.K. About 180,000 cases of BSE have been confirmed there in more than 33,000 herds of cattle. The U.K. epidemic peaked in January 1993 at nearly 1,000 new cases per week. Surveillance in Europe has also led to the identification of cases of BSE in Belgium, Denmark, France, Ireland, Liechtenstein, the Netherlands, Portugal, Switzerland and most recently, in Germany, Spain and Italy. European countries have instituted a variety of public health control measures, such as BSE surveillance, the culling (removal from the herd) of sick animals, the banning of specified risk materials, the banning of animal proteins in animal feed, or a combination of these, to prevent potentially BSE-infected tissues from entering the human food chain.

FDA PROTECTIONS

Many FDA regulated products contain bovine products, including food, animal feed, drugs, vaccines, tissues, dietary supplements, cosmetics, medical devices, and there also are theoretical concerns about transmitting CJD and vCJD through the human blood supply from a donor infected with CJD or vCJD. At this time there is no documented transmission of CJD or vCJD through blood/blood products. FDA has a long-standing commitment to consumer protection involving BSE and vCJD.

The focus for FDA and its Federal and state partners in other agencies has been prevention. Using the best science known at this time, the U.S. has an aggressive, multi-faceted program in place to try to prevent the establishment and spread of BSE within the U.S. FDA's restrictions on certain cattle feed ingredients and its import restrictions on various items and products are critical parts of this program.

CATTLE FEED RESTRICTIONS, INSPECTIONS AND EDUCATION

As I have stated, rendered feed ingredients contaminated with the BSE agent are believed to be the means by which BSE is amplified in cattle herds. The amplification is most closely associated with feed for cattle, particularly young calves that include ingredients processed from remnants of slaughtered animals, such as meat-and-bone meal, which may harbor the agent that causes BSE. Although the material is cooked, the BSE agent can survive.

In order to prevent the spread of BSE through feed, in August 1997, FDA published a regulation that prohibits the use of most mammalian protein in the manufacture of animal feeds for ruminants (Title 21, *Code of Federal Regulations* (CFR) Part 589). Even though there is no evidence of BSE in the U.S., FDA prohibited this feeding practice so that we established in our country feeding practices consistent with the best epidemiological knowledge available to prevent the spread of this disease throughout the U.S. cattle herd should it get into the U.S. With the strong support of renderers, cattle owners, feed manufacturers, and feed lot owners, FDA launched a compliance and education program, including a rigorous inspection program. The goal of these efforts is to achieve as close to 100 percent compliance with the labeling, record keeping, and contamination avoidance provisions of this new regulation as soon as possible. FDA recognizes that there were some early problems with compliances, as cited in the General Accounting Office's (GAO) report, "Controls Can Be Strengthened to Reduce the Risk of Disease Linked to Unsafe Animal Feed" (GAO/RCED-00255).

FDA and state regulators have conducted over 10,000 inspections of renderers, feed mills, ruminant feeders, dairy farms, protein blenders, feed haulers, and distributors since January 1998. On first inspection, about three-quarters of these es-

tablishments were found to be in compliance. Most of the establishments that had problems during the first inspection were found in compliance upon re-inspection.

FDA is continuing its compliance efforts by conducting additional inspections and re-inspecting non-compliant facilities. In January 2001, FDA field offices were issued an assignment to re-inspect 834 firms that were not in full compliance with the rule. Of 184 re-inspections conducted by April 2, 2001, only one firm continued to be out of compliance.

Education is also an extremely important part of the compliance program. FDA has sponsored workshops attended by state veterinarians and feed control officials from all 50 states, Puerto Rico, the U.S. Virgin Islands, and Canada. In addition, FDA has held briefing sessions with trade associations and consumer groups, and has developed additional guidances for complying with the regulation.

IMPORT CONTROLS

FDA and the USDA's Animal and Plant Health Inspection Service (APHIS) work in close cooperation with the Customs Service on items related to imports.

APHIS establishes and enforces import restrictions covering animals and animal products offered for import into the U.S. to prevent the importation of foreign exotic diseases. Beginning in 1989, APHIS has taken several actions to ban animals or products under their jurisdiction because of concerns about BSE.

FDA issues Import Alerts and Import Bulletins regarding problems or potential problems with imported products under FDA's jurisdiction. FDA coordinates its Import Alerts and Bulletins closely with APHIS. The Agency has issued the following:

• On September 1, 1992, FDA issued Import Bulletin 99-B03, alerting field units to imports, from BSE countries, of animal by-products and regulated products containing animal by-product ingredients.

• On October 19, 1994, FDA issued Import Alert 17-04 (replacing the 1992 Import Bulletin) calling for the detention, without examination, of bulk shipments of high-risk bovine tissues and tissue-derived ingredients from BSE countries (at that time this included the U.K., France, Ireland, Oman, Switzerland, and Portugal). FDA updated this alert whenever APHIS revised the list of BSE countries it included at 9 CFR § 94.18.

• On January 24, 2000, FDA updated the existing Import Alert 17-04, which called for detention of bulk shipments of high-risk bovine tissue from BSE countries to include countries in most of Europe, following APHIS's extension of import restrictions to those countries.

• On December 20, 2000, FDA issued Import Bulletin 71B-02, alerting FDA field personnel of the APHIS restrictions on animal feed ingredients from 31 countries, and instructing them to coordinate entry review with their local APHIS office. This Import Bulletin was canceled on January 23, 2001, after the issuance of Import Alert 99-25.

• On January 20, 2001, FDA issued Import Alert 99-25, which instructed FDA field personnel to detain animal feed, animal feed ingredients, and other products for animal use consisting of, or containing, ingredients of animal origin from the 31 countries where BSE is known to exist and/or have less restrictive import requirements then those that would be acceptable in the U.S.

• On March 1, 2001, FDA issued Import Bulletin 99B-14, alerting FDA field personnel that APHIS further prohibited the importation into the U.S. of certain edible ruminant products from Europe, Oman, and BSE at-risk countries. The Bulletin advises that FDA entry review should include assessment of product ingredients to determine whether they contain or may contain ruminant material subject to the APHIS prohibition.

PROTECTING FDA-REGULATED MEDICAL PRODUCTS AND DIETARY SUPPLEMENTS

FDA also has taken steps to protect medical products (such as drugs, blood, vaccines, and medical devices) for human use. Since 1993, FDA also has sent a number of letters to manufacturers of FDA-regulated products providing guidance on the use of bovine materials from countries affected by BSE and taken other actions.

• In 1993 and again in 1996, FDA requested that manufacturers of FDA-regulated products intended for humans not use bovine-derived materials from BSE countries.

• In September 1997, FDA released a Guidance for Industry, "The Sourcing and Processing of Gelatin to Reduce the Potential Risk Posed by Bovine Spongiform Encephalopathy (BSE) in FDA-Regulated Products for Human Use." FDA recommends that gelatin-containing products such as candy or capsules imported from the 31 countries identified as having BSE or at risk for having BSE be manufac-

tured under specific guidance. Gelatin is to be made from non-BSE herds and use only specific parts of BSE-free animals.

• In April 2000, FDA's Center for Biologics Evaluation and Research (CBER) issued a letter to manufacturers of biological products reminding them of the Agency's strong recommendations not to use materials derived from ruminant animals from countries where BSE is known to exist. This action was taken as a result of learning that its recommendations regarding the sourcing of bovine materials for the manufacture of vaccines had not been followed in at least one instance.

• In May 2000, CBER requested that all vaccine manufacturers review the source for all bovine-derived materials used in the manufacture of their products, including bovine derived material used to prepare working cell and seed banks.

• In July 2000, assessments of risk and recommendations regarding additional vaccines manufactured with bovine derived materials that had been obtained from European countries on the USDA list were discussed in a meeting held in July 2000 between CBER's Vaccines and Related Biological Advisory Committee and FDA's TSE Advisory Committee. The joint committees concluded that for licensed products, the risk to recipients, if any, was theoretical and remote and outweighed by the benefits of the vaccines. The joint committees, nonetheless, recommended that if bovine materials were found to be used in vaccine production that manufacturers change sources. They also agreed with CBER that if the working cell and seed banks were derived (after January 1, 1980) using bovine materials from countries on the USDA list, manufacturers re-derive those cell and seed banks using bovine materials from countries not on the USDA list. Manufacturers have agreed to, and have begun implementing, all of these changes.

• In November 2000, FDA sent a letter to manufacturers and importers of dietary supplements. The letter states the Agency's strong recommendation that firms manufacturing or importing dietary supplements that contain specific bovine tissues take whatever steps are necessary to assure themselves and the public that such ingredients do not come from cattle born, raised, or slaughtered in countries where BSE is known to exist. Since 1992, FDA has issued four letters to the dietary supplement industry to make sure the industry was aware of the problem and that they should be taking appropriate action.

FDA inspects manufacturers of FDA-regulated products to determine if manufacturers are following the Agency's current recommendations as part of current good manufacturing practices. In addition, as applications for new products or changes to products are submitted, FDA ensures that the recommendations are being followed, if those products are required to have FDA clearance prior to marketing in the U.S.

PROTECTING THE BLOOD SUPPLY

In November 1999, FDA issued guidance to blood centers to reduce the theoretical risk of transmission of vCJD to recipients of blood products. This precautionary measure recommended procedures for deferring potential donors who may have been significantly exposed to BSE due to travel or residence in the U.K. FDA's present guidance recommends that blood centers exclude potential donors who have spent six or more cumulative months in the U.K. between January 1, 1980, and December 31, 1996, from donating blood. Further revision to this guidance may be forthcoming as new information becomes available regarding other countries' BSE experiences.

TSE ADVISORY COMMITTEE

FDA has constituted a TSE Advisory Committee, which is composed of non-government experts in TSE matters and meets publicly on at least a semi-annual basis. This committee was chartered originally in 1995. The purpose of the TSE Advisory Committee, as with all of our advisory committees, is to consider policy and scientific issues and then provide FDA with insight and recommendations. One standing agenda item of this committee is review of current regulations and guidance to prevent exposure of the U.S. population to the agent(s) of BSE/TSE through blood, tissues, and other regulated products. FDA's TSE Advisory Committee recently offered advice on revising the guidelines to include potential donors who have lived an aggregate of 10 years in France, Ireland and Portugal. FDA is developing revisions to its current industry guidance and will consider the advice of the committee.

INTERAGENCY COORDINATION OF TSES ISSUES

Protecting the U.S. from BSE and all TSEs are top priorities of the Department of Health and Human Services (DHHS or Department). Secretary Thompson has made BSE one of his priorities, and has initiated a process to strengthen coordination of BSE/TSE activities across the Department.

In January 2001, FDA established an Interdepartmental Steering Committee for BSE/TSE Affairs. This committee is chaired by the Acting Commissioner of FDA and includes representatives of: CDC, FDA, NIH, USDA (FSIS, APHIS, FAS), the U.S. Trade Representative, the Office of Management and Budget, the Customs Service, the Department of State, the Department of Defense, the State Association of Feed Control Officials, the National Association of State Departments of Agriculture, and the White House Office of Science and Technology Policy.

The committee assures:

• Ongoing coordination between agencies.

• Integrated contingency planning for the possibility that a case of BSE or of vCJD might be found in the United States.

• Identification and action on high priority cross-departmental issues in the U.S. regarding BSE and vCJD.

• Coordination of risk communication plans by the various agencies.

DHHS. BSE/TSE activities can be divided into four major components: Surveillance, Protection, Research and Oversight. Surveillance for human disease is primarily the responsibility of the CDC. Protection and Surveillance of animals, feeds, and foods are responsibilities of FDA, which it shares with USDA. Research is primarily the responsibility of NIH, although FDA also conducts important research. Oversight is primarily the responsibility of the DHHS Office of the Secretary.

Within the Department, there also is a Public Health Service Blood Safety Committee (BSC) that is chaired by the Assistant Secretary for Health, who serves as the Blood Safety Director for the Department. The BSC includes among its members the directors of CDC, FDA, NIH, and the DHHS Assistant Secretary for Planning and Evaluation. The purpose of this committee is to enable threats to the safety or availability of the blood supply to be brought immediately to the highest levels of DHHS. The BSC has been convened on an urgent basis to review proposed recommendations to defer blood donors at risk of transmitting BSE by virtue of prior residence in the U.K. The BSC also met to consider issues relating to the development of CJD at an unusually young age in a hunter who had been a long time plasma donor. In addition, members of this group met to review issues related to the discovery of a poorly characterized TSE that recently appeared in flocks of East Freisian sheep, which had been imported to Vermont from Europe. The group stands ready to be convened for similar matters in the future.

The Department intends to ensure timely, accurate, thorough, and clear communication to the public about the nature and extent of the threats posed by BSE/TSE and about the actions that each agency of government is taking to protect the public from these threats. FDA has announced that it will hold a public meeting for consumers on BSE on April 16, 2001, in Washington, D.C. The purpose of this meeting will be to inform the public about FDA's BSE-related activities and to hear from various consumer groups about their concerns with and suggestions for addressing the challenge of BSE.

CONCLUSION

Let me close by again stating that currently there is no evidence that BSE or vCJD exists in the U.S. Working together with many counterpart agencies in the U.S., around the world and with various industry and consumer groups, FDA will continue to work to protect the health of the American people and of our animal population by acting to minimize the risk of BSE introduction or spread into the U.S.

Thank you again for the opportunity to testify.

Senator FITZGERALD. Thank you, doctor.

Dr. Hueston.

STATEMENT OF WILLIAM D. HUESTON, D.V.M., PH.D., PROFESSOR AND ASSOCIATE DEAN, UNIVERSITY OF MARYLAND CAMPUS, VIRGINIA-MARYLAND REGIONAL COLLEGE OF VETERINARY MEDICINE

Dr. HUESTON. Thank you, Mr. Chairman. I appreciate this opportunity to testify. I am Will Hueston, Professor at University of Maryland and Associate Dean of the Virginia-Maryland Regional College of Veterinary Medicine. My specialty is veterinary epidemiology. I have spent the last 12 years of my life working with this disease, including time in Great Britain on the investigatory team

and also 6 years as a member of the Spongiform Encephalopathy Advisory Committee for the United Kingdom.

It is a very interesting disease and interesting for us to look back now. Since this disease was first identified in 1986 in the United Kingdom, the United States has taken a series of preventive actions, including, as you have heard, import bans, feed bans, guidance documents, extensive education, and aggressive surveillance, which have been successful to date.

Why have these been successful? Because each step was scientifically sound, and our system has been sequentially enhanced as new scientific information becomes available. In addition, our prevention steps have been implemented with the cooperation between Federal agencies and also with the affected industries.

Interestingly enough, I think the response to BSE stands as an excellent example and the best example I am aware of of collaboration between both animal health and human health agencies within the Federal Government.

Well, have these steps been adequate, then? Yes, to date they have been adequate.

I would like to digress for a moment and address a comment that I feel is irresponsible that is being put forth by the media. That is a statement that says what the United States faces now is exactly what Europe faced 10 years ago. That statement, Mr. Chairman and Members of the Subcommittee, is absolutely ludicrous and incorrect. In fact, the other European countries that have identified BSE within the last 6 months realized and knew that they had a massive exposure to risk factors. They ignored that information. They failed to implement the corrective measures, and, in fact, now they are paying the price for their complacency.

While the risks of BSE in the United States are the lowest that they have ever been, it is not by accident, Mr. Chairman It is by a series of well thought out, scientifically sound steps.

Interesting, though, this challenge of prevention. There is an interesting conundrum for those of us who make prevention our life's career. If, in fact, we are successful, we will be criticized for wasting resources for a problem that has never occurred. If, on the other hand, we are unsuccessful, we will be criticized for not taking sufficient steps.

So let me follow that statement by saying this. The likelihood of BSE in the United States is very low. It is not zero. We realize there are potential exposures to BSE in the United States, but they are very, very few and very low. Nevertheless, the impact should this disease occur in the United States is quite large.

What are the next steps that need to be taken? We need to continue to look at ways to expand our risk communication, to replace perception with accurate, scientifically sound information. We need to continue to strengthen our surveillance program by focusing primarily on older cattle, those cattle that have potentially been exposed and have lived long enough to potentially develop the disease. Third—testing slaughter cattle, as an example—would be a complete and total waste of time and energy and money because those animals are not old enough and have not lived long enough to develop the disease even if they are exposed.

In our system, then, if we want to go for another step that has a potential for precluding potential exposure for animals and humans, that step ought to be driven by science and by an examination of risk. The highest risk, most risky tissues that have been mentioned before, are central nervous system, brain and spinal cord.

Well, if in fact, additional prevention steps are warranted, are taken, then they must be based on science and carefully planned implementation for those steps. In the absence of a careful implementation plan, we will be walking down the same path that some of our European colleagues have taken—to proclaim that they are taking additional prevention steps, but not have the wherewithal to carry them out.

Mr. Chairman, I would like to conclude with one comment. Healthy livestock are the foundation of safe food. I think the biggest concern that I see right now, and that perhaps my colleagues are constrained from saying, is the loss of infrastructure in the United States to respond to animal diseases. We desperately need an upgrade in our diagnostic laboratory capability for animal diseases. We need, in fact, to strengthen the infrastructure so that we can support both the surveillance and respond should there be an outbreak of disease. Finally, we need to dramatically increase the amount of research dollars that are going into assuring healthy animals. Healthy animals are the basis of safe food.

Again, I thank you very much for the ability to present to this Subcommittee, and I would ask that my full statement appear in the minutes.

[The prepared statement of Dr. Hueston follows:]

PREPARED STATEMENT OF WILLIAM D. HUESTON, D.V.M., PH.D., PROFESSOR AND ASSOCIATE DEAN, UNIVERSITY OF MARYLAND CAMPUS, VIRGINIA-MARYLAND REGIONAL COLLEGE OF VETERINARY MEDICINE

Mr. Chairman, I am Dr. Will Hueston and I am the Associate Dean of the Virginia-Maryland Regional College of Veterinary Medicine. I am here today to provide testimony based on 12 years of professional experience with bovine spongiform encephalopathy (BSE), commonly referred to as "Mad Cow Disease."

For the benefit of the committee, I have had the privilege to serve on both the U.S. and the UK scientific Advisory Committees on spongiform encephalopathies, so that I can compare the U.S. precautions to the situation that has evolved in Europe over the past 15 years.

I am pleased at the opportunity to present testimony before this committee and briefly share my thoughts on the adequacy of the current U.S. precautions.

EMERGENCE OF NEW DISEASES

New animal diseases emerge as a natural response to changes in disease agents, their animal hosts, and the environments in which they live. Discovery of new diseases is a regular occurrence throughout the world. Therefore, the emergence of new diseases such as BSE is to be expected and we must be prepared to respond to each new discovery.

FOREIGN ANIMAL DISEASE SURVEILLANCE AND EMERGENCY RESPONSE

The disease BSE was first discovered in 1986 in the UK through the cooperation of a concerned animal producer, an astute veterinarian and a dedicated laboratory scientist. Investigation of the cause of the disease in 1987-1988 identified animal feed containing rendered animal protein (meat and bone meal) as the source of the disease exposure. Therefore, BSE can be described as a common source feedborne epidemic. The most likely origin of BSE appears to be the sheep disease scrapie, a similar spongiform encephalopathy that is widespread in the UK. The first precaution taken to prevent BSE in the U.S. was the training of Federal and state vet-

erinarians and strengthening laboratory diagnostic capabilities so that the disease could be identified quickly should it occur.

EXCLUSION OF FOREIGN ANIMAL DISEASES THROUGH IMPORT BANS

The second step taken to exclude BSE from the U.S. was a ban on the importation of potentially infected animals and animal products. Importation of affected animals (cattle and other ruminants) and contaminated products of animal origin such as meat and bone meal represent the greatest risk for the introduction of BSE to the U.S. The U.S. initiated bans on the importation of live cattle and cattle products after the UK announced the results of their epidemiology investigations of the new disease BSE. These bans were based on scientific evidence concerning the nature of the disease and its major routes of transmission.

SCIENTIFIC RISK ANALYSIS

A risk analysis assessing the potential for BSE occurrence in the U.S. was initiated in 1989 immediately after the import bans were put in place. The risk analysis addressed the question of whether BSE would occur in the U.S., and if so, whether the U.S. would expect to see an epidemic of the magnitude of that unfolding in the UK. Serendipitously, the risk analysis identified that very few cattle (a total of 496) and very little meat and bone meal (<20 tons) had been imported from the UK and Ireland around the time of the emergence of BSE (1981-1989). Furthermore, major differences were identified in the livestock demographics and cattle industry structure between the U.S. and the UK. The risk analysis results concluded that while the possibility of a case of BSE in the U.S. could not be completely excluded, the likelihood of an epidemic of the magnitude of that seen in Great Britain was remote. The risk analysis also identified specific high risk populations of cattle where the disease would be expected to occur first, if it occurred at all in the U.S. The risk analysis process helps identify the most important precautions necessary to prevent BSE from occurring in the U.S.

TARGETED SURVEILLANCE OF HIGH-RISK POPULATIONS

Identification of BSE depends on the testing of brain material from cattle. No blood test or live animal diagnostic test is currently available. BSE has a very long latency period so that infected cattle do not show clinical signs of the disease until 3-5 years after exposure to the BSE agent in their feed. The disease can only be diagnosed close to or after the clinical signs appear. Therefore disease surveillance must be focused on older animals which have both the potential for exposure and sufficient time for the disease to develop. The risk analysis helped identify specific high risk populations for BSE such as the cattle imported from the UK and older dairy cattle which had been fed meat and bone meal in the U.S. Therefore, the BSE surveillance program in the U.S. was targeted toward these high risk cattle populations beginning in 1990.

RISK COMMUNICATION AND EDUCATION

Training of veterinarians and educating of producers began immediately after the British identification of this new disease and the results of the initial epidemiologic investigation. U.S. government veterinarians were sent to the UK to learn more about the disease and British experts were invited to the U.S. for consultations. Extensive educational efforts accompanied the risk analysis process. Futhermore, education of animal owners and veterinarians was and is a key component of the ongoing surveillance program.

GUIDANCE TO MANUFACTURERS

The incorporation of infected cattle tissues into biologics or medical devices represents another potential route for the transmission of BSE. Consequently, the Food and Drug Administration issued a series of guidance documents to manufacturers concerning the risks associated with BSE and the safe sourcing of raw materials of bovine origin.

INDUSTRY INITIATIVES

As the epidemiology of BSE became clear, producer groups and industry took voluntary initiatives to reduce the potential for BSE occurrence in the U.S. The rendering industry took steps to reduce the use of sheep potentially affected with scrapie as raw material for the production of rendered animal protein, such as meat and bone meal. Further, many of the animal industries inaugurated education cam-

paigns, urging producers to assist in the identification of high risk cattle for the surveillance program. Finally, the cattle industry played a critical role in helping to purchase and destroy many of the cattle imported from the UK which represented the greatest risk for the occurrence of BSE in the U.S.

ADDITIONAL ENHANCEMENTS TO SURVEILLANCE

The targeted surveillance of high risk cattle populations was expanded to include non-ambulatory cattle (downers) in 1993 as a further step to identify BSE if it existed in the U.S. Additionally, a second diagnostic test, immunohistochemistry (IHC) was added to the surveillance system to augment the histopathology used to test brains. The U.S. was the first country to implement IHC testing as part of the regular surveillance system. Throughout the 1990s, the numbers of high risk cattle screened for BSE grew annually. The U.S. developed the most extensive surveillance system of any country in the world outside of Europe where the BSE epidemic was centered.

FEED BANS TO BAR THE POTENTIAL FOR RECYCLING OF INFECTIVITY

Upon the recognition that the BSE agent was associated with a human disease, variant Creutzfeldt-Jakob Disease (vCJD), efforts were initiated to remove ruminant-derived meat and bone meal from U.S. cattle feed. The cattle producers initiated a voluntary program to exclude ruminant meat and bone meal and subsequently, the FDA promulgated a rule banning the feeding of most mammalian proteins to ruminants. The ban was science-based, targeting the feed ingredients that would be of highest risk for transmitting BSE should the disease be identified in the U.S.

EXTENSION OF IMPORT BANS

Recognition of the BSE risk for humans and the spread of BSE in Europe led to expansion of the import bans placed on cattle and cattle products from all of Europe. Extension of the bans further reduced the likelihood of potentially infected materials entering the U.S.

ADEQUACY OF CURRENT PRECAUTIONS

Since the first identification of BSE in the UK 1986, the U.S. has taken a series of steps to prevent the entry of the disease into the U.S. or the propagation of the disease if it occurred. All of the precautions against BSE taken by the U.S. have been science-based, targeting known risks. These prevention strategies have been successful to date, in that no BSE has been diagnosed in the U.S.

OPPORTUNITIES FOR STRENGTHENING SAFEGUARDS

Ignorance, complacency and lack of resources are the three greatest threats to the prevention of BSE and rapid diagnosis and response if it occurs. Precautions taken to preclude BSE from the U.S. must be regularly re-evaluated and enhanced when new science becomes available or weaknesses in the current system are identified. Documentation of our BSE status and rapid response to any potential BSE occurrence depends on an aggressive surveillance system. While the U.S. has the strongest surveillance system outside of Europe, the identification and testing of high risk cattle populations must be expanded. Testing of a broader sample of older cattle will strengthen our surveillance system. The testing also needs to target older cattle dying on the farm and debilitated animals that are euthanized or presented for slaughter. No additional surveillance benefit would be gained by testing of routine slaughter cattle, however. Most cattle in the U.S. are slaughtered before 24 months of age, which is too young to detect the disease even if these had been exposed. The most efficient and effective surveillance targets the high risk populations, i.e., cattle imported from Europe and U.S. cattle greater than 3 years of age which have been potentially exposed to feeds containing rendered ruminant protein. In terms of risks, the greatest remaining potential risk for animal or human exposure to BSE is cattle brain and spinal cord, the two tissues containing the highest infectivity in BSE affected cattle. Removal of brain and spinal cord from the raw material stream for rendering and from the human food supply would provide one additional safeguard against BSE. Continued education of animal producers, agribusiness and consumers represent a key component of the prevention program. The producer and consumer play an important role in managing risk. Finally, the U.S. lags behind Europe in diagnostic laboratory capabilities and research dollars directed toward BSE. Futhermore, the animal health infrastructure in the U.S. has eroded over the past two decades, reducing our potential for prevention, rapid detection and response.

CONCLUSION

The U.S. has implemented a series of prevention measures that have kept BSE out of the U.S. to date and created a series of safeguard to protect the American cattle herd and consumer if BSE should occur here. Surveillance, regulatory actions and voluntary initiatives taken by the U.S. Department of Agriculture, Food and Drug Administration, animal producers and agricultural industries have all contributed to this prevention effort to date. The future adequacy of the precautions taken by the U.S. must rely on the latest science available. As new risks are identified, the U.S. must respond quickly to strengthen the surveillance system, and if warranted, implement additional prevention measures. The conundrum of prevention is that, if it is successful, then people will ask why monies were spent on something that never occurred. On the other hand, if BSE occurs in the U.S., people will ask why more prevention measures were not taken. Given the insidious nature of this disease and its widespread ramifications for animal and human health, I would argue on the side of aggressive prevention. Protecting America's livestock populations is the first line of defense against BSE.

Senator FITZGERALD. Thank you very much, doctor, and we will take your full statement. That will be inserted into the record.

Senator Ensign, did you have an opening statement?

Senator ENSIGN. No, just questions.

Senator FITZGERALD. That is great.

Well, we will go right into questions. I was struck by the unanimity of opinion that we are doing a good job in the United States. A question arises, though, because a lot of Americans travel to Europe and clearly, as that map shows and all of you have testified, they have had a real problem in Europe, particularly Great Britain.

Would any of you care to weigh in on whether any precautions should be taken by American citizens traveling abroad as the summer months come upon us? Would any of you like to venture into that territory?

Dr. Torres.

Dr. TORRES. Mr. Chairman, the distinction needs to be made that BSE is not a contagious disease, meaning that people cannot catch it just from being in contact with the animals. There is a lot of confusion between foot and mouth disease right now and BSE.

Senator FITZGERALD. I think that is clear, but what about eating beef products in Great Britain while you are in Great Britain or anywhere in Europe this summer? My understanding, too, is that cruise ships in the Caribbean are advertising their meat as USDA-inspected.

Dr. Johnson.

Dr. JOHNSON. Certainly the amount of BSE in England has been cut back dramatically with the killing of herds. So at the present time the risk, small that it was before, is greatly diminished from that level.

I think that, to put it in perspective, food-borne disease, which we all worry about, is a big problem worldwide. We have 5,000 people a year in the United States die of food-borne illnesses. None of them are from TSE, none. So the danger of leafy green vegetables is greater. You can name a whole list of other foods, even potato salad, of which you might be more concerned than you would be about eating beef at this time, at least in my mind.

Senator FITZGERALD. Dr. Johnson, I have a question for you. You are very knowledgeable about prions. This is the first infectious disease that I have ever heard of that is not a bacteria or a virus. I guess it is a transmissible protein, and those were not discovered

until the 1970s, 1976. Somebody won a Nobel Prize, is that correct, for discovering prions?

Dr. JOHNSON. Two Nobel Prizes have been given in this area now. The person who really started the work back in the 1950s, Carlton Gajdusek, was in the intramural program at NIH, NINDS. He received the Nobel Prize for being the first to establish in humans the transmissibility of TSEs.

Then, more recently Stanley Prusiner, who is a recipient of NIH grants at the University of California, San Francisco, has gotten the Nobel Prize for the prion hypothesis and showing that the causative agent is associated with a human protein that is modified in its shape, not in its composition. So it looks like a post-translational modification. That is a very unique idea, and how that modified shape induces the modification of other proteins of that sort remains a mystery.

Senator FITZGERALD. Are there any other prions that manifest themselves in any kind of animal or human disease other than TSE?

Dr. JOHNSON. Well, by definition no, there are none.

Senator FITZGERALD. There are not.

Dr. JOHNSON. TSEs include all of them, and thus far all of them have shown this similar punched-out pathological change. Whether they are involved in some other kinds of diseases from different pathology, that has not been shown at all as yet.

Senator FITZGERALD. Let me ask Dr. Torres of the USDA. Although they are believed to be the most infectious part of a BSE-infected animal, I am told consumers can still buy brain and spinal cord tissue at the local grocery store. Should these sales be allowed to continue and is it possible that some of these products may have been imported into the United States and do not come from United States beef cattle?

Dr. TORRES. Since the ban has been in place, we are not importing animals or animal product from any BSE country. In addition to that, in 1997 we included countries that, although at the time did not have BSE, we felt that they were at high risk to having BSE, and so there is a number of countries from which we ban importation of those products. So if brain and spinal cord is available in the market, it would be from U.S.-origin animals and as far as we know that product is safe.

However, as mentioned by FDA, those are the risky materials that we need to continue to evaluate whether or not should be continued to be in the market or not. But at this point in time, there is no evidence that it would be an unsafe product.

Senator FITZGERALD. Apparently, in health food stores you can also buy brain supplements, some of which come from bovine sources. Would we be able to offer assurances that those do not come from any BSE-infected countries?

Dr. SUNDLOF. The answer to that is yes, that there is a prohibition, just as there is a prohibition on animal proteins coming into the U.S. from those countries that have BSE, and there is about 31 of those countries presently, there is also a ban currently, import alert, on any dietary supplements or raw bulk materials that contain animal protein from those 31 countries.

So if a product on a shelf in a U.S. grocery store contains bovine material, glandular material, spinal material, whatever, those firms are supposed to be operating in a manner such that they are not obtaining any of their source material from those 31 countries where BSE is present.

Senator FITZGERALD. Finally, some have been critical of regulations that allowed advanced meat recovery and mechanically separated product into processed meats. Could the public be eating brain or spinal cord tissue in processed meats? Are there risks to eating these neurological tissues?

Dr. Torres or Dr. Sundlof.

Dr. TORRES. Mr. Chairman, could I ask Dr. Linda Detwiler—she is our expert on these issues—to answer the question?

Senator FITZGERALD. Absolutely.

Dr. Linda Detwiler.

Dr. TORRES. Yes.

Senator FITZGERALD. Dr. Detwiler, thank you.

Dr. DETWILER. This actually comes under the jurisdiction of the Food Safety Inspection Service and there are currently directives for the advanced meat recovery process to remove spinal cord. Brain material does not go into that product, so that is removed in these processes.

Senator FITZGERALD. Thank you very much.

Dr. DETWILER. These too, the tissue in all these processes, is also being looked at in a risk assessment conducted by Harvard University, contracted by the Department of Agriculture.

Senator FITZGERALD. That report is due out shortly, as I understand; is that correct?

Dr. DETWILER. Right.

Senator FITZGERALD. Thank you, doctor.

Senator Dorgan, if you would like to ask some questions.

Senator DORGAN. Mr. Chairman, thank you very much.

First of all, I found the testimony from all four witnesses very interesting. Dr. Hueston, are you under contract with any of the Federal agencies?

Dr. HUESTON. No, sir, I am not.

Senator DORGAN. The reason I ask that question is, while I have great respect for the Federal agencies here, they obviously would want to come here and say, we are doing everything we can and doing a great job. Incidentally, I share that assessment, but that is what they would want to tell a Senate committee. You have a slightly different perspective, coming from perhaps a more independent side of this.

Again, the testimony from all four of you was interesting and I think very useful for us to have a better understanding of what the scientific community sees and how they assess this. But let me ask just a couple of other questions if I might.

I mentioned that we live in an increasingly global economy. Let me just tell you a quick story. I was on a dock in Seattle one day just trying to see what Customs and FDA and everybody is doing about our food supply. One of the containers that came off a container ship was opened and they had frozen broccoli from Poland. This was coming into our country to go into our marketplace, per-

haps to be served in a restaurant somewhere, because this was chopped broccoli frozen in large bags.

I asked: Does anybody here know the conditions under which this broccoli was produced? Anybody know the application of chemicals that might have been applied to this broccoli? No one had the foggiest idea the conditions under which that broccoli was produced.

In fact, it would only be serendipitous to have that particular container opened. Most of them would never be opened. They would come in and the bags would go to a restaurant somewhere.

The point I learned that day, as I have learned previous to that and since that time, that there is very little inspection done on all this food that comes back and forth across the border from all around the world. We have cattle coming in also, both live and slaughtered cattle from Canada and Mexico. We have in this country guidelines and requirements with respect to certification of the feed supply by American producers of cattle. Are we able to assure the same circumstances with respect to the cattle that are coming into this country from Canada and Mexico, as an example, that they are not being produced with a feed supply that would include prohibited materials that we want to keep out of the food chain? Can anyone respond to that?

Dr. TORRES. Senator, Canada has a feed ban similar to ours. Mexico does, too. Mexico implemented that more recently than Canada.

Senator DORGAN. Do you have any assurance at all that there is an enforcement of that ban, for example, in Mexico? I am well familiar with a lot of Mexican laws that read really well, but are not enforced at all. Just to use that as an example, do we have any conditions that would lead us to believe that it is enforced?

Dr. TORRES. I know it is enforced. I do not know the what level it is enforced, Senator.

Senator DORGAN. Well, I raise the question—Dr. Hueston, you wanted to respond?

Dr. HUESTON. Senator, I might interject that Canada suffered the unfortunate circumstance of having BSE in a cow that they imported from Great Britain. So they take this disease extremely seriously, and I have no doubt whatsoever that they have an aggressive enforcement and compliance in place.

Senator DORGAN. I only make the point that as this economy is increasingly global, now almost totally global in all respects, it makes our job even more difficult because we are not dealing just with an internal marketplace.

Dr. Sundlof.

Dr. SUNDLOF. Yes, thank you. Just an addendum to that statement is that we are inspecting several of the feed mills in Canada who we know are importing products into the United States. So our inspection authority goes outside of our borders and into Canada.

Senator DORGAN. Can I ask, Dr. Hueston, you made a comment in your testimony about the need for additional research and I believe implied at least the need for additional inspectors. If you are going to be vigilant about this, you have to have the resources at the front end. You know, we are going through this right now on the floor of the Senate on the debate about the budget. Some are

satisfied with the recommendations that are being produced, others are not.

For example, in agricultural research we see a proposed cutback in funding this coming year, which I will oppose and will join some others of my colleagues to try to, in fact, increase, rather than cut.

But were you responding to that sort of thing when you made your comment, Dr. Hueston?

Dr. HUESTON. I was, and I was also commenting about the level of support for agricultural research that is now in place in Europe, including the United Kingdom. I think we can learn a great lesson. They put a tremendous amount of resources to back up their compliance plans and to back up their prevention measures by doing research—discovery of additional diagnostic tests, determination, in fact, a study of the epidemiology of this disease and evaluation of alternative prevention measures.

Senator DORGAN. Are you saying we are short of resources to do that at the present time, in your opinion?

Dr. HUESTON. Yes, sir, I am.

Senator FITZGERALD. How would others of you respond to that allegation, recognizing that you are also in a delicate position speaking for your agencies on a larger issue? But I do think this really is a very important question. To provide the assurances that you have provided and will want to provide in the future, we also must have the resources to make sure that the research and the food inspections to assure a safe food supply are adequate.

Dr. Hueston suggests that that is not the case.

Dr. TORRES. Senator, in my previous life I used to be a university researcher dealing with animal health. As Dr. Hueston said, healthy livestock is an insurance of the safety of the food as well. The amount of money available to extramural research funding from USDA for universities is very, very meager. It is I think $12-$14 million, compared to the billion dollars that NIH has in extramural research programs.

Just an increase in that amount of money that could be allocated to universities for competitive grants on animal health will increase significantly the amount of knowledge and the expertise in this country for animal health in general.

Senator DORGAN. Thank you very much, Mr. Chairman.

Senator FITZGERALD. Thank you, Senator Dorgan.

Senator Ensign.

STATEMENT OF HON. JOHN ENSIGN,
U.S. SENATOR FROM NEVADA

Senator ENSIGN. Thank you, Mr. Chairman.

Let me just begin by stating that I am very proud of the veterinarians on the staff. It is obvious veterinarians can do a lot of good other than what people normally think that veterinarians do. So I am very proud of you on the panel here today.

I do have some questions relating to the transmission and the possible etiology. Obviously, we do not know what the exact etiology is. But when we are looking at possible transmission between the disease, when you were stating that you can really only diagnose this in older animals, yet we have it out there, it is endemic in these various countries, but yet it is not highly contagious.

So do we know the transmission routes? OK, we say it is from ingestion, but do we really know that, in that we cannot diagnose it until later in life, but yet most of the food products, especially with the zoonotic aspect of this is from eating younger animals. So is it transmissible, I guess, before the pathological signs are shown, or is it as soon as they are infected then those animals are then infectious? Or do we know that?

Dr. HUESTON. Senator Ensign, the infectivity is associated the specific tissues. Late in the course of the disease, you have the brain and the spinal cord that achieve the highest level of infectivity. Much earlier in the pathogenesis of the disease, you have infectivity identified in the lower GI tract, the distal ilium. It would appear from all the epidemiologic evidence that it is incorporation of this infective material in animal feeds or rendered animal products incorporating these materials that are the source of the exposure.

It turns out that the infective dose is very, very small. Less than 1 gram of infected brain material will cause a cow to develop the disease.

The other epidemiologic evidence you might find interesting is, if a farmer purchased an affected animal prior to its showing clinical disease and that animal developed clinical disease on the farm, as long as that farmer has never fed feeds containing this infected material the other cattle on the farm are at no additional risk.

Senator ENSIGN. Having said that, do we know, are peripheral nerves involved at all, or is it just central nervous?

Dr. HUESTON. The tests to date looking at peripheral nerves have detected no infectivity. The closest is that you have brain, spinal cord, and then you have some of the nerve bundles coming directly off of the spinal cord. You have the dorsal root ganglia and the trigeminal ganglia. But the work today of transmission studies looking at these nerves out in the rest of the body, none of those have proven or have demonstrated any infectivity.

Senator ENSIGN. It just seems to me, with the difficulty in transmission, it would seem to me to be a disease that you can rid a country of. Are the Europeans countries taking the steps necessary, and is that something that the United States needs to be involved in? There is always this big debate over foreign aid and to me foreign aid is especially appropriate when we have a vital U.S. American interest, and this is certainly a vital U.S. American interest involved.

How are we involved in helping the Europeans, or do they need our help?

Dr. SUNDLOF. Thank you, Senator Ensign. Well, I think you raise a very valid point and I think there is agreement that this is a disease that is subject to eradication because you can control it by controlling the animal feed.

I think that most people will agree that this is a disease which can be eradicated, which should be eradicated. Your question about what has happened in Europe that has led to the current situation—I just brought a quote with me that I thought was insightful and pertinent to this discussion. It is from David Byrne, the European Commissioner for Health and Consumer Protection. This was presented to the Commission Policy on Health Aspects of BSE in

Brussels in February of this year. He says—this is the person responsible, now, for managing the European situation. He says: "It disappoints me that every time the crisis takes a new turn the response is to immediately look to some magic solution or to some new measure which will impress the public. If the same effort was given to the implementation of measures already in place, I am convinced that the situation would be far less serious. Unfortunately, again and again the Commission has found that BSE is only taken seriously when the damage is already done. Left to account for past mistakes, the reaction is far too often to call for new measures, rather than to acknowledge past failures." I thought that was particularly insightful.

Senator ENSIGN. The reason I brought up that question was also because of scrapie as one of the TSEs that we have in this country and the difficulty in eradicating scrapie. Why have we not been able to eradicate scrapie in the United States?

Dr. TORRES. Senator, there are multiple factors. One is the diagnosis. In scrapie, like in other TSE diseases, we need to almost see the dead animal or clinically ill animal to be able to provide diagnosis. We do not have a reliable in vivo diagnostic test. We have now a new test being evaluated, but that test, it helps, but it is not the ultimate test to detect the animals early on in infection.

If I may make a comment about your previous question, one thing that we are going to see perhaps is an increase of BSE in less developed countries that imported a lot of the contaminated meat and bone meal from Europe unknowingly to them, and we are going to see a peak in a few years of a lot of less developed countries and those are going to need our aid.

Senator ENSIGN. Last, just real quickly because I want to make sure I get the question in, has to do with the importation of zoo animals. Do we have anything in place as far as trying to prevent some of these things from coming as far as zoo animals are concerned?

Dr. TORRES. The only zoo animals that we know were affected were those that received the contaminated feed in the United Kingdom. So there are provisions to be sure that animals that come in have not been fed contaminated—ruminant origin proteins in the countries affected.

Senator ENSIGN. Dr. Hueston, did you have a comment?

Dr. HUESTON. I was just going to add to the comment about scrapie and scrapie eradication. Another of the challenges, you will understand, is that there was insufficient money to carry out the programs regardless of how scientifically sound the programs have been in the past. In addition, I think there is an important point here that, unlike some of the earlier scrapie efforts, there has been a very strong collaboration in these current prevention actions for BSE between government agencies and between the potentially affected industries and the government agencies.

Senator ENSIGN. Do you think that is something, as far as the scrapie, the reason for the funding, because of the lack of zoonotic potential there?

Dr. HUESTON. I think that, too. A disease of sheep does not gain a whole lot of public attention or is not a very highly visible and attractive area for Congress to support in terms of funding.

Senator FITZGERALD. Thank you, Senator Ensign. It is good to have a veterinarian in the Senate. I guess we have two now, you and Senator Allard, and maybe you can be even more helpful in the future.

Senator Gordon Smith has joined us. I do not know if you have an opening statement or would like to ask any questions of this panel. We are going to have another panel shortly.

STATEMENT OF HON. GORDON SMITH,
U.S. SENATOR FROM OREGON

Senator SMITH. Thank you, Mr. Chairman. I do not have an opening statement. I came out of, frankly, an interest in the issue, but also wearing two hats, one as a Member of the Commerce Committee and your Subcommittee, but also as the Subcommittee Chairman on European Affairs in Foreign Relations.

I think my question is more one to elicit information for the general public, Americans who may want to travel to Europe, and concern that they may have about being infected by these issues, these diseases, or the possibility of their bringing them back to our shores. I wonder if, for the sake of our European friends, if you can speak to this issue as their relates to tourism, as it relates to other commerce that we have with Europe, so as not to unnecessarily alarm the American public or to unnecessarily disadvantage our European brothers and sisters who would like to see us over there this summer.

Any comments?

Senator FITZGERALD. Dr. Johnson, you kind of touched upon this earlier. Maybe you would want to reiterate what you said.

Dr. JOHNSON. I think there are two different issues. One is Britain, where there has been concern in the past and where the number of animals with the diseases has plummeted to very low levels now. It is obviously much safer now to eat beef in Britain, although I must say I have eaten beef in Britain throughout this thing. It is a personal taste.

In Europe, and in the other countries where there have been cases, there have been small numbers so far of cases and there have been no human cases except in France and Ireland, and those are trivial numbers.

The danger of driving to the airport is probably greater than the danger of eating meat in Europe, I would just on a relative risk basis put it at the present time. I would reassure your constituents to feel free to travel.

Senator SMITH. So if they want to go and hunt and fish and things like that, they are not going to be getting it on their shoes and bringing it back?

Dr. JOHNSON. That is a different disease, and they may not be able to hunt in England because of that, but that is another issue.

Senator SMITH. I understand that they are different, but I do not think the general public does. I think it is important to elucidate this for them, because I have heard comments, you know: Can I go and eat at McDonald's? Can I go golfing? Can I go fishing? Will there be farm soils that I bring on my shoes that will somehow be problematic for this country? Your answer is, no, it will not be?

Dr. JOHNSON. As far as BSE is concerned. The foot and mouth problem is a very different problem, with very different solutions.

Senator SMITH. Thank you, Mr. Chairman.

Senator FITZGERALD. Thank you to this panel. You have all been wonderful, very good expert testimony, and we appreciate all of your coming here today. Thank you very much.

We will move now quickly to the second panel. On the second panel we are going to have: Chuck Schroeder, who is the CEO of the National Cattlemen's Beef Association; Mr. James Hodges, President of the American Meat Institute Foundation; Mr. Richard Sellers, Vice President, Feed Control and Nutrition, at the American Feed Industry Association; and Ms. Caroline Smith DeWaal, Director of the Food Safety Program, the Center for Science in the Public Interest; and finally, Dr. Peter Lurie, the Deputy Director, Health Research Group, at Public Citizen.

All of you, thank you very much for coming. I will start with Mr. Schroeder. We anticipate that while you are testifying there is going to be a vote coming up, and when there is just a few minutes left for the vote I am going to temporarily adjourn this hearing, and then we will come right back as soon as the votes have been concluded, but there might be a temporary respite. We are going to go right up until we have a few minutes to get over to the floor to vote.

So, Mr. Schroeder, welcome and thank you for being here.

STATEMENT OF CHUCK SCHROEDER, CHIEF EXECUTIVE OFFICER, NATIONAL CATTLEMEN'S BEEF ASSOCIATION

Mr. SCHROEDER. Senator Fitzgerald, thank you and thanks to the Members of your Subcommittee for the opportunity to provide some testimony today on what is clearly one of the major challenges facing our industry.

I am Chuck Schroeder. I am Chief Executive Officer of the National Cattlemen's Beef Association. We are a producer-directed, consumer-oriented trade association representing America's cattle farmers and ranchers.

I hope that the testimony I provide today and that of my colleagues will help this body take actions that will ensure that American consumers continue to have the safest, most wholesome food supply in the world. I also hope that through the course of this hearing we can remind American consumers, as well as our producers and our consumers abroad, of three very important points about the BSE situation in this country:

No. 1, as has been pointed out by the previous panel, there has not been a confirmed case of BSE in this country, and that is no accident. We have taken important actions.

Second, the U.S. Government, with full cooperation from America's beef cattle industry, has taken and continues to take steps that are necessary to prevent the introduction of the agent that causes BSE to this country.

Third, it is important that the United States, with the support of the Congress, continue to set the world standard for research, for inspection, for surveillance, and for food safety monitoring systems that will instill confidence in our consumers, again both domestically and around the world.

Speaking of consumer confidence, it is important to note that a recent consumer survey which we had conducted indicates that consumer confidence in the safety of beef has actually increased, in spite of negative media coverage of BSE and other safety issues and the fact that 81 percent of American consumers have demonstrated that they have heard something about BSE in the last quarter. In spite of that, their confidence has increased.

Again, we believe that that current high consumer confidence in our beef system is not just an accident. It is the result of industry and government efforts to insist on science-based measures, science-based decisions to keep our industry free from the disease and to keep our consumers confident in the wholesomeness of our product.

Three important steps have been taken and they have been described in some depth by previous panelists, so I will just highlight them. But those three firewalls have been very key to protecting the U.S. beef industry and reassuring consumers that BSE is not present in the U.S., nor in the U.S. beef supply.

First is the ban of all imported products that could contain the BSE agent from all countries who have cases of BSE. You have heard that described in some detail.

The second firewall is the continued ban on the feeding of ruminant-derived feed products to ruminants. Again, you have heard the details of that.

Third, and an extremely important one, is an active BSE surveillance system that is targeted to animals over 30 months of age that have symptoms of neurological disorders. We have had that system in place since 1989, and since that program was put in place we have examined post-harvest more than 12,000 tissue samples from animals that have been analyzed, that showed some signs of potentially having the disease.

Despite that 10 years of surveillance, we have not had one confirmed case in this country. While we believe that surveillance system has been sound, NCBA does support USDA actions to double the number of animals that are undergoing testing in the surveillance system, to further reassure consumers that indeed the disease has not arrived in this country.

It is important to remember that, given the fact that the BSE agent is exclusively localized in brain and spinal cord, several years ago USDA and the processing industry took steps to ensure that those tissues do not inadvertently enter the human food supply, and we had a question on that here earlier.

It is important to note as well that this is a North American effort. We had some discussion about risks from our neighbors. Currently, Canada and Mexico have taken the same steps that the U.S. has to protect their industry from introduction of the agent and to prevent its spread should it ever be found in North America.

NCBA met with our counterparts, the CNG in Mexico and the Canadian Cattlemen's Association, at our recent convention the reaffirm, which we put out in a joint statement, our collective commitment to seeing that we are complying with the regulations that are in place and that we in North America are protecting our beef herds.

We would encourage Congress and Federal agencies to maintain their focus, as Dr. Hueston recommended earlier, maintain their focus on science-based decisionmaking. We would urge you to avoid policy changes that are proposed by those seeking to accomplish political objectives that simply do not support the science-based animal disease firewalls that we have in place. We ask that any decisions you make be based on the best available science and we have tried to support continuing discovery in these areas.

As referenced earlier, USDA has asked the Harvard Center for Risk Analysis to review what has been done and to assess the risk of BSE in this country. The preliminary findings of Dr. George Grey, who is the Center's Program Director for Food Safety in Agriculture, confirms our belief that indeed BSE is "not likely to occur here." Dr. Grey has stated that, "Although our work is not complete, what we have learned so far suggests that consumers have little to fear. In our judgment," he says, "the risk that mad cow disease could happen in the USA is low and the risk that it could spread as it did in Europe is lower still."

I would like to offer three recommendations to Congress, recommendations in three areas. First, in the area of regulatory enforcement, as Dr. Sundlof I believe stated, we would encourage you to remain focused on enforcing the regulations that we currently have. Congress should provide support for state departments of agriculture, for the Food and Drug Administration, and private industry to ensure 100 percent compliance with the FDA feed ban that again was discussed by the previous panel.

We also would request that Congress provide the resources that are required by USDA, the Food and Drug Administration, and Customs to enforce the fully regulatory framework that will keep our beef industry free of BSE.

Second, in the area of research, we are calling upon Congress—and Senator Dorgan, I appreciated your question earlier—we are calling upon Congress to commit to doubling funding for agricultural research to $2.4 billion annually over the next 5 years. We think it is critically important. This funding would include construction of a national animal disease center at Ames, Iowa, at a cost of approximately $400 million.

Third, in the area of discretionary funding, we certainly understand as we work around this town the many priorities and interests that are competing for limited resources. But to protect our industry from today's animal health concerns, we believe that we have to commit to providing the resources that are needed to protect livestock health.

Specific increases in funding we believe are needed for USDA's Animal and Plant Health Inspection Service, for the Agricultural Research Service, the Cooperative State Research, Education, and Extension Service, and the Food Safety Inspection Service.

The cattle producers and our colleagues across the industry—and you will hear from some of the rest of them here today—are absolutely committed to ensuring that the U.S. continues to remain free of BSE and that the safety and health of the U.S. beef industry is maintained. Further, we are always committed to protecting our consumers. If they are not buying our product, we are all out of business.

Mr. Chairman, I thank you for the opportunity to provide this testimony. I would be glad to answer questions as we get to that point.

[The prepared statement of Mr. Schroeder follows:]

PREPARED STATEMENT OF CHUCK SCHROEDER, CHIEF EXECUTIVE OFFICER, NATIONAL CATTLEMEN'S BEEF ASSOCIATION

I would like to thank the Chairman and members of this Subcommittee for the opportunity to testify today. My name is Chuck Schroeder and I am the Chief Executive Officer of the National Cattlemen's Beef Association. NCBA is a producer-directed and consumer-focused trade association representing America's cattle farmers and ranchers. I hope that my testimony today can help this body to take the appropriate action to ensure that American consumers continue to have the safest and most wholesome food supply in the world.

NCBA hopes that this hearing and others like it will help us clearly point out the facts regarding BSE to both our consumers around the world and our producers here in the United States:

- No cases of BSE have ever been identified in the U.S.
- The U.S. government, with full cooperation of the U.S. beef industry, continues to take actions to prevent the introduction of the agent that causes BSE.

The U.S. Government, at the request of beef producers and consumers, invests 100s of millions of dollars annually to prevent the introduction of foreign animal diseases such as BSE. The United States must continue to set the world standard for research, inspection, surveillance and food safety monitoring systems to instill confidence in our beef customers, both domestically and abroad.

BACKGROUND

NCBA has been involved in making sure that the U.S. continues to be free of Bovine Spongiform Encephalopathy (BSE) for a number of years. NCBA would first remind Senators that BSE has been and remains a foreign animal disease. American consumers have been bombarded with the scenes from the United Kingdom, almost on a daily basis in every form of media for months. While the U.S. needs to learn from the crisis in Europe, NCBA's focus continues to be on keeping the U.S. and North America free of BSE. We believe it is vital that U.S. consumers are assured that their beef supply continues to be safe and BSE free.

A recent consumer survey conducted on behalf of the beef industry indicates that consumer confidence in beef's safety has actually increased despite the fact that 81 percent of consumers have heard of BSE since the fourth quarter of 2000. The NCBA believes that current high consumer confidence in our beef system is not an accident. It is the result of industry and government efforts to insist on science-based measures and decisions to keep our industry free from disease and our consumers confident in the wholesomeness of our product.

The absence of BSE in this country is due to great and positive cooperation between the public and private sector. The American cattle industry and the U.S. government have been working together for more than a decade to keep BSE out of the United States and North America and keep it from spreading if it does appear. The U.S. has taken the following actions that are fully supported by all facets of the beef industry:

1. Import ban of all products that could contain the BSE agent from all countries with cases of BSE.
2. Ban on the feeding of ruminant derived feed products to ruminants.
3. Active BSE surveillance system targeted to the animals over 30 months and with symptoms of neurological disorders.

NCBA believes that as an industry and as a nation we can be proud of our success in keeping the U.S. cattle herd healthy and free of diseases like BSE and Foot and Mouth Disease. These three steps are keys to protecting the U.S. beef industry and reassuring consumers that BSE is not present in the U.S. or the U.S. beef supply.

IMPORT BAN

In 1989, the USDA banned the importation of all cattle and animal products that could carry the BSE agent from the United Kingdom. Cattle imported from the United Kingdom prior to this ban were traced and eliminated with the exception of 4 animals that are essentially pets. They will never enter the food supply.

In December 1997, the USDA banned the importation of all cattle and products that could possibly carry the BSE agent from all of Europe. All cattle imported from

Europe prior to this ban have been traced. None will enter the food supply and efforts are underway to purchase them and submit them to the BSE surveillance program. Since this ban was put into place, the U.S. has stopped the importation of many products including bone china, fish food, and supplements.

FEEDING BAN

In an effort to remain proactive and aggressive in our protection of the U.S. livestock industry, in 1996, NCBA asked the beef and dairy cattle sectors in the U.S. to stop feeding meat and bone meal to cattle derived from all ruminants, meaning cattle, sheep, goats, deer, elk, etc. Beef and dairy producers have worked hard to meet the challenge and have taken a number of steps to assure compliance within the industry. NCBA also asked the Food and Drug Administration to develop regulations in this regard. The FDA agreed with NCBA and new regulations went into effect on June 2, 1997. The U.S. was the first country to take this major step before there was any evidence of the disease. Since that time, virtually all other beef-producing countries in the world have followed suit.

This adds additional protection and ensures they do not represent a risk for use in other species. Meat and bone meal is a high quality product, not any different conceptually to giving your dog a steak bone. In this case it is processed to destroy all known bacteria, viruses or spores and transformed so animals can more readily utilize these valuable and much needed nutrients.

SURVEILLANCE

The United States has had an active BSE specific surveillance program since 1989. We have always had an aggressive surveillance program for neurological disease due to the threat of Rabies. Since the BSE surveillance program was instituted, more than 12,000 brain samples from animals old enough and with conditions that might share symptoms with BSE have been analyzed. It is important to note that these samples have been taken from cattle considered to be the highest risk of identifying BSE if it were present. Our surveillance program exceeds the international requirements set by the Office of International Epizootics, the international animal health organization linked to the World Trade Organization. Despite over 10 years of active government surveillance for the disease in the United States, not a single case of BSE—not one—has been found in the U.S.

From the beginning, the U.S. surveillance program has been ahead of its time. Starting in 1993, the diagnostic program began using an Immuno-Histo-Chemistry (IHC) method. This method is as sensitive as any system in use in the world today. It can pick up BSE more than 3 weeks prior to the animal showing any signs. All samples submitted are evaluated by both histology (how the brain looks under a microscope) and IHC.

The USDA has announced it will double the number of animals submitted to the surveillance program, a move we fully support. The current testing program gives us great confidence that we have successfully kept BSE out of the U.S. As a result of the steps taken to prevent BSE in the U.S., we are confident the animal protein by-products produced from U.S. cattle are BSE free.

ADDITIONAL INFORMATION ON BSE

The BSE agent has NEVER been identified in the U.S. or in beef. In March, the USDA held a comprehensive BSE research briefing in Beltsville, Maryland. Dr. Danny Mathews of the Veterinary Laboratory Agency in Weybridge, United Kingdom, discussed current research on the disease. It is important to note that they have reaffirmed that the ONLY tissues from cattle that carry the BSE agent are brain, spinal cord and part of the intestine. Blood from animals with BSE has NEVER been shown to carry the disease agent. Once again, they documented that beef itself NEVER carries the infectious agent, even from cows with full-blown BSE.

Given the fact the that BSE agent would exclusively be localized in the brain and spinal cord, several years ago the USDA and packing industry took steps to ensure these tissues do not inadvertently enter the human food supply. For this reason, the use of pneumatic, air-injection stunning devices has been discontinued in the U.S. and spinal cords must be completely removed in packing plants.

NCBA and the U.S. beef industry are focused on more than just keeping the U.S. BSE-free. We have joined with our Canadian and Mexican counterparts to develop a North American plan to keep BSE from our continent. Currently, Canada and Mexico have taken the same steps that the U.S. has to protect their industry from introduction of the agent and its spread should it ever be found.

SUGGESTED CONGRESSIONAL ACTION

The NCBA requests that Congress consider the following steps to continue the prevention and introduction of BSE into the U.S.:

SCIENCE-BASED DECISION-MAKING

We ask that any decisions you make be based on science. NCBA asks that you avoid decisions based on rumor and rhetoric spread by those more interested in stopping the consumption of beef and meat products than protecting the rights and needs of consumers. NCBA also urges you to avoid policy changes proposed by those seeking to accomplish political objectives that do not support the science-based animal disease firewall but would prevent the U.S. producer from operating in a global market.

REGULATORY ENFORCEMENT

We must remain focused on enforcing the regulations we currently have. If we continue to do so, we will remain BSE free and our beef, dairy cattle, and consumers will be protected. Congress should provide support for state departments of agriculture, FDA and private industry to ensure 100 percent compliance with the FDA feed ban. Private industry and state partnerships with the FDA play a significant role in ensuring compliance. We know how to prevent BSE in the United States. To date, we have accomplished this important task and the U.S. remains free of BSE.

NCBA has asked that USDA, FDA and Customs officials continue to monitor their own actions and programs to look for ways to improve the firewall that protects U.S. livestock producers and keeps the U.S. free of the diseases of immediate concern. We request that Congress provide the resources needed by USDA, FDA and Customs to enforce the regulations that will keep our beef industry free of BSE.

RESEARCH FUNDING

The NCBA calls upon Congress to commit to doubling funding for agricultural research to $2.4 billion annually over the next 5 years. This funding would include construction of a National Animal Disease Center at Ames, Iowa at a cost of $350 million. This facility could help provide important diagnostic, monitoring, and surveillance for diseases that could infect the national livestock herd. The cost of this facility may seem high, but it would provide long-term benefits for agriculture, particularly in light of the Foreign Animal Diseases that exist around the world.

IMPLEMENT IMPROVEMENTS SUGGESTED BY HARVARD BSE RISK ASSESSMENT

USDA asked the Harvard Center for Risk Analysis to review what has been done and to assess the risk of BSE in this country. The preliminary finding of Dr. George Gray, the center's program director for food safety and agriculture confirms our belief. BSE is "not likely to occur here", according to Dr. Gray in a preliminary finding. Gray further stated that "Although our work is not complete, what we have learned so far suggest that consumers have little to fear. In our judgment, the risk that mad cow disease could happen in the USA is low, and the risk that it could spread as it did in Europe is lower still." The preliminary report from Harvard would further indicate that even if an infected animal shows up in this country, the safeguards in place would keep that animal from reaching the human food chain.

NCBA is confident that the final version of the Harvard Center for Risk Analysis, due out in the coming days, will be supportive of the systems for surveillance and testing already in place. We must take the steps needed to ensure that we will be ready in the future. A failure to prepare for future challenges will leave us in a precarious and unpredictable condition during some future challenge.

DISCRETIONARY SPENDING

The NCBA understands that there are many priorities and many interests competing for limited resources. We are hopeful that NCBA and current events have demonstrated the need for significant spending on the discretionary side. We are also optimistic that you can support these programs to the greatest degree possible given the allocation and budget constraints with which you must comply. To protect our industry from BSE, FMD and other diseases, the NCBA believes that we must commit to providing the resources needed to protect our livestock health.

Specific increases in funding will be needed for USDA's Animal Plant Health Inspection Service, Agriculture Research Service, Cooperative State Research Education and Extension Service, and Food Safety Inspection Service. Additionally,

other areas in USDA and FDA will have new and additional needs that must be addressed to provide for any measures that may be required in the future. In recent years the United States has followed the EU model of supporting agriculture with increased levels of funding for commodity programs at the expense of many of the systems that provide support for our firewall against foreign animal disease. New losses in funding in these critical areas would undermine our ability to protect our consumers, our producers and the livestock of the United States.

CONCLUSION

The NCBA appreciates the opportunity to visit with you today. More information about BSE can be found at our peer-reviewed site *http://www.bseinfo.org*. BSE has been of concern to the U.S. beef industry since it was first identified in the UK in 1986. NCBA has supported the actions that the U.S. government has taken to protect the U.S. beef industry and U.S. consumers from BSE. BSE has not ever been identified in North America and we will continue to take steps to ensure that it does not occur. We will pay careful attention to the results and recommendations in the Harvard BSE Risk Assessment. NCBA looks forward to working with Congress, the Administration, BSE experts and our partners in the beef industry to make sure that all scientifically justified measures that need to be taken, are taken. The NCBA is committed to ensuring that the U.S. continues to remain free of BSE and that the safety and health of the U.S. beef industry and our consumers is protected.

Senator FITZGERALD. Thank you, Mr. Schroeder.

We are going to go adjourn now temporarily for a vote, and I think there is a second vote right after that. We will try and rush back quickly, and then, Dr. Lurie, we will open up with you after the break.

[Recess from 11:02 a.m. to 11:57 a.m.]

Senator FITZGERALD. Thank you all very much for your patience. That was a long roll call, and we are pleased the resume the Subcommittee hearing.

Dr. Lurie, you are next. So please give us your testimony. Thank you for being here.

STATEMENT OF PETER LURIE, M.D., MPH,
DIRECTOR, HEALTH RESEARCH GROUP, PUBLIC CITIZEN

Dr. LURIE. Thank you for having me. I am Deputy Director of Public Citizen's Health Research Group and also a member of FDA's TSE Advisory Committee.

The theme of my testimony is that, even though we heard much about the safeguards that USDA, FDA, and so forth have in place, there are, in fact, a number of holes in these safeguards that need to be plugged, for in these safeguards there are a number of exemptions, there is clear evidence that enforcement is often poor, and in many cases, although not clearly stated today by the agencies, compliance is, in fact, voluntary, and that is especially true for FDA.

On the last page of my testimony, we have listed 17 concrete actions that we think the government could take that would reduce the risk of transmission of BSE to cattle or vCJD to humans, and I urge you to look at those closely.

The first question that I will address is how the BSE agent could actually enter the country. We heard somewhat about the Customs inspectors and what is being done at the borders. What was not said is that the current Administration has proposed an overall 7 percent cut in the USDA budget and no increase whatsoever in the APHIS budget, even though they now are expanding the testing of downer cows and they have to look at the increasing problem of foot and mouth disease.

I think that you really cannot adequately police the borders if the demands are increasing, yet the budget remains the same.

We are very worried about dietary supplements as a way of the BSE agent entering the country. In 1994, the government, unwisely in our view, effectively deregulated the dietary supplement industry through the Dietary Supplement Health and Education Act, called DSHEA. It is literally possible, despite the assertions of FDA, if one were an unscrupulous manufacturer to source material for a dietary supplement, which often includes such delectable materials as pineal, brain, pituitary, you could literally source that from a BSE country, dry it out, crush it up, put it in a pill, and then import it into the United States.

Yes, there is an import alert, but the FDA only inspects about 1 percent of all materials that enter the country and the import alert is, in fact, voluntary. So we are not in the least bit reassured by the statements of FDA this morning.

Now, if the BSE agent actually entered the country, how might it spread? Well, the first place would be through feeding practices. As you know, there is a mammal-to-ruminant feeding ban, but we know from FDA inspections that commingling of the food that is allowed to be fed to cows and that which cannot be fed to cows is, in fact, not only possible, but, in fact, has happened. The most recent reports from the FDA show that 14 percent of renderers and 13 percent of FDA-licensed feeding mills do not have adequate procedures to prevent mammalian parts from being recycled and entered into the ruminant feed chain.

This is what has resulted in the need for the slaughter of 1222 cows in Texas after exactly that kind of commingling happened. It is precisely that kind of commingling that led to the great expansion in the BSE epidemic in Britain. We need to cut it off at the pass.

But the problem is that 23 percent of renderers and 63 percent of FDA-licensed feed mills still have not been inspected for compliance by the FDA and there are another 6,000 to 8,000 feed mills that do not even have to register with the FDA. So it is fine and well to have a ban, but it does not do much good if inspection rates are low and compliance is not all it should be.

There are also exemptions, as I mentioned earlier, to the feed ban. One of them is on so-called plate waste, which is leftover food that has been prepared and/or served to humans, and that is collected by that industry and can, in fact, be fed to ruminants. The European Union, Canada, and Mexico do not permit such practices and neither should we.

Chronic wasting disease is a disease not shown so far to be spread to humans, but it is true is that if you had a herd which has a positive animal based on looking at the animal's brain, sure, that animal would not enter the food supply, but the remaining animals could, in fact, enter the food supply. One of the reasons for that is because there is no ability to compensate the farmers for their herds.

So, I think that the Congress needs to take action or else regulatory action will be necessary that would exclude any animal from a chronic wasting disease—CWD (Chronic Wasting Diesase)-affected herd from entering the food chain.

Now, the second issue is meat processing and I think that Ms. DeWaal will talk about this in perhaps more detail, so I will just mention a couple of things. One are pneumatic stunning devices, which are used at least in some parts of the industry. These devices stun the animal, in part by injecting compressed air into the brain. This has been shown to spread neurological tissue to various parts of the animal.

These devices have been banned for use with cattle in Europe and they ought to be banned here as well. Moreover, European countries require that the brain and spinal cord be removed early in the slaughtering process, but in this country there is very little regulation of the slaughtering process and practices vary widely across the country. So I think that we need a regulation that would require removal of the brain and spinal cord early on in the slaughtering process.

Ms. DeWaal will talk about advanced meat recovery, so I shall not get into it in detail, except to say that it is literally possible through either of these processes to include parts of the spinal cord in material that might end up in the food chain, including in ground beef. Although it is stated that advanced meat recovery, one of these two processes, does not include spinal cord, in fact, documents obtained by the Government Accountability Project from the USDA in 1997 showed that 4 of 34 advanced meat recovery samples that were sent to a laboratory for suspicion of containing spinal cord, in fact, did contain spinal cord.

The USDA began a rulemaking 3 years ago to clarify the rules on advanced meat recovery so that this kind of contamination of advanced meat recovery product would not happen, but 3 years later they still have not been finalized.

Is the U.S. doing enough to detect the disease? I think that up to now the answer is no, but I think that there is an effort now to expand particularly testing of the downer cow population and I think that that is a reasonable step and should be supported, not only in general, but with funds.

Surveillance for human and new variant CJD is coordinated through the CDC and a group of pathologists up at Case Western Reserve University. However, they only see about 39 percent of the brains of patients with CJD, whereas in Germany and Britain essentially all of the patients with CJD have their brains examined by a pathologist. Canada has also improved its system lately, but we are trailing far behind.

Part of the problem is that autopsy rates have been falling dramatically in this country ever since World War II, when the autopsy rate was about 40 percent. It is down to under 10 percent at present and not all of those have brain specimens taken. One reason is that hospitals and families wind up bearing the cost of autopsies, and obviously, that reduces the probability that autopsy will actually happen.

Finally, are there medical practices that might transmit BSE and vCJD? The TSE Advisory Committee on which I sit recommended a ban on blood donations from any donor that had spent a cumulative total of 6 months in Britain between 1980 and 1996. I think that was a good plan. Earlier this year when new cases of vCJD and BSE started to show up in Britain and in Europe, we extended

this recommendation to include France, Portugal, and Ireland, although with a longer cumulative residence requirement because the number of cases in those countries is much lower than in Britain.

The FDA needs to adopt that committee recommendation. It is now 2 months since the recommendation, and I just think we need to make sure that gets adopted.

I think there should be similar travel restrictions placed on cadaveric cornea donors because there have, in fact, been—depending on how you count them—as many as three cases of CJD that have been transmitted through cornea donation. So I think we need to worry with regard to that, and travel restrictions similar to those for blood donors need to be in place. The U.S. is a net exporter of corneas, so I do not think we need to worry about creating any kind of shortage from a doner fund restriction.

I want to close off by talking about the debacle of vaccines. The story as told this morning focused on the low risk of vaccines with regard to variant CJD for the American population and I think that that is actually true. But there is an untold story here and this is it. Back in 1993, the FDA wrote to the manufacturers of FDA-regulated products and in a voluntary guidance asked the manufacturers to no longer source their materials from BSE affected countries. It repeated that admonition in 1996.

But six manufacturers who produced eight vaccines at a minimum decided not to follow that guidance. They did not need to follow the guidance because it was a guidance and not a regulation. They went ahead and made eight vaccines and millions of doses were injected into Americans, including into small children.

Again, I do not think that the risk of vCJD was high, but there are two lessons from this. Lesson one, if the government has a chance to take action it should do so by regulation, not by voluntary guidance. Second, if we leave the industry with the ability to exploit voluntary guidances by simply ignoring them, in some cases the industry will step in and do just that, and then we wind up with the vaccine situation.

So the lesson of the vaccine debacle applies more broadly to our efforts to reduce the risks of BSE and vCJD in this country. For the public to be protected, the government needs to take forceful action. We need to have bans that have fewer exemptions. We need bans that are truly bans and are not often voluntary, and we need to make sure that the better of the existing bans are adequately enforced.

Thank you.

[The prepared statement of Dr. Lurie follows:]

PREPARED STATEMENT OF PETER LURIE, M.D., MPH, DIRECTOR, HEALTH RESEARCH GROUP, PUBLIC CITIZEN

While the U.S., to the best of our knowledge, remains free of both Bovine Spongiform Encephalopathy (BSE), otherwise known as "Mad Cow Disease," as well as its human counterpart, variant Creutzfeldt-Jacob Disease (vCJD), the experiences of European countries that grew complacent and now are suffering from epidemics of BSE and, in some cases, vCJD should make us more vigilant than we are at present. The agent that causes BSE has often found a way to pierce small chinks in the public health armor. For this reason, it is critical not only to maintain our defenses but also to strengthen them in the several areas I will highlight in this testimony.

I will address four areas: 1. How the agent that causes BSE might enter the country; 2. How the agent, if it entered the country or arose spontaneously within the country, could spread; 3. Whether the U.S. is doing enough testing to detect the disease; and 4. Whether there are medical practices that might spread the disease.

HOW COULD THE BSE AGENT ENTER THE COUNTRY?

We have serious concerns about the ability of customs inspectors to adequately police the borders. With the dramatic increase in global trade, the workload of these inspectors is only likely to grow. Transhipments between countries can make determining the origin of meat and bone meal quite difficult. This is, of course, an issue that extends well beyond BSE to encompass broader issues of food safety.

An issue of particular concern is that of dietary supplements. In 1994, the government, unwisely, essentially deregulated the dietary supplement industry. Whereas, prior to the Dietary Supplement, Health and Education Act (DSHEA), the industry had the burden of demonstrating the safety of its products, now the Food and Drug Administration (FDA) must demonstrate that a particular dietary supplement is unsafe before it can take action. Moreover, this now-$14 billion industry is not required to prove the efficacy of its products and the FDA has still failed to issue Good Manufacturing Practice (GMP) regulations for dietary supplements 4 years after the agency commenced rulemaking on this issue and 7 years after DSHEA. Manufacturers are not required to register with the FDA and the agency only inspects approximately 1 percent of imported items subject to its jurisdiction, a fraction that may be still lower for dietary supplements. The agency has issued an Import Alert for materials sourced from BSE countries, but compliance is voluntary.

For BSE, this means that an unscrupulous manufacturer could literally take a British cow brain, crush it, dry it out, formulate it into a dietary supplement and export it to the U.S. Indeed, a letter by Dr. Scott Norton in the *New England Journal of Medicine* mentions a product available in the U.S. with 17 cow organs including brain, pituitary, and pineal gland. Due to DSHEA, the FDA is limited in what it can do. Instead of claiming that its regulatory authority over dietary supplements is adequate, as it often does publicly, the agency should be coming back to the Congress to undo the damage done by DSHEA. The best option would be to simply repeal DSHEA. In the alternative, we recommend a variety of improvements, including a mandatory adverse event reporting requirement for all dietary supplement manufacturers, mandatory risk warnings, requirements for company and product registration, and identification of the raw ingredients and the source (by country) for each of the ingredients in each product. This is, of course, a problem that goes well beyond the risk of vCJD; over 100 people have been killed by ephedra, and the agency seems essentially powerless to act. Releasing the GMP regulations for dietary supplements is necessary, but will not suffice to adequately protect American consumers from vCJD that might be caused by these products.

IF THE BSE AGENT ENTERED THE COUNTRY, HOW MIGHT IT SPREAD?

A. Feeding Practices

Since 1997, the FDA has had a ban on the feeding of mammalian parts to ruminants (e.g., cows, goats, sheep), the main route by which the BSE epidemic occurred in Britain and would be amplified in the U.S. This ban requires that manufacturers take action to prevent the commingling of two types of feed: those intended for ruminants, and those intended for non-ruminants (e.g., pigs, fish, chickens which can be fed material from mammals).

FDA inspections to date provide evidence that this commingling is possible. The March 2001 FDA inspection report findings (*http://www.fda.gov/cvm/index/updates/bsemar3.htm*), while improved from the January 2001 findings, still shows that 14 percent of renderers and 13 percent of FDA-licensed feed mills do not have adequate procedures to prevent mammalian parts from entering ruminant feed: i.e., cows could still be recycled and fed to other cows. (This is precisely what happened in the Purina Mills plant in Texas in which, purely through the voluntary admission of the company, the FDA learned that cow parts had entered cow feed. One-thousand, two-hundred and twenty-two cows had to be removed from the food chain.) Moreover, 23 percent of renderers and 63 percent of FDA-licensed feed mills have still not been inspected for compliance with the feed restrictions and some 6,000 to 8,000 feed mills are not even required to register with the FDA. Of the 1,829 non-FDA licensed feed mills that handle material prohibited from use in ruminant feed, 18 percent do not have adequate procedures to prevent the recycling of mammalian parts as feed for ruminants. If the industry does not come into better compliance with the mammal-to-ruminant ban, the FDA should consider whether a mammal-to-mammal ban is justified.

In addition, the FDA feed ban contains an exemption that should be ended. Despite U.S. Department of Agriculture (USDA) objections, the FDA permits the feeding of so-called plate waste (leftover food that has been prepared and/or served to humans) in feed for ruminants. The European Union, Canada and Mexico have banned such practices and so should we.

Finally, there is the issue of Chronic Wasting Disease (CWD), a Transmissible Spongiform Encephalopathy (TSE) of wild and captive elk and deer. While there exists no evidence that humans have become infected from eating deer or elk, current USDA procedures permit deer and elk from a herd with a proven case of CWD to enter the food chain. The problem is that deer and elk are exempt from the USDA's Meat Inspection Act, under which the packer has the burden of demonstrating the safety of his or her product. Instead, deer and elk would have to be restricted under the FDA's Food, Drug and Cosmetic Act, which places the burden upon the agency to demonstrate potential harm and provides no funds to compensate farmers if their herd is seized. This creates an incentive for farmers not to be forthcoming about CWD in their herds. This could be addressed either by a specific regulation excluding CWD-affected herds from the food chain and providing for compensation for the rancher or by bringing deer and elk under the Meat Inspection Act, which does provide for compensation.

B. Meat Processing

The processes of slaughtering and processing are not, by their nature, extremely precise ones. Infectious material from the most infectious parts of the cow, the brain and spinal cord, may spread to other parts of the animal. Pneumatic stunning devices, which stun the animal prior to slaughter by injecting a bolt and compressed air into the head, have been shown to spread potentially infectious brain tissue to other parts of the body. Although the industry appears to be reducing its use of pneumatic stunning devices, this should be given the force of Federal regulation and banned. These devices are now banned for use in cattle in Europe.

European countries require that the brain and spinal cord be removed early in the slaughtering process. However, in the United States, processes vary widely and are not effectively regulated. We therefore support a regulation that would require the removal of the brain and spinal cord before further processing, since these organs contain the highest levels of infectious material.

Two other meat processing methods have also come under scrutiny. In one, mechanically separated product (MSP), bones with attached muscle are crushed and pushed through an extruder to create a paste. Bone fragments are removed by a sieve-like mechanism. Both spinal cord and dorsal root ganglia (nerve tissue next to the vertebrae), which have demonstrable BSE infectivity, can enter MSP. In the other processing method, advanced meat recovery (AMR), muscle fragments are also removed from bone; this material can become part of ground beef. Early AMR machines used a belt to shave meat off bones, but later AMR machines use a "bone press" that differs from MSP only in degree. While MSP inherently involves the crushing of bones and is thus more likely to introduce nerve tissue into the product than AMR, 1997 USDA inspection records obtained by the Government Accountability Project through the Freedom of Information Act clearly demonstrate that spinal cord can be part of the material generated by AMR. Four of 34 AMR samples sent by USDA inspectors to a USDA laboratory because they were suspected of containing spinal cord tissue turned out to actually contain central nervous system tissue. It is possible that AMR machines could be redesigned to minimize the probability of crushing bones and thus including spinal cord. The USDA began such a rulemaking procedure 3 years ago, but the rule has still not been finalized. To prevent vCJD, we therefore support a ban on the production of MSP from vertebrae and the issuance of a final rule for better-designed AMR processes that would prevent the inclusion of spinal cord.

IS THE U.S. DOING ENOUGH TESTING TO DETECT THE DISEASE?

To date, the U.S. surveillance efforts for BSE have been quite inadequate. Only 11,954 cow brains had been examined by the USDA in the 10-year span ending in 2000. (Some 40 million cattle are slaughtered annually in the U.S.) By comparison, France, a country which, importantly, has a proven BSE epidemic, is now testing about 20,000 brains per week.

Under current USDA procedures, all cows with neurological symptoms are supposed to be tested for BSE and, regardless of the result, excluded from the food chain. Cows that are unable to ambulate, so-called downer cows, are only occasionally tested. The USDA did not begin testing downer cows until 1993 but has now increased such testing to about 1,900 in 2000 (*http://www.aphis.usda.gov/oa/bse/bsesurvey.html*).

This represents about 1 percent of all downer cows brought to slaughter in the U.S. The USDA has promised to increase such testing to 5,000 per year in 2001, a move we fully support. Testing of healthy cows does not seem justified in the U.S. at present as the prevalence of disease would almost certainly be lower than in downer cows or those with neurological symptoms. Moreover, even in countries with clear BSE epidemics, BSE-positive normal animals have only been detected extremely rarely if ever, even as the disease is detected in downer cows and those with neurological symptoms.

Testing for the presence of BSE in cow brain can be very time-consuming. However, while three rapid tests for BSE are on the market in Europe, none are on the market in the U.S. It is imperative that these tests be evaluated by the FDA and that test performance characteristics be made public.

Surveillance for human CJD and vCJD is coordinated through the Centers for Disease Control and the National Prion Disease Pathology Surveillance Center at Case Western Reserve University. The Center has examined the brains of about 300 patients with CJD in the past 4 years. This represents an estimated 39 percent of patients with CJD in 2000, whereas in Germany and Britain the brains of almost all patients with CJD are examined by pathologists. Canada has recently revamped its surveillance system and provides much more funding for such efforts than does the U.S.

The U.S. Government also needs to do more to increase the overall hospital autopsy rate in this country, which has declined from over 40 percent after World War II to under 10 percent at present, as well as to increase the rate of examination of brain material specifically. Currently, hospitals and families bear the costs of autopsies, including transportation costs; they should be reimbursed for these costs. The government should also consider creating a network of regional pathology centers to do brain examinations for CJD and needs to do more to contact all neurologists to inform them of the current surveillance system.

ARE THERE MEDICAL PRACTICES THAT MIGHT TRANSMIT BSE AND VCJD?

In weighing whether products that are transfused or transplanted into humans should be restricted, the essential questions are: 1. What is the probability of transmission of infection?; 2. Are their suitable alternatives to the material?; and 3. Would the restriction of the material produce a shortage of a vital medical product?

While there has never been a documented case of CJD or vCJD transmitted by blood transfusion, the agent is present in white blood cells (inevitably present to some extent in even red blood cell transfusions) and, in an experiment, a sheep was recently infected by transfusion from a cow with BSE. In 1999, the FDA's TSE Advisory Committee recommended a ban on blood donations from potential donors who had spent more than a total of 6 months in Britain between 1980 and 1996. The Committee determined that the impact on the blood supply would be manageable and data collected since the restriction on British donors confirm that the supply of blood remained stable after the ban was enacted. In January 2001, with cases of vCJD in France and of BSE in Europe mounting, the Committee extended this recommendation to include France, Portugal and Ireland, although with a 10-year cumulative residency requirement, since BSE and vCJD case rates are lower in those countries than in Britain. The FDA should adopt the Committee's recommendation.

Similar travel restrictions should be placed on cadaveric cornea donors, especially because as many as three cases of CJD due to corneal transplantation have been documented. Due to the existing shortages of other transplantable organs such as heart and bone marrow, and the failure to document CJD transmission associated with their transplantation, a travel restriction on such organ donors is not justified. On the other hand, because the U.S. is a net exporter of cornea, we are not concerned that there would be a shortage of cornea were a travel restriction to be implemented.

Finally, there is the issue of vaccines. In 1993, the FDA wrote to the manufacturers of FDA-regulated products and in a voluntary Guidance instructed manufacturers to no longer source materials for their products from BSE-affected countries. It repeated the admonition in 1996. Nonetheless, at least six manufacturers simply ignored the Guidance, which does not have the force of a regulation, and continued to source bovine materials for the production of vaccines from BSE-affected countries. The FDA only learnt that its recommendation had been disregarded in early 2000. By then, millions of doses of vaccines such as polio and diphtheria, tetanus, and pertussis (DTP) were injected into Americans, including small children. At a TSE Advisory Committee meeting in July 2000, Committee members agreed that the risk of disease transmission through these vaccines is extremely small and that

there is no evidence that vCJD has been spread through this route. Nonetheless, this event was a reminder of the dangers presented by agencies that fail to regulate and industries that act in arrogant disregard of the government.

The lesson of the vaccine debacle applies more broadly to our efforts to reduce the risks of BSE and vCJD: for the public to be adequately protected, government will have to take forceful action—regulations, not guidelines—and not simply depend upon voluntary actions by industry.

SUMMARY OF ACTIONS NECESSARY TO REDUCE THE RISK OF BSE AND VCJD IN THE U.S.

- Increase inspection capacity at the borders.
- Repeal the Dietary Supplement Health and Education Act.
- As an alternative to repeal, pass legislation that would require mandatory adverse event reporting for all dietary supplement manufacturers, mandatory risk warnings, company and product registration, and identification of the raw ingredients and the source (by country) for each of the ingredients.
- Release Good Manufacturing Practice regulations for dietary supplements.
- Enforce compliance with the mammal-to-ruminant feeding ban.
- Remove the plate waste exemption from the feeding ban.
- Assure that CWD-affected deer and elk herds do not enter the food chain.
- Provide compensation for ranchers with CWD-affected deer and elk herds.
- Ban pneumatic stunning devices.
- Remove brain and spinal cord from slaughtered cows before further processing.
- Ban mechanically separated product produced from vertebrae.
- Issue regulations on advanced meat recovery to preclude the introduction of spinal cord.
- Continue to expand testing of downer cows.
- Expand the current CJD and vCJD surveillance system and notify neurologists of its existence.
- Adopt the FDA's TSE Advisory Committee's recommendation restricting blood donations from those with extensive histories of residence in France, Portugal and Ireland.
- Create travel restrictions for cornea donors similar to those for blood donors.
- Promulgate regulations preventing the sourcing of materials for the production of vaccines from BSE-affected countries.

Senator FITZGERALD. Thank you very much, doctor.

Mr. Hodges, you are next.

STATEMENT OF JAMES H. HODGES, PRESIDENT, AMERICAN MEAT INSTITUTE FOUNDATION

Mr. HODGES. Thank you, Mr. Chairman. I represent the American Meat Institute, the nation's oldest and largest meatpacking and processing association. I speak to you today as a meat scientist with 30 years experience in the meatpacking and supermarket industries, as well as having some time at USDA's Food Safety and Inspection Service.

Never in my career have I seen so much public concern over an animal disease as I have seen over BSE. Given our nation's phenomenal history of animal disease control, it is perplexing and disappointing to see attention being focused on what we are doing wrong instead of what we are doing right.

I have three messages to leave with you today. First, we do not have BSE in this country. Second, we have taken prudent steps to prevent BSE from entering this country. Third, if, heaven forbid, BSE were ever to find its way into this country, we can diagnose it, isolate it, contain it, and prevent it from reaching consumers in a swift and decisive way.

Our risk of BSE in domestic cattle is not zero, nor can it ever be. But our risks are lower today than at any time since the disease was determined to be a potential threat to our domestic cattle population.

Let me focus for a moment on my first message. We have no evidence that BSE exists in this country. That fact bears repeating over and over because it has been largely lost in some hysterical and speculative news reporting. The British and now the European situation has provided strong incentive for the U.S. Government and the U.S. beef industry to take aggressive actions to prevent this devastating animal disease in the U.S. herds.

In fact, we took action so early that some people now seem to question why we are not announcing major new efforts today. The answer: We took swift, science-based actions early on that have protected our livestock and given us the coveted distinction of being a BSE-free nation. The U.S. approach to BSE prevention can best be described, as it has been earlier, as a triple firewall strategy.

Because BSE is not present in the U.S. herds, the first critical firewall in protecting U.S. cattle involves protecting U.S. borders. As early as 1989, USDA banned the importation of cattle and most beef products from countries with BSE.

The second critical firewall involves careful surveillance. Veterinarians are present at every U.S. meatpacking plant and check cattle for signs of any disease, including BSE. No animal can be processed from meat without inspection. Additionally, USDA routinely conducts laboratory tests for BSE in animals most likely to exhibit the disease.

For a country in which BSE has never been detected in the native cattle population, the U.S. has one of the most statistically sound and comprehensive surveillance programs in the world. Of the roughly 1200 animals tested for BSE thus far, as you have heard earlier, none have been positive.

The third critical firewall involves controlling what cattle are fed. Evidence indicates that BSE may have been spread in the U.K. and Europe by contaminated feed. Even though we have no evidence that BSE exists in the U.S. cattle population, the feeding of any protein derived from ruminant animals to cattle is prohibited. In fact, there is a growing trend within the beef industry to require certification from producers that cattle have met all requirements with respect to complying with FDA regulations. AMI has provided its members with model certification language and we understand that it is beginning to be utilized widely.

Taken together, all of these efforts provide the best reasonable assurance that U.S. cattle will remain BSE-free and that U.S. consumers will not be exposed to any related health risk. That is not to say that we should rest on our laurels. We must continually evaluate and improve our preventative control measures if they are warranted and we must assure our regulatory agencies are provided the necessary resources to do their job.

It is important to remember that BSE has been diagnosed only in livestock of European origin. The U.S. is a long way from Europe. Our livestock populations are very different, as are many of our rendering, feeding, and production practices. In addition, Europe is in the midst of a crisis. Crisis warrants strong and dramatic action. In contrast, we do not have a crisis in the U.S. It is critical that our BSE prevention policies reflect that fact.

While our media have begun to mirror British tabloid coverage of BSE, our cattle herds are and will remain very different from

those in the U.K. and Europe. Our policies must reflect these differences and be supported by the best available science, lest we head down the slippery slope of creating our own hysteria.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Hodges follows:]

PREPARED STATEMENT OF JAMES H. HODGES, PRESIDENT, AMERICAN MEAT INSTITUTE FOUNDATION

Good morning, Chairman Fitzgerald and members of this subcommittee. I represent the American Meat Institute, the nation's oldest and largest meatpacking and processing industry association. Our members slaughter and process 70 percent of the nation's beef, pork, lamb, veal and turkey products. Most of our members are small, family owned businesses with a single manufacturing plant. However, we also represent some of the largest meat companies in the world.

I speak to you today as a meat scientist with 30 years of experience in the meatpacking and supermarket industries, as well as USDA's Food Safety and Inspection Service. Never in my career have I seen so much public anguish over an animal disease as I've seen in the last 6 months over BSE. Given our nation's phenomenal history of animal disease eradication—we are world leaders in this regard—it is perplexing and disappointing to see attention being focused on what we are doing wrong instead of what we are doing right.

I have three messages to leave with you today. First, we do not have BSE in this country. Second, we have taken prudent steps to prevent BSE from entering this country. And third, if, heaven forbid, BSE were ever to find its way into this country, we can diagnose it, isolate it, contain it and prevent it from reaching consumers in a swift and decisive way. Our risk of BSE in domestic cattle is not zero, nor can it ever be, be we are a long way from a BSE crisis in the U.S.

Let me focus for a moment on my first message: We do not have BSE in this country. That fact bears repeating because it's been lost lately in some hysterical and speculative news reporting.

The BSE crisis in Europe has been a frightening situation to watch. It was tragic when it first impacted British cattle. And it was horrific when science began to support a relationship between eating products contaminated with the infective agent and the development of a human illness by young people in Britain.

The British problem—now shared by 12 other European nations—has provided strong incentive for the U.S. Government and U.S. beef industry to take aggressive actions to prevent this devastating animal disease in U.S. herds. In fact, we took action so early that some people now seem to question why we aren't announcing major new efforts today. The answer: we took swift, science-based actions early on that have protected our livestock and given us the coveted distinction of being a BSE-free nation.

The U.S. approach to BSE prevention can best be described as a "triple firewall" strategy. Because BSE is not present in U.S. herds, the first critical firewall in protecting U.S. cattle involves protecting U.S. borders. As early as 1989, the U.S. Department of Agriculture (USDA) banned the importation of cattle and most beef products from countries with BSE.

The second critical firewall involves careful surveillance. Veterinarians are present at every U.S. meat packing plant and check cattle for signs of any disease—including BSE. No animal can be processed for meat without inspection. Additionally, USDA routinely conducts laboratory tests for BSE. For a country in which BSE is not endemic—has never been detected in the native cattle population—the U.S. has one of the most statistically sound and comprehensive surveillance programs in the world. Of the roughly 12,000 animals tested for BSE by the U.S. Government, none have been positive.

The third critical firewall involves controlling what cattle are fed. Evidence indicates that BSE may have been spread in the U.K. and Europe by contaminated feed. Even though the U.S. has no BSE in cattle, the feeding of any protein derived from ruminant animals to cattle is prohibited in this country. In fact, there is a growing trend within the beef industry to require certification from producers that cattle have met all requirements with respect to complying with FDA regulations. AMI has provided its members with model certification language and we understand it is beginning to be widely used.

Taken together, these efforts provide the best reasonable assurance that U.S. cattle will remain BSE-free and that U.S. consumers will not be exposed to any related health risks. That is not to say we should rest on our laurels. We must continually

evaluate and improve our preventative control measures, if warranted, and we must assure our regulatory agencies are provided the necessary resources to do their job.

It is important to remember that BSE has been diagnosed only in European livestock. The U.S. is a long way from Europe. Our livestock populations are very different, as are many of our rendering, feeding and production practices. In addition, Europe is in the midst of a crisis and crises warrant strong and dramatic actions. In contrast, we do not have a crisis in the U.S. It is critical that our BSE prevention policies reflect this fact. While our media have begun to mirror British tabloid coverage of BSE, our cattle herds are, and will remain, very different from those in the U.K. and Europe. Our policies must reflect these differences and be supported by the best available science lest we head down the slippery slope of creating our own hysteria.

Senator FITZGERALD. Thank you, Mr. Hodges.

Ms. DEWAAL. Is that the right pronunciation?

STATEMENT OF CAROLINE S. DE WAAL, DIRECTOR, FOOD SAFETY PROGRAM, CENTER FOR SCIENCE IN THE PUBLIC INTEREST

Ms. DEWAAL. Yes, that is. Thank you so much, and good morning. I guess it is early afternoon now.

I want to start out first, off my written text, with the fact that I agree with Secretary Glickman's letter. That was kind of how you started the hearing. I think what we are dealing with in this hearing is something that is a potential risk and it is very serious, but we should also be aware there are very real risks associated with the food supply, things like E. coli 015787, listeria, campobacter, things that are making people sick, putting them in the hospital, and sometimes, tragically, even killing them. Those things exist in the U.S. food supply. Luckily, mad cow disease does not.

I want to thank you for inviting us. We represent 850,000 members and subscribers to our Nutrition Action Health Letter.

Thankfully, as I have said, no cases of BSE are in the cattle population in the U.S., and that is good news both for the cattle producers and very much for the American public. However, as we have seen the recent outbreak of foot and mouth disease in Europe, this reminds us that even the absence of diseases is really no excuse for complacency. So I am glad you are having this hearing.

To the government's credit, USDA has instituted a critical first line of defense to prevent BSE from infecting U.S. cattle herds, and we have heard a lot about that today. It was done back in the late 1980s. They banned cattle from countries with BSE. More recently, in 1997, they have banned cattle and cattle products and ruminant products from all over Europe.

This precaution has paid off, both for consumers and for the meat industry. But we need more precautions instituted to protect the human food supply if we are to prevent American consumers from the crisis in confidence that has emerged in Europe in recent years.

In the late 1980s, or it may have been the early 1990s, BSE jumped the species barrier between cattle and humans during an epidemic of disease that started in Great Britain. Unlike the human form of the disease, which seldom strikes those under 50, the variant Creutzfeldt-Jakob disease shows up in young men and women. It often starts with leg pain and difficulty walking, but eventually leads to progressive brain damage that leaves its vic-

tims hallucinating, unable to see, speak, or feed themselves, and ultimately it kills them.

In 1996, vCJD killed 10 people in Europe. Last year it killed 27. In all, nearly 100 people have died from this disease in Europe. No one knows how many more are already infected with this horrible disease.

BSE in cows and vCJD in humans are both caused by prions. These are virtually indestructible proteins that have the remarkable ability to induce other proteins to become deformed. Scientists are not certain how prions do their damage, but it is clear that we must keep these prions out of the food and the feed supplies.

Major efforts have been made to prevent bovine material from getting into animal feed, cattle feed, and that is good. However, recent studies indicate that these standards are not adequately enforced. With just a few hundred inspectors at FDA to examine the safety of over 57,000 food manufacturers and warehouses in the U.S., it is clear that feed mill inspections by the Federal Government, by FDA, are a rare event at best.

FDA has only a handful of inspectors who are regularly tasked to check feed mills for compliance with its requirements. CSPI has called for doubling FDA's food safety budget the increase their number of inspectors so there can be more, both for food plants and feed mills.

These holes in the firewall protecting cattle feed support the need for another layer of protection to safeguard the human food supply. For the last 5 years, CSPI has urged USDA to erect a firewall to protect consumers from the possibility that infectious prions could enter the meat supply through advanced meat recovery systems. Advanced meat recovery systems that use infected parts of cattle with BSE could clearly transmit this disease to humans.

These machines take the bones with attached meat and put them through a device that removes the meat from the bone. Advanced meat recovery systems produce a product that is called meat and it is labeled "meat" on the package. If spinal cord is attached to the spinal columns that enter these machines, it is bound to be incorporated into the meat that is produced. Spinal cords from cows with BSE, which we hope do not exist in this country, but we know we cannot be dead certain that there are not cows here, spinal cords from cows with BSE are highly infectious.

The advanced meat recovery systems provide the best single opportunity for BSE-infected material to enter the food supply. This meat is used in several staples of the American diet, including hot dogs, hamburgers, and sausages. In fact, the USDA says that hot dogs and sausages can contain up to 20 percent mechanically separated beef or pork.

In 1997, following a request by the Center for Science in the Public Interest, USDA directed its employees to periodically check the product going into the advanced meat recovery systems to ensure that the plant's employees are "completely removing spinal cord from neck and/or back bones" before the bones enter the AMR, the advanced meat recovery system.

In addition, inspectors were instructed to sample the product if they thought that plant employees were not adequately removing

spinal cord. There was no other enforcement outlined in this directive.

Evidence to date suggests that these inspections are rarely performed, in part because USDA has said that they are not critical to protect food safety. Between 1998 and 2000, fewer than 60 samples of meat were analyzed under this directive. This is a pitifully small number, especially considering that in just one of those years 45 million pounds of beef was produced using advanced meat recovery.

Two of the 60 samples were positive for central nervous system tissue and others were positive for peripheral nerve tissue. Clearly, this system is not adequate to protect consumers if—and "if" is an important word here—if BSE were found in U.S. cattle. Therefore, CSPI will petition USDA next month to ban the spinal column and neck bones from cattle in advanced meat recovery systems. We believe the magnitude of the human illness justifies these precautions in meat production.

Europe has opted for a more radical solution. This year the European Union outlawed the production of all mechanically separated meat that comes from cows or sheep.

By any public health measure, the U.S. program to control mad cow disease appears to be a success so far. We have no documented cases of the disease in either the human or the cattle populations. However, the seriousness of the public health concerns means that regulators cannot be complacent. There are gaps in the firewall constructed by both FDA and USDA and these gaps should be filled before, long before, the first case of mad cow disease in the U.S. is ever discovered. Otherwise, we will face the very real risk that the consumer concerns that we are seeing in Europe about food safety overall could spread to the U.S., and I think we will all agree that is something we would like to prevent.

Thank you.

[The prepared statement of Ms. DeWaal follows:]

PREPARED STATEMENT OF CAROLINE S. DEWAAL, DIRECTOR, FOOD SAFETY PROGRAM, CENTER FOR SCIENCE IN THE PUBLIC INTEREST

My name is Caroline Smith DeWaal and I am director of food safety for the Center for Science in the Public Interest (CSPI). CSPI is a non-profit organization based in Washington, DC. Since 1971, CSPI has been working to improve the public's health, largely through its work on nutrition, food-safety and alcohol issues. CSPI is supported primarily by 850,000 subscribers to its Nutrition Action Healthletter, the largest circulation health newsletter in North America.

Thank you for inviting us to present testimony today on "Mad Cow Disease: Are Our Precautions Adequate?" Thankfully, for both American cattle producers and the public, no case of bovine spongiform encephalopathy (BSE), the scientific name, has ever been identified in U.S. cattle. However, as the outbreak of foot and mouth disease in Europe has recently reminded U.S., the absence of disease should not be an excuse for complacency.

To USDA's great credit, in the late 1980s, it instituted a critical first line of defense to prevent BSE from infecting U.S. cattle herds. Before the human health consequences were even known, to protect U.S. cattle herds, the USDA banned the importation of ruminants (cattle, sheep, and goats) and ruminant by-products from the United Kingdom and other countries where BSE had been found.[1] In 1997, the ban was extended to cover all of Europe. Clearly the U.S. Government has been very

[1] U.S. Department of Agriculture, "U.S.D.A. Actions to Prevent Bovine Spongiform Encephalopathy (BSE)," April 1998, available at (*http://www.aphis.U.S.da.gov/oa/bse/bsechron.html*). Internet.

proactive to prevent mad cow disease from infecting our animal population. This precaution has paid off, both for consumers and for the meat industry.

The meat industry also deserves credit. Up until 1998, many slaughterhouses stunned their cattle with an air-injection rifle before killing them.[2] But then, CSPI disclosed several studies in Nutrition Action Healthletter showing that the explosive blast of air could scatter brain tissue throughout the carcass. In cows with BSE, brain tissue is highly infectious. First, the meat industry did a study that confirmed the risk of spreading brain tissue using this type of stunning equipment, then companies voluntarily changed to safer devices. According to an industry representative, no one is even manufacturing the air-injection stunning equipment in the U.S. anymore.[3]

While these steps have been very important, there is more that must be done in order to protect American consumers from the crisis in confidence that has emerged in Europe in recent years.

TSES ARE DEVASTATING DISEASES

BSE is one of a family of neurologic diseases called transmissible spongiform encephalopathies (TSEs), which are characterized by a relatively long incubation period, short duration of clinical signs, and a 100 percent mortality rate.[4] TSEs have been documented in a wide number of species, including sheep (scrapie), cattle (BSE), humans (Creutzfeldt-Jakob disease or CJD), deer, mink, cats, and others.

Many cases of TSEs, including 90 percent of CJD cases, are sporadic, which means that the disease can show up in an individual with no apparent cause.[5] The disease is also infectious. TSEs can be spread mainly through consumption of infectious tissue. TSEs can be transmitted from one species to another, although significant barriers exist to prevent this.

Sometime in the late 1980s or early 1990s, BSE jumped the species barrier between cattle and humans during the British BSE epidemic in cattle.[6] Consumption of BSE-infected cattle has been linked to the development of a new variant of CJD in humans. Unlike the sporadic form of the disease, which seldom strikes those under age 50, the variant Creutzfeldt-Jakob Disease (vCJD) shows up in young men and women. It often starts with leg pain and difficulty walking but eventually leads to a progressive brain damage that leaves its victims hallucinating, unable to see, speak, or feed themselves, and, within a year or two, dead.

In 1996, vCJD killed ten people in Europe; last year it killed 27.[7] In all, nearly 100 people have died from the disease in Europe.[8] No one knows how many more are already infected and will develop vCJD, which can take 5 to 10 years to emerge. BSE in cows and vCJD in humans are both caused by prions—virtually indestructible proteins that have the remarkable ability to induce other proteins to become deformed.

TRACKING BSE IN U.S. CATTLE

U.S. law currently requires that a Federal veterinarian check every cow or steer before it is slaughtered. If a cow appears to be suffering from a central nervous system disorder, it is segregated and slaughtered separately. If a cow is suspected of having BSE, its meat is held while its brain is sent off for testing in an Animal Plant and Health Inspection Service (APHIS) laboratory. Currently, the brains of about 1,000 suspicious cattle are tested each year by the government. But in 12,000 tests conducted since 1990, not one has been positive.[9]

In addition to this government-run system, every veterinarian and university researcher in the U.S. knows that being the first to identify a case of mad cow disease will bring a certain prominence that can be helpful in getting future research funded. If the disease was present in the U.S. cattle population, it would likely show

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[2] Schardt, David and Schmidt, Stephen, "Mad about BSE", Nutrition Action Healthletter, Vol. 24, No. 6, July/August 1997.

[3] Personal conversation with AMI Representative.

[4] 1U. S. Department of Health and Human Services, "FDA Proposes Precautionary Ban Against Ruminant-to-Ruminant Feedings," HHS News, P97-1, January 2, 1997, p. 1.

[5] The World Health Organization, "Bovine Spongiform Encephalopathy (BSE)," Fact Sheet No. 113, (Revised), December 2000, p. 3, available at *http://www.who.int/inf-fs/en/fact113.html* Internet.

[6] *Id.*

[7] UK Department of Health. "Monthly Creutzfeld-Jakob Disease Statistics," March 5, 2001, p.1., available at *http://www.doh.gov.uk/cjd/stats/mar01.htm* Internet.

[8] *Id.*

[9] U.S. Department of Agriculture, Animal and Plant Health Inspection Service, "BSE Surveillance," p. 5., available at *http://www.aphis.U.S.da.gov/oa/bse/bsesurvey.html* Internet.

up in the dairy cattle population first, but no cases have been documented. While the absence of a positive doesn't prove that BSE isn't here, it does increase our level of confidence. If it is here at all, BSE is very rare.

But it may take only one infected cow to spread the disease. Since 1996, when BSE was first identified as a human health hazard, the U.S. Government has tried to create "firewalls" to prevent BSE from gaining a foothold here. One firewall protects cattle from BSE; the other prevents people from getting sick if the first part fails. Currently both parts have holes in them.

PROTECTING U.S. CATTLE FROM BSE

The first firewall was USDA's import ban covering cattle from countries with BSE. In 1997, the Food and Drug Administration (FDA) erected a second firewall by prohibiting cattle operations from feeding meat-and-bone meal supplements made from rendered cows or sheep to cows or sheep. However, several gaps in the feed ban need to be filled.

The banned meat-and-bonemeal can still be fed to pigs and poultry. While cows get BSE and sheep get a BSE-like disease called scrapie, there is no evidence that pigs and poultry get BSE-like diseases from their food. However, processing ruminants into animal feed opens the door for banned material to inadvertently be fed to cattle.

Recent events have shown that this is fact happening. In a survey of feed mills and renderers, FDA found that more than 20 percent had no system in place to prevent commingling and cross-contamination, as required by the feed ban. And 85 feed plants of over 400 surveyed didn't label their feed with a warning about which animals it was (and, more importantly, wasn't) intended for.[10]

The problem made headlines in January, when a Texas feedlot inadvertently fed meat-and-bone meal intended for pigs and poultry to more than 1,200 cattle.[11] A clerk at Purina Mills in St. Louis had mistakenly mixed the pig-and-poultry supplement into the company's cattle feed. Although the meal was produced in the U.S. from BSE-free cattle, Purina Mills said it would purchase the animals to keep their meat out of the food supply.[12] If further breaches like this occur, FDA should consider banning the use of meat-and-bone meal in all types of animal feed.

Unless Congress gives FDA additional inspection resources, violations of the feed ban are certain to occur. With just a few hundred inspectors to examine the safety of over 57,000 food manufacturers and warehouses in the U.S., feed mill inspections are a relatively rare event. FDA has only a handful of inspectors regularly tasked to feed mills to check for compliance with its requirements. Although feed mills and renderers are trying to remedy the situation by setting up third-party verification systems, that is not a substitute for government enforcement of the law.

In addition, FDA needs to strengthen enforcement of the feed ban by using modern scientific tests to ensure that companies are complying. When FDA developed the feed ban, it did not require companies to utilize a sampling system to check that the feed is free of prohibited material. This testing is critical to effectively enforce the feed ban. The British government uses a test that differentiates mammalian from non-mammalian tissues to enforce their mammalian-to-ruminant feed ban,[13] and a similar test should be used in the United States to enforce the feed ban. Otherwise, enforcement largely depends on a paper trail.

These regulatory holes in the firewall protecting cattle feed are troubling. They also support the need for another level of protection to safeguard the human food supply. For the last 5 years, CSPI has urged USDA to erect another firewall to protect consumers from the possibility that infectious prions could enter the meat supply through advanced meat recovery systems.

PROTECTING U.S. CONSUMERS FROM BSE

Advanced meat recovery systems that use infected parts of cattle with BSE could transmit the disease to humans. These machines take bones with attached meat and put them through a device that removes the meat from the bone. They claim to detach the meat without crushing, pulverizing or grinding the bone itself. According to the Food Safety and Inspection Service (FSIS), bones must emerge from these

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[10] General Accounting Office. Report to the Honorable Richard J. Durbin, U.S. Senate. "Food Safety Controls Can Be Strengthened to Reduce the Risk of Disease Linked to Unsafe Animal Feed," September 2000.

[11] "Texas Cattle are Quarantined to Determine Mad-Cow Risk," *New York Times*, January 27, 2001, p. A8.

[12] Blakeslee, Sandra. "Agency Clears Texas Cattle in Quarantine," *New York Times*, January 31, 2001, p. A18.

[13] Telephone conversation with Michael Hansen of Consumers' Union, April 28, 1997.

machines essentially intact and in natural conformation so that they are recognizable, i.e., comparable to those resulting from hand-deboning. Advanced meat recovery systems produce a product that can be called "meat" under current government requirements.[14]

If spinal cord is attached to the spinal column that enters these machines, it is bound to be incorporated into the meat that is produced.[15] Spinal cords from cows with BSE are highly infectious. Advanced meat recovery systems provide the single best opportunity for BSE-infected material to enter the food supply today. And this meat is used in several staples of the American diet, like hot dogs, hamburgers and sausages. In fact, the USDA says that hot dogs and sausages can contain up to 20 percent mechanically separated beef or pork. (An even riskier process is used to produce mechanically separated meat, one that allows the spinal cord to become part of the meat produced. This practice should clearly be banned.)

The parts of the cattle known to carry the infectious agent that can cause BSE include the spinal cord, brain and retina.[16] Great Britain has banned "specified bovine offal" from the human food chain, including the brain, spinal cord, tonsils, thymus, spleen and intestines. To minimize the risk of BSE entering the human food supply, it is critically important that FSIS place restrictions on the use of those cattle parts in mechanical meat recovery systems.

In 1997, following a request by the Center for Science in the Public Interest,[17] the USDA directed its employees to periodically check the spinal columns going into the advanced meat recovery systems to ensure that plant employees are "completely removing spinal cord from neck and/or back bones before the bones enter the [AMR] system."[18] In addition, inspectors were instructed to sample product if they thought plant employees were not adequately removing the spinal cord.

Evidence to date suggests that these inspections are rarely performed, in part because the USDA believes they are not food safety violations. Between 1998 and 2000, fewer than 60 samples of meat were analyzed under this directive. This is a pitifully small number, considering that 45.3 million pounds of beef was produced by A.M.R. systems in just one of those years. Two of those samples were positive for central nervous system tissue, and peripheral nerve tissue was found in other samples as well.

Clearly, this system is not adequate to protect consumers if BSE occurred in U.S. cattle. Therefore, CSPI will petition USDA next month to ban the spinal column and neck bones from cattle in advanced meat recovery systems. We believe the horrifying human illness justifies that additional precaution. Europe has opted for a more radical solution. This year, the European Union outlawed the production of all mechanically separated meat that comes from cows or sheep.[19]

In addition, USDA should ban the use in human food of all bovine offal that has been identified as containing the infectious agent for BSE, including but not limited to the brain, retina, spinal cord, spleen, thymus, nostrils, and intestines. Britain has also banned "beef on the bone," for example, T-bone steaks. Such a ban would mirror the recommendation of the World Health Organization, as well as the ban implemented by the British government.[20]

OTHER FDA-REGULATED PRODUCTS

The Food and Drug Administration (FDA) has responsibility for assuring the safety of a number of products that could transmit BSE from cattle to humans. Here is a brief review of some matters regulated by FDA:

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[14] U.S. Department of Agriculture, Food Safety and Inspection Service, Proposed Rule, Meat Produced by Advanced Meat/Bone Separation Machinery and Recovery Systems, 9 CFR Parts 301, 318, and 320, Docket No. 96-027P.

[15] B.P. Demos and R.W. Mandigo, "Chemistry and Composition of Mechanically Recovered Beef Neck Bone Lean," Journal Series, Nebraska Agricultural Research Division, Paper No. 10997, p. 64-65.

[16] European Commission Listing of Specified Risk Materials: a scheme for assessing relative risks to man. Opinion of the Scientific Steering Committee adopted on 9 December 1997 (Re-edited version adopted by the Scientific Steering Committee during its Third Plenary Session of 22-23 January 1998), available at *http://europa.eu.int.comm/food/fs/sc/ssc/out22—en.html* Internet.

[17] Center for Science in the Public Interest, Letter to Secretary Glickman and Administrator Billy, January 7, 1997.

[18] U.S. Department of Agriculture, FSIS Directive 7160.2, "Meat" Prepared using Advanced Mechanical Meat/Bone Separation Machinery and Meat Recovery Systems, 1997.

[19] The European Commission, Health and Consumer Protection Directorate-General Press Release, "Commission approves further protection measures against BSE," Brussels, February 7, 2001, p. 3, available at *http://europa.eu.int/comm/dgs/health—consumer/library/press/press106—en.html* Internet.

[20] WHO Factsheet 113.

• Gelatin is an animal protein that comes from the hides and bones of cows and pigs. It's what makes Jell-O gel and gummy bears soft and pliable. It's used as a thickener in some yogurt, ice creams, and other foods. And it's in the capsules, gel caps, and coatings of many over-the-counter supplements and prescription drugs.

Is gelatin infectious if it's made from animals that have mad cow disease? Probably not. Skin and hides don't seem to carry any risk, while bones have a "low infectivity" (because they contain bone marrow), according to the World Health Organization. Few, if any, BSE experts see a problem.

Even so, in 1992, the FDA asked gelatin manufacturers not to use hides and bones from cows that were raised in countries where BSE has been found. The industry says that it's complying. Food companies also point out that much of the gelatin used to make desserts and candy comes from pig skins, not cow hides or bones.

• Vaccines are often made using cattle by-products that could be infectious. In 1993, the FDA asked vaccine manufacturers to stop importing animal products from countries where BSE has been found or where there isn't adequate surveillance for BSE. Last year, though, the government learned that five vaccine-makers hadn't complied.[21] It ordered them to do so. There is no evidence that any of the world's cases of variant Creutzfeldt-Jakob Disease were caused by contaminated vaccines, and the U.S. Public Health Service recommends that children and adults continue to be immunized.

• Glandular dietary supplements are made from animal glands. Example: Rejuvex, which is marketed as a tonic for menopausal women, contains extracts from cow mammary, ovary, uterus, adrenal, and pituitary glands. But the uterus and adrenal gland of cattle with mad cow disease can contain infectious prions, according to the World Health Organization. So can the placenta and thymus, which are found in other supplements.

Supplement-makers say that they're complying with a 1993 FDA request that they not use cow organs from countries where BSE exists. Rejuvex labels, for example, say that its cow gland extracts come from "countries that are certified to be BSE-disease free." They are also planning to utilize a third-party auditing system to address the lack of FDA oversight.

The National Nutritional Foods Association, a trade group of 4,000 health food and supplement producers, distributors, and retailers, is urging its members to eliminate all cow neurological tissues from their dietary supplements.[22] But the FDA has no system in place to monitor what supplement companies actually put into their products.

Senator FITZGERALD. Ms. DeWaal, thank you.

Mr. Sellers, thank you very much for being here.

STATEMENT OF RICHARD SELLERS, PAS, VICE PRESIDENT, FEED CONTROL AND NUTRITION, AMERICAN FEED INDUSTRY ASSOCIATION

Mr. SELLERS. Mr. Chairman, my name is Richard Sellers and I serve as Vice President for Feed Control and Nutrition of the American Feed Industry Association and am an animal nutritionist. Thank you for the invitation to be here today to explain how the feed industry views the U.S. efforts to prevent mad cow disease—or BSE—from entering the U.S.

We commend you, Senator Fitzgerald, for calling this hearing. This forum gives both the Federal Government and animal agriculture the opportunity the describe our actions and demonstrate our collective commitment to keep BSE out of the U.S.

AFIA is the national trade association representing more than 75 percent of the nation's primary feed producers of livestock, poultry, aquaculture, and pet food. AFIA's membership is nearly 700 com-

[21] U.S. FDA, Bovine Spongiform Encephalopathy (BSE), MMWR Notice to Readers: PHS Recommendations for the Use of Vaccines Manufactured with Bovine-Derived Materials, available at *http://www.fda.gov/cber/bse/bse.htm* Internet.

[22] Zwillich, Todd. "Group Says Cow Tissue in U.S. Supplements Risky," Reuters Health, March 19, 2001, available at *http://dailynews.yahoo.com/h/nm/20010319/hl/supplements—madcow—1.html.*

panies, with state and regional affiliates, and represents more than 5,000 facilities in all 50 states.

Food safety and consumer confidence in foods of animal origin are AFIA's highest priority. We are justifiably proud that no case of BSE has ever been detected in the U.S. and are united in our resolve that an effective marriage of government and industry actions will keep the U.S. BSE-free. We have been involved with the groups in this room and others for more than a decade to ensure that government actions and programs instituted by industry create the necessary firewalls to prevent BSE from entering the U.S. and also to reinforce government safety initiatives.

AFIA calls on Congress to do two things to help industry and government live up to their joint commitment to keep the U.S. BSE-free. First, Congress must ensure FDA and USDA and other Federal agencies have adequate funding to conduct government BSE prevention and control programs. We are especially concerned about the limits of budget in both FDA, and especially APHIS', budget. They seem to be stretched to the limit at this time dealing with both BSE prevention and foot and mouth disease.

Second, we urge Congress to assist industry and government in making sure that public discussions of BSE are free of hyperbole, emotional exaggeration, and inaccuracies. This hearing is an important step in making sure the public record is accurate and objective. We must avoid the mistakes made in Europe and learn from the lessons of their experience.

AFIA has been involved in the battle to control and exclude BSE for more than a decade by working with our sister organizations in Europe and supporting government initiatives like the FDA's regulations governing use of animal protein in ruminant feed. AFIA worked with a coalition of animal agriculture organizations to support a voluntary ban on these products in 1996 and asked FDA to broaden its proposed restriction in 1997. This broadening was needed because of the practicality of separating these types of materials in feed mills. FDA opted to provide limited exceptions to the rule based on scientific studies regarding the transmissibility of infected tissue. AFIA continues to support the existing exemptions based on the sound science.

In early February, AFIA's board of directors approved the creation of a third party certification program to assure consumers of the continued safety of feed and food. The Facility Certification Institute, or FCI, was created as a stand-alone nonprofit entity. It provides the entire feed industry with the opportunity to have facilities certified for compliance with FDA's regulations and acts as an adjunct program to the current government inspection.

There are approximately 500 to 1,000 feed inspectors at the state level in the United States. Every state has a feed law. Most of these states are cooperating with the Food and Drug Administration in the inspection process. Nearly 80 percent of the inspections have been done by state feed control officials.

FCI has two levels of certification. Level one is for those facilities that do not use restricted use proteins in facilities manufacturing ruminant feed, that is dairy or cattle feed. Level two certification is for those facilities using these products in ruminant feed facili-

ties, but fully complying with the FDA regulations regarding prevention of commingling of products.

To date, over 100 facilities, including six major facilities in Canada, have been certified since the program began on March 13th. These facilities are listed on FCI's website at *www.certifiedfeed.org* by state. Facilities are required to notify their customers of decertification, notify FCI of any noncompliance with government inspections, and any changes in procedures affecting certification. So the program has teeth.

AFIA shares FDA's goal of 100 percent inspections and 100 percent compliance, as witnessed by our industry's third party certification program. FDA's most recent compliance report shows substantial progress toward that goal. Nearly all the firms inspected met the recordkeeping requirements of FDA's rule, but several had problems with labeling and commingling prevention plan requirements.

This report has generated customer and media attention. As for the general media, covering a complex issue such as BSE is understandably difficult. However, media must take a responsible approach to its reporting of the issue, not as a food safety issue. Media must resist the temptation to demonize the ingredients, which have a long history of safe and nutritious use.

Again, we do not have BSE in the United States. What the public needs is straightforward factual reporting on the issue.

In conclusion, AFIA believes the mandate is clear. A marriage of science-based Federal Government and industry proactive measures is the working mechanism to prevent BSE from entering the U.S. These measures are working and adequate to control BSE introduction into the U.S. However, vigilance and continued innovation are required as situations and scientific evidence may shift.

Congress can assist this effort by ensuring Federal agencies are adequately funded for research, surveillance, and compliance and can assist industry in assuring that the public debate over BSE is accurate, measured, and fact-based.

Mr. Chairman, let me assure you that industry support and innovation will continue, and we appreciate the invitation the appear here today. Thank you.

[The prepared statement of Mr. Sellers follows:]

PREPARED STATEMENT OF RICHARD SELLERS, PAS, VICE PRESIDENT, FEED CONTROL AND NUTRITION, AMERICAN FEED INDUSTRY ASSOCIATION

Mr. Chairman, members of the Subcommittee, my name is Richard Sellers. I serve as Vice President for Feed Control and Nutrition for the American Feed Industry Association (AFIA). Thank you for the invitation to be here today to explain how the feed industry views U.S. efforts to prevent so-called "mad cow disease" from entering the U.S.

AFIA commends you, Sen. Fitzgerald, for calling this hearing. This forum gives both the Federal Government and animal agriculture the opportunity to describe our actions and demonstrate our collective commitment to keeping bovine spongiform encephalopathy (BSE) out of the U.S.

I respectfully request, Mr. Chairman, that AFIA be allowed to provide the full text of its statement, along with several pieces of documentation, for the formal record of this hearing.

AFIA is the national trade association representing more than 75 percent of the primary livestock, poultry and pet food sold annually in the U.S. AFIA's membership of nearly 700 companies is supported by 30 national, state and regional associations. Together we represent more than 5,000 facilities in all 50 states.

Food safety and consumer confidence in this nation's production of foods of animal origin is AFIA's highest priority. We share this priority with every group sitting at this witness table and with every agriculture organization and company in this room today.

We are all justifiably proud that no case of BSE has ever been detected in the U.S., and we are united in our resolve that an effective marriage of government and industry actions will continue to keep the U.S. BSE-free.

This consensus extends well beyond mere philosophy or lipservice. AFIA, the American Meat Institute, the National Renderers Assn., the National Cattlemen's Beef Assn., the National Milk Producers Federation, the American Sheep Industry Assn., and others have worked consistently and collectively for more than a decade to ensure that government actions—and programs instituted by industry—create not only the necessary "firewalls" to prevent BSE introduction to the U.S., but also reinforcement or redundancy to these government safety initiatives.

DOLLARS AND RESTRAINT NEEDED

AFIA calls on Congress today to do two things to help industry and government live up to their joint commitment to keep the U.S. BSE-free. First, Congress must ensure adequate funding is available to the Food & Drug Administration's (FDA) Center for Veterinary Medicine (CVM) and the U.S. Department of Agriculture's Animal & Plant Health Inspection Service (APHIS) and other Federal agencies. These monies are needed to conduct government BSE prevention and control programs in the most effective manner possible.

This funding is necessary to increase and accelerate research on prion disease transmission, to find quick diagnosis and analytical test methods, increase manpower and technology at U.S. ports of entry to detect prohibited products and animals from entering the U.S., and should the unthinkable occur, contain any BSE outbreak to prevent any spread.

Second, we urge Congress to assist industry and government in making sure that public discussions of BSE are free of hyperbole, emotional exaggeration and inaccuracies. This hearing is an important step in making sure the public record on BSE prevention—is accurate and objective.

We must avoid at all costs mistakes made in Europe. We must take lessons from the European experience—adopting effective measures where justified by science—and constantly moving forward, ensuring the public is not the victim of demagoguery, grandstanding or propaganda.

AFIA'S INVOLVEMENT IN THE WORLD BSE DEBATE

AFIA's involvement in the battle to control and contain BSE goes back more than a decade to our initial consultations with sister organizations in Europe. These began in the late 1980s and early 1990s, as the BSE situation in the United Kingdom and continental Europe reached crisis proportions, both through independent meetings and through AFIA's role as an officer in the International Feed Industry Federation.

AFIA strongly supported the emergency USDA/APHIS ban on ruminant animals with confirmed cases of BSE in 1989, and likewise supported the expansion of the ban to include at-risk ruminant products from the same countries. AFIA advocated the formalization of these bans, as well as the intensified U.S. surveillance and testing that began here in 1990–93.

In 1996, based upon our consultations with international feed and scientific organizations and visits to European nations struggling to control the BSE outbreak, AFIA met with U.S. livestock and professional animal health groups. These discussions led to formation of a coalition, which announced a voluntary industry program to cease the use of ruminant-derived proteins in ruminant feeds. At the same, industry urged FDA/CVM and USDA/APHIS to accelerate their review to determine if additional regulations were needed to prevent the introduction of BSE to the U.S.

FDA announced in 1997 that it intended to ban the use of ruminant products in livestock feed. AFIA and the coalition of producer and scientific organizations successfully urged FDA to broaden its proposal on restricted proteins to include a restriction on all at-risk mammalian protein used in ruminant feeds.

This broadening of the Federal restriction was needed for two reasons: First, all materials posing a potential risk to ruminant animal health needed to be segregated to use in non-ruminant feeds. Second, the broader ban recognized the logistical reality of the rendering, feed and feeding industries, and would not unnecessarily cause economic hardship nor take legitimate feed ingredients for non-ruminants out of the feed chain.

FDA opted to provide limited exceptions to the list of restricted use protein products (RUPP). These include blood, milk or gelatin products, and equine and porcine proteins derived from species not demonstrated to develop transmissible spongiform encephalopathies (TSE) naturally. AFIA supports the existing exceptions based upon sound science.

AFIA'S FACILITY CERTIFICATION INSTITUTE (FCI)

AFIA believes there cannot be too many industry or government science-based precautions, firewalls, or safety program redundancies when it comes to BSE prevention. Putting money, effort and manpower behind this belief, AFIA capitalized on its ongoing membership quality control programs and has modified its general Q/A recommendations to provide specific education and assistance to members and nonmembers relative to feed mill compliance with the government's RUPP rule.

AFIA's Board of Directors approved in early February creation of a third-party certification program to assure consumers of the continued safety of feed and food. This certification program was created as an entirely stand-alone entity—the Facility Certification Institute (FCI). It provides the entire feed industry the opportunity to have facilities certified for compliance with the FDA's mammalian protein regulations.

AFIA created FCI, and its Certified Facility Program for RUPP, to incorporate FDA's inspection program for compliance with Title 21, CFR § 589.2000, *Substances Prohibited in Ruminant Feed.* The program is designed for an independent certifying agent to visit facilities which use restricted use protein products, as well as those that do not use these products. The agent reviews procedures, examines records and issues interim certifications to those facilities, when an inspection finds the facility meets the program's requirements.

FCI provides two levels of certification, based upon third party, in-plant inspections. Level 1 certified facilities do not use restricted use protein products in their ruminant feed manufacturing facilities. Level 2 plants use restricted use protein, but conform to FDA's regulations. FCI has contracted with certifying agents to handle the program, and is adding more trained personnel as demand dictates. All personnel have extensive feed industry/FDA compliance experience.

Upon certification, facilities are authorized to use one of two distinctive seals and the FCI logo, as well as statements regarding the program. These will be promoted widely as quality certification marks. The program is open to any feed manufacturing, rendering or related facility.

To date, over 100 feed and rendering facilities have received FCI certification, with 10–15 applications arriving daily. To provide farm and ranch customers additional service, all certified mills are listed on the Institute's website—*www.certifiedfeed.org.* In addition, if a facility loses or gives up its certification, that facility is listed separately. Facilities are also required to notify their customers if they surrender their certification for any reason. Likewise, if a facility is found in violation of Federal or state rules during a government inspection, it is required to notify FCI.

FCI is designed to grow into other areas needing third party certification as needed. It represents the organization which will contract for certifications, invoicing and processing and form links and partnerships with other groups and organizations to further strengthen its mission, which is to provide certification with integrity.

FDA COMPLIANCE REPORTING

AFIA shares FDA/CVM's goal of 100 percent compliance with the RUPP rule as quickly as possible, as witnessed by our industry third party certification program.

The most recent FDA/CVM compliance report shows substantial progress toward this goal. The report, released March 23, shows that of the estimated 1,290 licensed feed mills in the U.S., FDA has inspected 1,069, and of that universe, 397 mills (37 percent the licensed mills inspected) report handling RUPP materials.

Of those 397 mills, 99 percent are in compliance with recordkeeping requirements, i.e. where they bought RUPP materials, in which feeds it was mixed, and to whom those products were sold; 87 percent have a written in-plant program to prevent commingling, and 85 percent were in compliance with labeling requirements, i.e. "do not feed to ruminant animals."

There are approximately 6–8,000 non-FDA licensed feed mills in the U.S., and FDA/CVM has conducted inspections of nearly 5,100. About 1,800 mills report handling RUPP materials. Again, more than 99 percent of these facilities are in compliance with recordkeeping requirements, 82 percent are in compliance with requirements for written plans to prevent commingling, and 67 percent are in compliance with labeling requirements It should be noted FDA/CVM began these inspections

over 3 years ago, and published its interim "compliance report" in January 2001. This report, taken on its face, reflected high compliance with paperwork and record-keeping requirements, but less successful compliance with labeling requirements and required written programs to prevent commingling.

AFIA believes this compliance report reflects an evolving government compliance inspection program, one coordinated between and among the FDA/CVM and state inspection programs under contract to the Federal Government. Anecdotal field reports indicate some inspected facilities were made aware of deficiencies, corrected them on the spot, but showed up as "out of compliance" on reports to FDA.

This report has generated customer and media attention. As for the general media, covering an issue as technically complex as BSE is understandably difficult, especially given the amount of unresolved scientific debate and "urban myth" that has sprung up around the issue. However, media must take a responsible approach to its reporting of this animal health issue—you'll note I did not say "food safety issue." Media must resist the temptation to demonize ingredients, practices, industries and food products. What the public needs is straightforward factual reporting on this issue. There is no room for journalistic shortcuts.

CONCLUSION

AFIA believes the mandate is clear: A marriage of science-based Federal Government and industry proactive measures is the working mechanism to prevent BSE from entering the U.S.

The firewalls, reinforcements and redundancies to ensure prevention include the following:

- FDA/USDA/Customs Service enforcement of import controls on animals, meat products and animal byproducts.
- FDA/CVM's rules prohibiting the feeding of restricted use protein products.
- FDA/CVM in-plant compliance inspections on its restricted use protein products rule.
- APHIS is conducting on-going animal, tissue and brain testing.
- Industry has initiated private third party certification of rendering facilities.
- Industry has initiated private third party certification of feed facilities.
- Industry has initiated livestock sales affidavit programs on livestock feeding.
- Industry has initiated certification to retailers on ingredient, feed and feeding compliance.

These measures are working, and are adequate to control BSE introduction to the U.S. However, vigilance and continued innovation are required as situations and scientific evidence may shift.

Congress can assist these efforts dramatically by insuring that FDA, USDA and other Federal agencies are adequately funded to conduct research, testing and diagnostics development and other necessary research on prevention, detection and containment of this animal disease.

Congress can also assist industry in assuring that public debate over BSE is accurate, measured and fact-based. We must avoid the hysteria that has led to food panics and Europe.

AFIA stands by the joint industry statement issued by 12 animal agriculture and scientific organizations in January of this year.

"(W)e affirm our commitment to effective implementation and enforcement of sound, science-based measure to prevent BSE in the United States. Active surveillance has not revealed a single case of BSE. BSE regulations have a firm scientific foundation. They reflect the wisdom of careful consideration and open debate. Surveillance and enforcement in the U.S. have been vigilant."

And, Mr. Chairman, let me add, industry support and innovation, will continue.

Thank you again for the invitation to appear here today. I'll answer any questions you may have.

Senator FITZGERALD. Thank you very much, Mr. Sellers.

That was exactly 5 minutes. Thank you very much.

I would like to direct this question to Mr. Schroeder. In your testimony you say that the industry has worked with the USDA to protect the public against the risk of contamination from bovine brain and spinal cord. What measures have been taken?

Mr. SCHROEDER. Mr. Chairman, perhaps my colleague Mr. Hodges would like to address it from the packing industry's perspective. Our role from the producers' perspective has been focused

very heavily on the feed ban that has been described significantly here today. We put out a directive very early on when the voluntary program began that we encouraged producers to follow that ban. Since the mandatory ban was put in place, we have made it clear that we support 100 percent compliance in seeing to it that those at-risk feed products do not enter the feeding system for our livestock.

We have taken a number of measures to encourage that activity, including a joint meeting of all industry sectors at our offices here in Washington back in December, the establishment of a joint statement from all sectors that we are committed to 100 percent compliance, and we have continued to encourage both the industry and the regulators to see to it that that is done.

Senator FITZGERALD. Based on Mrs. DeWaal's testimony, I would like to ask Mr. Hodges and Mr. Schroeder if you believe that brains and spinal cords are kept out of the human food supply.

Mr. HODGES. I would be happy to answer that, Mr. Chairman The issue of brain and spinal cords I think can appropriately be addressed as follows. No scientific evidence exists to document that these materials or advanced meat recovery materials present a food safety risk. The reason that they do not present a food safety risk is BSE is not present in this country. Therefore, any products derived from the beef animal are safe.

Furthermore, FSIS requires spinal cords to be removed from raw materials used in advanced meat recovery systems. They are further prohibited from being used to formulate meat food products, primarily because spinal cords are not meat by the regulations. Before we would change any of these regulations to eliminate these products from the food supply, I would suggest that we need a thorough, careful evaluation of what risk, if any, that they present.

Senator FITZGERALD. Would Dr. Lurie or Ms. DeWaal wish to talk about that?

Dr. LURIE. If the question was do brains or spinal cord enter the American food supply, the answer is simply, yes. There are about a million cattle brains a year that are consumed by American consumers. It is legal to buy cow brain and eat it in this country. So the answer is yes.

Now, a subsidiary question is whether or not the advanced meat recovery process, for example, which is supposed to have meat, might have spinal cord in it. Whereas FDA regulations are supposed to preclude it, the empiric evidence as presented both by myself and Ms. DeWaal show that, in fact, on occasion there is spinal cord that does enter into the food chain.

It is no surprise. These processes involve in part the crushing—and this is not supposed to happen with advanced meat recovery, but it does—the crushing of bones, including the vertebral column, such that the contents of the vertebral column, i.e., the spinal cord, could very well enter into the food supply.

Finally, the point I made earlier is that in the processing process or the slaughtering process one might remove brain and spinal cord early the way they do in Europe, but at present that is not the situation in the United States.

Again, the answer to your question is very simply, yes.

Ms. DEWAAL. I would just like to make one further comment. The spinal cord is allowed in products that are not called meat. So for example, in mechanically separated meat spinal cords do make their way into the process.

The issue about advanced meat recovery—we would like to see that stopped. The issue about this issue of spinal cord showing up in the meat and whether it should be allowed is one of a firewall. When the first cow with BSE is discovered in the U.S. is not the time to start making these changes, as we have seen. We have seen success in keeping infected animals out of the U.S. starting in 1980. We have seen success perhaps in keeping—in a feed ban to prevent transmission of the disease to cattle, all of this before we have had our first case identified in the U.S.

I think consumers deserve the same level of protection. Before the first cow is discovered we would like to see additional firewalls to protect the human food supply.

Thank you.

Senator FITZGERALD. Mr. Schroeder, your testimony also discusses a USDA briefing that the National Cattlemen's Beef Association participated in this month. At this briefing, you write that "In addition to the brain and spinal cord, a speaker from the U.K. identified part of the intestine as an animal part that carries the infectious agent for BSE."

Are we taking any precautions with respect to the animal's intestines?

Mr. SCHROEDER. Mr. Chairman, our position all along in this process is that we need to be using the very best available science. I know that there is scientific examination of that issue, are there other beef animal products that we should be concerned with. If the science confirms that, tells us that we ought to be making that change, we would be supportive.

Again, as cattle producers we have to trust the leadership of scientists in this field, both domestically and internationally. By the way, we are putting together a group of qualified scientists and technicians to help us look at a broad range of issues related to BSE so that we can continue to look down the road and be proactive. Certainly this is one of the issues that we would expect to be examined.

Senator FITZGERALD. Mr. Sellers, in your testimony you describe a new voluntary certification system for renderers, feed mills, and related facilities. What do you expect will be the significance of certification?

Mr. SELLERS. Thank you. This is obviously being driven by market requests from customers, purchasers of beef. It is an adjunct program with the government inspection to ensure 100 percent compliance and 100 percent inspections.

Senator FITZGERALD. So, the certification would be that they are 100 percent complying with government requirements?

Mr. SELLERS. Yes, sir.

Senator FITZGERALD. Some purchasers are requesting this?

Mr. SELLERS. Yes, sir.

Senator FITZGERALD. I understand—Mr. Schroeder, again to you. I understand that Federal regulators prohibit the use of animals

showing signs of neurological damage in the human food supply. Are these animals kept out of the animal food chain?

Mr. SCHROEDER. They are. Again, any animals that are presented for slaughter are examined, as Mr. Hodges presented here, by qualified veterinary medicine practitioners to determine whether indeed they are showing any neurological signs that might be related to BSE. When those animals are identified, they are held separately, are examined to determine whether or not they show the post-harvest signs, examining brain and spinal cord tissue, of the disease, and certainly if that were ever confirmed they would not enter either the animal or the human food supply.

I cannot speak with authority, frankly, on other handling of those animals beyond that process. My colleagues might.

Senator FITZGERALD. Mr. Hodges, if you have anything to add?

Mr. HODGES. Any animal that exhibits a nervous system disorder is condemned on ante-mortem inspection. "Ante-mortem" means before slaughter. Those animals are then disposed of outside of the feed and food supply. The Animal Health Inspection Service collects samples, in this case brain samples, from those animals and sends them to the National Veterinary Service Laboratory for analysis.

Those animals that exhibit central nervous system disorders never enter the feed or food supply.

Senator FITZGERALD. Dr. Lurie suggested in his comments that perhaps Congress should move more carefully to control deer and elk meat. Apparently, deer and elk meat is currently exempted from the Meat Inspection Act. Mr. Hodges and Mr. Schroeder, do you believe that deer and elk meat should continue to be exempted?

I guess just yesterday the USDA made some announcement with respect to a deer herd in northern Colorado. Apparently the chronic wasting disease is found commonly in North American deer and elk. I wonder about the wisdom of exempting those meats from the Meat Inspection Act.

Mr. HODGES. Chronic wasting disease has been diagnosed in elk and deer herds, in Wyoming, Colorado, and parts of Nebraska and other domestic herds that have originated from those areas. This question was addressed by the TSE Advisory Committee that looked at the risk posed to consumption of deer, elk, and if association with those animals presented any human health risk.

There is no evidence that chronic wasting disease in these species has had any implications for human health, and the TSE committee essentially said that at this time that they would not take additional actions.

Senator FITZGERALD. Dr. Lurie, I would like to ask you, then, what is the medical basis for your recommendation?

Dr. LURIE. Since I sit on that committee, it is a true statement that the committee could not find any evidence of transmission. Obviously, trans-species transmission of TSE agents has happened. That after all is why we are here today. So there is legitimate reason for concern even if there has not been a documented case.

The committee decided that the risks had not been demonstrated, but the committee did not vote, as I recall it, in any way on whether or not further action was necessary. That was not

something put before us. Many of us were upset to learn from the USDA that, in fact, animals from a CWD positive herd could, in fact, enter into the food supply. The reason for that, as I said, is because there is a lack of compensation for the farmer. So that we are more or less stuck in that position, and that in turn related to the exemption from the Meat Inspection Act.

So I think that this is an area where the precautionary principle certainly applies. Even in the absence of clear evidence of transmission, I think that once you have infected herds then I think you have to take action. No one is saying do not eat deer or elk meat. We are saying do not eat deer or elk meat from infected herds.

Senator FITZGERALD. Well, with that I am going to conclude this hearing. I want to thank the panelists both from the first and second panel. I think this has been a very good hearing and I appreciate all of you coming forward. I look forward to working with all of you in the future and compliment you on your interest and expertise. Thank you all very much.

This hearing is adjourned.

[Whereupon, at 12:43 p.m., the hearing was adjourned.]

A P P E N D I X

RESPONSES TO WRITTEN QUESTIONS SUBMITTED BY HON. PETER G. FITZGERALD TO STEPHEN SUNDLOF, D.V.M.

Question 1. Is the FDA up to date on inspections of feed mills and renderers to ensure compliance with the regulations concerning meat and bone meal?

Answer. Since issuing its BSE feed rule, FDA and its state partners have conducted 10,725 inspections of renderers, feed mills, protein blenders and other relevant operations. Currently, FDA is completing the remaining initial inspections. In addition, we have begun reinspections of those establishments with compliance deficiencies found during their initial inspection. FDA will take, as appropriate, enforcement actions. FDA is on schedule to complete all initial inspections and currently identified reinspections by the end of fiscal year 2001.

FDA and the United States Department of Agriculture (USDA) will continue to aggressively enforce their regulations and to work closely with those in the cattle and feed industries to minimize the risk of BSE introduction or spread in the United States (U.S.) cattle herds. FDA will develop new guidance and regulations as the scientific knowledge about BSE expands.

Working together with many counterpart agencies in the U.S. and around the world and with various industry and consumer groups, FDA will continue to do its best to protect the health of Americans and American cattle herds.

Question 2. What steps have you taken to work with state veterinary and agricultural agencies to prevent outbreaks of BSE or Foot and Mouth Disease?

FDA continues to work closely with USDA, state agricultural and veterinary agencies on implementation of the BSE regulation and on controlling imported products that might introduce BSE into the U.S. States have conducted approximately 80 percent of the inspections under the BSE regulation. USDA and FDA have worked closely to develop import alerts that ensure all animal products that might contain the BSE agent are identified and listed in the alerts/bulletins and are prevented from entering the U.S.

FDA has conducted two conference calls open to all 50 states including state veterinary and agricultural agencies in January and April to discuss the BSE issue. Both FDA and USDA participated in the call. FDA has met with the National Association of State Departments of Agriculture and American Association of Feed Control Officials to discuss FDA regulation on prohibited materials and BSE and other transmissible spongiform encephalopathies and Foot and Mouth Disease (FMD). FDA conducted one seminar on feed issues including BSE and FDA regulations during the week of May 1st in Texas and will conduct another seminar during the week of May 14th in Minnesota. It is expected that 100 feed control officials from all 50 states will attend the two seminars.

FDA has jurisdiction over a number of products that could potentially initiate or exacerbate an outbreak of FMD in the U.S. FDA resources for this issue would be focused on regulating those commodities over which the Agency has direct authority. That would most likely include animal feed (and possibly human food) products contaminated or potentially contaminated with FMD virus. These products may be considered adulterated under the Federal Food, Drug, and Cosmetic Act. FDA will need to carefully consider how its feed-related inspectional resources can best be apportioned between the need to control FMD and the need to prevent and/or control, for example, BSE, a disease that has both significant animal health and human health implications. FDA is working to the best of its ability with USDA to limit importation and movement of such products into and within the U.S. in an effort to prevent or curtail FMD. FDA would coordinate with USDA on BSE, FMD and other animal related issues.

RESPONSES TO WRITTEN QUESTIONS SUBMITTED BY HON. GORDON SMITH TO ALFONSO TORRES

Question 1. What contingency plans does USDA have in place should either BSE or FMD appear in the U.S.?

Answer. USDA's Animal and Plant Health Inspection Service (APHIS) has developed emergency response plans for several highly contagious animal diseases including bovine spongiform encephalopathy (BSE) and foot-and-mouth disease (FMD). Because APHIS officials are currently in the process of updating the specific plan, or redbook, for FMD, we are enclosing a copy of our more general emergency response plan for highly contagious diseases that includes FMD operational guidelines. In addition, we are enclosing a copy of our BSE response plan summary; we are also revising our BSE response plan to include updated surveillance statistics and reflect the new Administration's personnel changes.

Question 2. Are current funding levels for USDA's APHIS adequate to fully implement necessary inspections at ports of entry?

Answer. Due to the recent outbreak of FMD in the United Kingdom (UK), USDA has increased staffing at all U.S. ports handling flights from the UK and other European Union (EU) countries. USDA is also training additional Beagle Brigade teams to assist with inspection efforts. Secretary Veneman has recently authorized the use of an additional $32 million from APHIS' user fee account to hire approximately 350 added APHIS personnel at international air and sea ports to augment our safeguarding efforts during fiscal years 2001 and 2002.

Although we are confident that our port of entry inspection program will successfully prevent the introduction of foreign animal diseases, including FMD, we expect to take additional steps to strengthen surveillance on farms and at livestock markets, zoos, theme parks with designated wildlife areas, swine garbage feeding operations, and wildlife refuges. We are evaluating these activities and related resource needs.

While increased international passenger inspections are covered from the user fee account, we must also intensify our inspections along the Canadian and Mexican borders. No user fees are currently charged for these inspections. We are currently evaluating the need to hire more inspectors and acquire more x-ray machines for these activities. Also, we are evaluating the need to enhance inspections .at high risk cargo ports of entry. There would be costs associated with additional cargo inspectors and canine teams for these port of entry activities as well.

Secretary Veneman has personally contacted officials at the Department of the Treasury to ask for their assistance in our inspection efforts. The Secretary has also requested the Customs Service's continued vigilance in referring travelers who are carrying any agricultural goods with them, or have visited farms in FMD-affected countries, to APHIS port officials for further inspection. In addition, at the local level, APHIS port officials and other state agricultural officials are meeting with Customs and other Federal Inspection Services leaders at high-risk ports to stress the need for a heightened awareness of possible FMD pathways at this time. This is especially true at smaller, less active U.S. ports of entry, where USDA has no presence and relies on Customs personnel to inspect for and confiscate prohibited agricultural items. APHIS also utilizes Customs' electronic data base system to identify import shipments that potentially pose a risk for the introduction of exotic pests or diseases. Customs officials can identify such high-risk shipments according to the tariff codes they are assigned in the electronic data base and flag them for APHIS inspection.

Question 3. What steps have you taken to work with state veterinary and agricultural agencies to prevent outbreaks of BSE or FMD?

Answer. APHIS' Transmissible Spongiform Encephalopathy (TSE) working group cooperates with state veterinary agencies to conduct surveillance for BSE within the United States. As of March 31, 2001, the brains from 12,341 animals in the United States and Puerto Rico had been examined with no evidence of BSE or other TSEs detected. Many state laboratories initially screen brains from rabies-negative cattle for evidence of BSE. In addition, APHIS officials work with state counterparts to provide information and education about this disease.

APHIS officials have been working closely with state counterparts to coordinate exclusion efforts for FMD for 20 years. Over the last 5 years, APHIS veterinarians have been meeting with officials from several states to help plan and discuss the states' responses to any highly contagious animal disease such as FMD. At these meetings, APHIS officials give the states an overview of FMD, USDA's exclusion activities, and USDA's response system and emergency management plans. APHIS has designed, coordinated, and participated with several state agencies in working through a scenario for the initial response to a diagnosis of FMD.

APHIS has assumed a leadership role in the creation of the National Animal Health Emergency Management Steering Committee (NAHEMS), created in 1996. NAHEMS is a joint state-Federal-industry effort to improve the United States' ability to deal successfully with animal health emergencies. These emergencies can range from flood and drought to introductions of deadly foreign animal diseases such as FMD, hog cholera, or African swine fever. In addition to addressing the threat of a major foreign animal disease outbreak, NAHEMS looks at bioterrorism, emerging diseases, and diseases that pose a threat to production and international trade.

By being better able to deal with animal health emergencies, we reduce the threat to the nation's food supply and help maintain the economic well-being of U.S. animal agriculture. Our focus is on four key elements: prevention, preparedness, response, and recovery.

APHIS is also collaborating closely with state officials in their extensive outreach to garbage feeders.

Question 4. Does the Administration believe new restrictions on imported cattle or meat products would substantially help to prevent these diseases?

Answer. We can assure you that one of our highest priorities is preventing these foreign animal diseases from entering the United States, and we have in place a comprehensive set of measures to safeguard the United States from BSE and FMD. Preventive measures have included prohibiting imports of cattle, other ruminants, and ruminant products from countries where BSE is known to exist. USDA import regulations now also cover all ruminant and ruminant-origin products and other rendered animal protein products from Europe.

After FMD was confirmed in southeast England in February, APHIS immediately moved to suspend imports of live ruminants and swine, semen, embryos, and other products from the UK. Fortunately, many of these products were already included in the list of animals and goods prohibited due to concerns about BSE. These FMD restrictions, which are identical to those applied to other countries currently considered affected by the disease, effectively prevent the importation of products susceptible to infection with the FMD virus, such as fresh meat and milk and other ruminant or swine byproducts.

While some products, under certain specified conditions, are still allowed entry into the United States from FMD-affected countries, such products must either have been processed in an approved manner that kills the FMD virus or must be destined for a USDA-approved facility for suitable processing. Importers interested in bringing these products into the United States must first apply for and receive a veterinary import permit from APHIS. To receive a permit, the importer must provide APHIS with government certification from the country of origin attesting to the product's processing. APHIS recently extended these restrictions to cover all EU countries after learning of an FMD case in France. These stringent import restrictions will remain in place for as long as necessary to protect U.S. livestock.

U.S. DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE:

NATIONAL EMERGENCY: RESPONSE TO A HIGHLY CONTAGIOUS ANIMAL DISEASE

EXECUTIVE SUMMARY

This document provides guidance for a response to a highly contagious animal disease and includes a Concept of Operations, Movement Control Guidelines, and Foot-and-Mouth Disease Operational Guidelines.

CONCEPT OF OPERATIONS FOR AN EMERGENCY RESPONSE TO A HIGHLY CONTAGIOUS ANIMAL DISEASE

The goal of an emergency response plan is to detect, control and eradicate a highly contagious disease as quickly as possible to return the United States to free status. A presumptive positive case will generate immediate, appropriate local and national measures to eliminate the crisis and minimize the consequences. A confirmed positive case will generate additional measures on a regional, national and international scale.

During the investigation of a suspect Foreign Animal Disease / Emerging Disease Incident (FAD/EDI), the Foreign Animal Disease Diagnostician (FADD) will use clinical signs, history and professional experience to determine the likelihood of a highly contagious disease (See VS Memorandum 580.4). They will classify the assessment as "unlikely", "possible" or "highly likely".

For "unlikely" and "possible" scenarios, the FADD should at a minimum request that the producers voluntarily quarantine themselves until laboratory results rule out an FAD/EDI. A policy of officially issuing a state quarantine until laboratory results rule out an FAD/EDI should be considered. The following focuses exclusively on the "highly likely" scenario.

When the FADD determines that the condition under investigation is "highly likely" to be a FAD/EDI, the FADD notifies and consults with the AVIC and/or state Veterinarian. The samples submitted to an approved laboratory are considered Priority 1 so that a presumptive diagnosis can be reached in less than 24 hours. Based on the outcome of the consultation, a state quarantine will be placed on the farm; an appropriate movement control zone will be established around the farm (see Appendix 1); the local agricultural and emergency officials will be notified; and all contacts to the farm will be traced.[1] Before leaving the farm, the FADD will work with the producer to institute appropriate bio-security and public health measures, if warranted, and will thoroughly clean and disinfect their clothing, equipment and vehicle. Until a presumptive diagnosis is made, the FADD will not go on any other farms of unknown or negative status. If the presumptive diagnosis is positive, the FADD should not go on another farm of unknown or negative status for at least 48 hours.

If a highly contagious FAD/EDI is classified as a presumptive positive or confirmed positive case the following actions would occur.

Presumptive Positive (Index Case): Clinical signs consistent with an FAD/EDI plus the following: (1) sample is positive (antigen or antibody); (2) other epidemiological information is indicative of the FAD/EDI. Once the laboratory indicates it has positive sample, a cascade of events will occur starting with a conference call between the Laboratory, state Veterinarian, AVIC, FADD, and EMLT. This conference call will outline action steps, some of which are listed below.

The State Veterinarian will:

- Quarantine the affected premises.
- Consider stopping movement of animals within the state.
- Consider active case finding based on suggestive clinical signs in the states to include the field veterinarians, FSIS, Extension Agents, Industry partners, and public awareness campaigns.
- Consider depopulation of affected herd in consultation with USDA, Industry and other stakeholders.
- Determine whether wild animals may be a risk factor in the dissemination or persistence of infection.
- Notify appropriate contacts (such as Commissioner of Agriculture, State Emergency Management Director, and others deemed necessary) that would be needed to support a response.
- Review the operational guidelines for a highly contagious FAD/EDI (see Appendix II, Foot and Mouth Disease Operational Guidelines).
- Identify the joint incident commanders and operations center with local APHIS officials and State Emergency Managers.

The Area Veterinarian In Charge (AVIC) will:

- Notify appropriate contacts that would be needed to support a response (e.g., USDA State Emergency Board, field force and others as predetermined during discussions with the State Veterinarian).
- Prepare to participate in the Joint Incident Command as described in the State Emergency Plan.

The Regional Emergency Animal Disease Eradication Organization (READEO) Director will:

- Notify all AVICs in the region of the presence of an FAD/EDI and traceback findings.
- Give the READEO team members notice to be prepared for deployment.
- Prepare to support the Joint Incident Command in their actions or be Incident Commander in States unable or unwilling to take appropriate actions to control and eradicate the disease.

The USDA, APHIS will:

- Conduct isolation and typing of the highly contagious FAD/EDI agent.
- Initiate National and North American Communication Plans.
- Place National READEO leaders on high alert.
- Alert USDA Crisis Management Staff.
- Activate APHIS Emergency Operation Center.

[1] Trace-backs should be applied for a minimum of 2 times the maximum incubation period before the onset of clinical signs. Trace-forward should be applied up to the time the quarantine is imposed.

• Institute active case finding based on suggestive clinical signs in all States, to include the State Veterinarians, FSIS, Extension Agents, Industry partners, and public awareness campaigns.

Industry will:

• Communicate with their constituencies.

• Support State and National response efforts.

Confirmed Positive Case: Agent is isolated and identified.

The State Veterinarian, AVIC or Incident Commanders will:

• Initiate depopulation and disposal procedures of the infected herd/flock if not accomplished under presumptive positive diagnosis.

• Initiate the process to request a Governor's Declaration of Emergency thus implementing the State Emergency Response Plan.

• Continue quarantine and movement restrictions.

• Continue active case finding.

The State Emergency Management Director/Emergency Management System will:

• Activate the State Response Plan.

• Support local Emergency Management System efforts at the site of the outbreak.

• Request a Governor's Declaration of Emergency.

• Enforce movement controls within the State.

• Evaluate the need for a request for a Presidential Declaration of Emergency thus implementing the Federal Response Plan.

USDA will:

• Notify appropriate Federal agencies of the emergency declaration.

• Consolidate and present the official daily situation report to the Secretary.

• Coordinate the response activities of all USDA agencies to support APHIS and, until Presidential Emergency Declaration, coordinate all requests for the support of other Federal agencies.

• Impose on the affected State a Federal quarantine for interstate commerce and request enforcement by the affected state and adjoining states.

• Identify a source and start evaluating a process of acquiring an effective vaccine.

• Coordinate national surveillance activities.

The Deputy Administrator of Veterinary Services through the APHIS Emergency Management Operations Center will:

• Provide international and national communication on the status of the situation.

• Involve Federal, state and Industry partners in the decisionmaking process with respect to the consequences of the disease on the U.S.

• Designate the Associate Deputy Administrator of Veterinary Services as the National Incident Coordinator.

The Secretary of Agriculture will:

• Declare an emergency or extra-ordinary emergency, if necessary, to release the funds to cover expenses for response activities, including funds for indemnity.

• Call on other Federal Agencies to provide assistance.

• Mobilize Federal agricultural resources to assist the state.

Industry will:

• Communicate with their constituencies.

• Support State and National response efforts.

• Coordinate efforts with State, national and international industry groups.

Presumptive Positive (Secondary Case)—Subsequent investigations which identify an animal(s) with clinical signs consistent with FAD/EDI plus one or both of the following: (1) sample is positive; (2) other epidemiological information is indicative of the FAD/EDI, will be treated as confirmed case.

Glossary

APHIS—The Animal and Plant Health Inspection Service of the USDA responsible for ensuring the health and care of animals and plants.

Area Veterinarian in Charge (AVIC)—the lead Federal Veterinarian for APHIS Veterinary Services in an Area. Nationwide, there are 42 Areas that encompass one or more states.

Case classification:

• Suspect—Animal with clinical signs, which may be consistent with an FAD/EDI.

• Presumptive positive (Index case)—Animal with clinical signs consistent with FAD/EDI plus the following: (1) sample is positive; (2) other epidemiological information is indicative of the FAD/EDI.

• Presumptive positive (Secondary case)—Animal with clinical signs consistent with FAD/EDI plus one or both of the following: (1) sample is positive; (2) other epidemiological information is indicative of the FAD/EDI.

• Confirmed positive—Agent is isolated and identified.

Case Priority Designation—Indicates APHIS response levels, sample handling and testing protocols. Designated 1 to 3 for investigations.

Chief Veterinary Officer (CVO)—The Chief Veterinary Officer of the United States is usually the Deputy Administrator of Veterinary Services.

Emergency Management Leadership Team (EMLT)—consists of VS leaders responsible for animal health emergency management.

Epidemiological information—includes tracing all contacts with affected animals and premises including movements of non-susceptible livestock, humans, fomites, animal products or by-products, crops/grains, feedstuffs.

Foreign Animal Disease Diagnostician (FADD)—a veterinarian who has been through the foreign animal disease training course at Plum Island and receives continuing education in FADs and animal health emergency management.

Foreign Animal Disease/Emerging Disease Incident (FAD/EDI) Investigation—On site assessment conducted by FADDs, as part of the national surveillance program for exotic or emerging animal diseases. The assessment includes: a history of clinical and epidemiological findings, results of physical examinations, necropsy findings, specimen collection and submission to approved laboratory, reporting, initiating appropriate control measures, et al.

Highly Contagious Disease—rapidly spreading from animal to animal as well as herd to herd. Transmission can occur via direct and indirect modes; has above normal morbidity/mortality per unit time; could be based on species or production.

READEO—Regional Emergency Animal Disease Eradication Organization—This is a USDA, APHIS, VS organization that has trained animal health emergency managers and can be mobilized to support and fight an outbreak.

State Veterinarian—the veterinary officer for a particular state or territory of the U.S. in charge of animal health activities.

Appendix I—Movement Control Zones

In the declaration of areas the following factors need to be taken into account:
- Industries involved.
- Environmental factors.
- Livestock movement patterns.
- Processing options (livestock and products).
- Natural vs. artificial barriers/boundaries.
- Nature of the outbreak.
- Livestock species involved.
- Wildlife involvement.
- Effect on non-risk commodities due to intrastate commerce restrictions.

Infected Zone

The actual distance in any one direction for the zone is determined by factors such as terrain, the pattern of livestock movements, livestock concentrations, the weather and prevailing winds, the distribution and movements of susceptible wildlife, and known characteristics of the agent. The infected zone should extend at least 6 miles (10 kilometers) beyond the presumptive or confirmed infected premises.

In this zone:
- Conduct epidemiologic investigation to: Identify trace-ins and trace-outs; Determine source of infection.
- Movement restrictions are in place.
- To leave the zone: No animals or animal products can leave the zone; Vehicles, equipment and people may leave if strict biosecurity procedures are followed; Clean and disinfect; Shower out; Human-to-animal contact policies are dependent on the agent.
- Evaluate the possibility that state authority could depopulate all susceptible animals in this zone.

Surveillance or Movement Control Zone

This zone will surround the infected zone. The exact boundary of the zone will be established to assure containment of the outbreak. Early in the outbreak all movement should be stopped. Once the extent of the outbreak is understood, susceptible livestock can move within that zone with permit but not out of the zone. Non-susceptible livestock or poultry can move within and out of the zone with a permit.

In this zone:
- Conduct active case finding; Increased awareness by of all animal health professionals.
- Conduct surveillance at concentration points.
- Non-susceptible livestock and poultry can move out of the zone but require appropriate bio-security such as C&D of vehicles.

Appendix II—Foot and Mouth Disease Operational Guidelines

Depopulation and Disposal

- Depopulation and disposal operations are linked. If depopulation gets ahead of the ability to dispose of the carcasses, there will be bio-security, animal welfare and pest management issues. Procedure must keep the agent from spreading so it is important that disposal follow euthanasia as soon as possible.
- The preferred method of disposal of carcasses, milk and feedstuff is by burial rather than cremation. Burial is generally easier, quicker, uses fewer resources, and is less polluting. However, several factors, such as topography, soil type, and water-table depth, must be considered in selecting a burial site. Forty-two cubic feet are required to bury 1 bovine, 5 pigs, or 5 sheep.
- Burning, rendering, composting and alkaline hydrolysis are possibilities.

Cleaning and Disinfection

- Remove all organic material.
- Follow label directions.
- Use appropriate disinfectant. Agents that destroy FMD virus include; (See Appendix III): Acids (eg. as acetic acid); Alkalis (eg. sodium hydroxide, sodium carbonate).
- Any disinfectants or pesticides used must be approved by EPA.

Estimated Personnel Requirements

- Depopulation and disposal crew—5 for a heard of 40 per day.
- Vaccination Crew—3 for two herds of 40 per day (consider using farm personnel if the states practice act allows it).
- C&D Crew—3 and only one farm per day.
- Appraisal Crew—1 person can do a variable number of herds per day depending on appraisal process adopted.
- Trace back—1 person can do 1 to 3 traces per day.
- Epidemiological evaluation—1 person can do 1 to 2 per day.
- FAD/EDI Investigation—1 person.

Animal Welfare

- Animals will be treated humanely from the time animals are identified as presumptive or confirmed positive until they are depopulated. When depopulation occurs, euthanasia must be performed as rapidly and humanely as possible. Consideration must be given to the owners and their families and provided with complete explanation of what to expect.
- Lactating animals must be milked.
- Euthanasia will be carried out humanely by chemical, mechanical or electrical means.

Equipment

- Sources of equipment: With a Gubernatorial declaration, all states assets are made available. With a Presidential declaration, Federal assets are made available.

Indemnity and Appraisal

- Title 9, Code of Federal Regulations, Part 53.
- Three independent appraisals, eliminate the lowest and average the highest two.
- Future improvements would explore alternate procedures.

Milk and Milk Products

- Milk from known infected farms is destroyed on the farm.
- Milk from herds not known to be infected could be moved to processing plants within a control zone and processed to eliminate virus and distributed only within control zone.

Meat

- Meat products from FMD exposed animals are not a food safety issue.
- Clinically normal animals may be permitted to be slaughtered and processed. Fresh, chilled and frozen deboned meat and meat products should be marketed only within the infected zone.

Zoologic Parks

- Bio-security plans need to be in place to protect susceptible species.

• If infected, all animals will be placed on daily surveillance with sentinel animals to ensure the zoo is free of FMD before the quarantine is released.

Germplasm Centers

• Semen: FMD may be transmitted by infected semen (virus is shed in semen).
• Embryo Transfer: Follow USDA regulation.

Appendix III—Disinfectants for Foot-and-Mouth Disease—Field Use

Product	Dilution (Percent)	Mixing Instructions	Notes
5.25% Sodium Hypochlorite (NaOCl) (household bleach).	3	Add 3 gallons of chlorine bleach to 2 gallons of water, mix thoroughly.	
Acetic acid[1]	4-5	Add 6.5 ounces of glacial acetic acid to 1 gallon of water, mix thoroughly.	Vinegar is a 4% solution of acetic acid.
Potassium Peroxymonosulfate and Sodium Chloride (i.e. Virkon-S).	1	Follow label directions	Virkon-S.
Sodium Carbonate (soda ash)[1]	4	Add 5.33 ounces of sodium carbonate to 1 gallon of hot water (or 1 pound to 3 gallons of hot water), mix thoroughly.	The solution is mildly caustic, but can dull paint and varnished surfaces.
Sodium Hydroxide (NaOH) (lye)[1]	2	Add 1/3 cup of NaOH pellets (2.7 ounces of the lye) to 1 gallon of cold water, mix thoroughly.	This solution is highly caustic. Use protective rubber clothing, gloves and safety glasses. WARNING: Always add the lye to the water. Never pour the water over the lye.

[1] Section 18 application submitted and EPA approval is pending.

U.S. DEPARTMENT OF AGRICULTURE, ANIMAL AND PLANT HEALTH INSPECTION SERVICE

BOVINE SPONGIFORM ENCEPHALOPATHY (BSE) RESPONSE PLAN SUMMARY

INTRODUCTION

The mission of the U.S. Department of Agriculture (USDA) is to enhance the quality of life for the American people by supporting production agriculture; ensuring a safe, affordable, nutritious, and accessible food supply; caring for agricultural, forest, and range lands; supporting sound development of rural communities; providing economic opportunities for farm and rural residents; expanding global markets for agricultural and forest products and services; and working to reduce hunger in America and throughout the world.

USDA's Animal and Plant Health Inspection Service (APHIS) is responsible for ensuring the health and care of animals and plants. APHIS improves agricultural productivity and competitiveness and contributes to the national economy and the public health. USDA's Food Safety and Inspection Service (FSIS) is responsible for protecting the nation's meat and poultry supply—making sure it is safe, wholesome, unadulterated, and properly labeled and packaged. These two agencies have come together to lead USDA's actions in the prevention, monitoring, and control of bovine spongiform encephalopathy (BSE) in the U.S. livestock and food supply.

The public knows BSE as "mad cow disease," a disease linked to human cases of new-variant Creutzfeldt-Jakob disease (nvCJD). USDA knows BSE as the disease that devastated the livestock industry in the United Kingdom and shattered consumer confidence in Europe. BSE has affected international trade and all aspects of the animal and public health communities. It has called even greater attention to the U.S. Government's accountability for a safe food supply.

No case of BSE has ever been found in the United States. Since 1989, USDA has had a number of stringent safeguards in place to prevent BSE from entering the country. USDA conducts an ongoing, comprehensive interagency surveillance program for BSE. This surveillance program allows USDA to monitor actively for BSE

to ensure immediate detection in the event that BSE were to be introduced into the United States.

Immediate detection allows for swift response. As an emergency preparedness measure, USDA has developed this BSE Response Plan to be initiated in the event that a case of BSE is diagnosed in the United States. The Plan details comprehensive instructions for USDA staff as to who is to do what, when, where, and how in the event that BSE were to be diagnosed in the United States.

APHIS and FSIS have come together to lead USDA's actions in the prevention, monitoring, and control of bovine spongiform encephalopathy (BSE) in U.S. livestock and the food supply.

BACKGROUND

APHIS is responsible for being prepared for potential foreign animal disease outbreaks. The purpose of such preparation is to provide a step-by-step plan of action in the event that a foreign animal disease, such as BSE, is detected in the United States. These plans, often referred to as "Red Books," provide guidance by outlining certain actions that should take place, such as identification of a suspect animal, laboratory confirmation, epidemiologic investigation, and animal and herd disposition activities. Copies of Red Books for specific foreign animal diseases are distributed to agency headquarters and each regional and field office to have in preparation for a disease outbreak.

In 1990, APHIS developed a plan to respond to a confirmation of BSE in the United States. In August 1996, a joint APHIS-FSIS working group updated the BSE Red Book in accordance with current science and research surrounding BSE and the related family of diseases called transmissible spongiform encephalopathies (TSE's). The BSE Red Book is officially entitled *BSE Emergency Disease Guidelines.*

The APHIS-FSIS working group determined that the BSE Red Book, which detailed laboratory and field activities to be carried out in an emergency, needed another component. After the March 1996 announcement by the United Kingdom that BSE was linked to nvCJD, it became apparent to the working group that the Plan needed to address communication issues, both internally within USDA and the Federal Government and externally to the public at large. A confirmed case of BSE would affect such a vast array of stakeholders—consumers, cattle producers, the food animal industry, international trading partners, animal and public health communities, media, and others. Having clear, accurate information readily available would build trust and credibility and facilitate any response measures needed. There needed to be a notification plan. Who was responsible for notifying who, what, when, and how? The Plan needed to identify clear channels of communication as to ensure immediate collection and dissemination of accurate information.

The joint APHIS-FSIS working group became formally known as the *BSE Response Team* and is responsible for the development of this BSE Response Plan. BSE Response Team members represent a mix of backgrounds and expertise, including veterinary medicine, food safety, public health, epidemiology, pathology, international trade, and public affairs. The Team is coordinated by two Team leaders, one each from APHIS and FSIS, who serve as liaisons and technical advisors to their respective agencies on regulations and policies regarding BSE.

Over the past 2 years, the BSE Response Plan has been reviewed, edited, revised, and approved by officials at all levels of APHIS, FSIS, and USDA. The Plan has also been shared with other Government agencies, such as the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the National Institutes of Health (NIH), and other stakeholders, such as the Animal Ag Coalition.

The BSE Response Team monitors and assesses all ongoing events and research findings regarding TSE's. The Team leaders are responsible for ensuring that prevention and diagnostic measures are continually revised and adjusted as new information and knowledge become available.

NOTIFICATION: ROLES AND RESPONSIBILITIES

Surveillance

As part of USDA's surveillance program for BSE in the United States, veterinary pathologists and field investigators from APHIS and FSIS have received training from British counterparts in diagnosing BSE. FSIS inspects cattle before they go to slaughter; these inspection procedures include identifying animals with central nervous system conditions. Animals with such conditions are considered suspect for BSE, prohibited from slaughter, and referred to APHIS for examination as explained below.

Pathologists at APHIS' National Veterinary Services Laboratories (NVSL) histopathologically examine the brains from these condemned animals. In addition, samples are tested using a technique called immunohistochemistry, which tests for the presence of the protease-resistant prion protein (a marker for BSE). NVSL also examines samples from neurologically ill cattle and nonambulatory ("downer") cattle identified on the farm or at slaughter and from rabiesnegative cattle submitted to veterinary diagnostic laboratories and teaching hospitals.

Notification

Because of their responsibility for examining condemned or BSE-suspect animals, NVSL is the organization responsible for activating the notification and BSE response process. It is NVSL that will begin the activation of the BSE Response Plan. From the time a sample is submitted, it takes 14 to 18 days to confirm a diagnosis of BSE In the first 10 to 13 days, pathologists at NVSL have enough information to either rule out BSE or determine the need for additional tests. If it is determined that there is no evidence of BSE, the results are added to the more than 7,500 others that have also been negative. NVSL maintains these data.

If additional tests do suggest a presumptive diagnosis of BSE, an NVSL pathologist will hand carry the sample to the United Kingdom for confirmation. It is at this critical point, when NVSL suggests a diagnosis of BSE and is preparing to send the sample to the United Kingdom, that this BSE Response Plan is initiated. The Plan begins the preliminary notification from NVSL to APHIS.

Preliminary Notification

The director of NVSL is responsible for immediately notifying the APHIS, Veterinary Services (VS) deputy administrator when tests suggest a presumptive diagnosis of BSE.

Once NVSL has made a presumptive diagnosis of BSE, APHIS and FSIS field activities will also be initiated. APHIS will receive notification (either confirming or not confirming NVSL's diagnosis) from the United Kingdom anywhere between 24 and 96 hours. (The international animal health community has recognized the United Kingdom's Central Veterinary Laboratory [CVL] as the world's reference laboratory for diagnosing BSE. Other countries, including Belgium, France, Ireland, Luxembourg, the Netherlands, Portugal, and Switzerland, have all sent samples to this lab to confirm their first cases of BSE.)

NVSL

NVSL will provide all laboratory support in carrying out this BSE Response Plan and serve as the liaison with the CVL. NVSL will prepare its facility to receive and process additional samples from the suspect animal's progeny or herdmates or other suspects. NVSL will also coordinate any other assistance from state or university diagnostic laboratories if necessary.

APHIS, VS Deputy Administrator

Veterinary Services is the animal health arm of APHIS and the program responsible for carrying out field actions in response to BSE. Upon notification of a presumptive diagnosis from NVSL, the APHIS, VS deputy administrator immediately notifies the FSIS, Office of Public Health and Science (OPHS) deputy administrator. APHIS and FSIS deputy administrators will alert the BSE Response Team leaders and instruct them to assemble the BSE Response Team and activate the Response Plan. The VS deputy administrator serves as the liaison between the BSE Response Team and the APHIS administrator The APHIS, VS deputy administrator notifies the APHIS administrator and the VS regional director of the state from which the suspect animal originated.

APHIS Administrator

The APHIS Administrator immediately notifies the USDA Assistant Secretary for Marketing and Regulatory Programs. This immediate notification will be followed by an official informational memorandum from the APHIS Administrator, through the Assistant Secretary for Marketing and Regulatory Programs, to the Secretary of Agriculture. This memorandum will be prepared by the BSE Response Team; a draft is maintained by the Team leaders in the reserved section of their Plans.

The APHIS Administrator is responsible for securing indemnity funds for depopulation of the herd if CVL confirms NVSL's diagnosis.

Assistant Secretary for Marketing and Regulatory Programs

The Assistant Secretary for Marketing and Regulatory Programs, in conjunction with the Undersecretary for Food Safety, is responsible for notifying the Secretary.

The Assistant Secretary serves as the liaison between APHIS and Department-level officials.

Secretary of Agriculture

The Secretary has the authority to declare a Federal emergency if appropriate and approve funding as necessary. Information will be provided to the Secretary up the chain of command from the BSE Response Team.

FSIS, OPHS Deputy Administrator

The OPHS Deputy Administrator, together with the APHIS, VS Deputy Administrator, alert the BSE Response Team leaders and instruct them to assemble the BSE Response Team and activate the Plan. The OPHS Deputy Administrator serves as the liaison between the BSE Response Team and the FSIS Administrator.

The OPHS Deputy Administrator is responsible for notifying the FSIS regional director in charge of the state from which the suspect animal originated.

FSIS Deputy Administrator

The FSIS Deputy Administrator is responsible for notifying the Undersecretary for Food Safety.

Undersecretary for Food Safety

The Undersecretary for Food Safety, in conjuction with the Assistant Secretary for Marketing and Regulatory Programs, notifies the Secretary of Agriculture.

APHIS, VS Regional Director

The APHIS, VS regional director in charge of the state from which the suspect animal originated notifies the VS Area Veterinarian-in-Charge (AVIC) for that state. The regional director is the liaison between VS field staff and the VS Deputy Administrator at headquarters. In addition, the regional director shares all information with the BSE Response Team.

APHIS, VS, AVIC

The VS AVIC, in cooperation with state animal health authorities, is responsible for coordinating the field activities surrounding the emergency response to BSE. The AVIC assembles the local VS staff to initiate activities outlined in the BSE Red Book, including tracing the progeny and herdmates of the suspect animal and beginning an epidemiologic investigation. The VS AVIC coordinates with the State Veterinarian to quarantine the suspect animal's herd of origin. The state has the authority to order a routine quarantine for a neurological disease. The BSE Response Team surveyed every state to determine if they would utilize this authority in the event that NVSL identifies a presumptive diagnosis of BSE. All states responded that they would issue a quarantine.

BSE Response Team

The BSE Response Team leaders will notify each team member and instruct them to assemble in the Situation Room at APHIS headquarters in Riverdale, MD. The Team leaders are responsible for ensuring that all of the Team's duties are fulfilled. It is their responsibility to ensure that the technical information and expert recommendations reach the decisionmakers in a timely fashion. Together with VS' Emergency Programs staff, the Team leaders will obtain APHIS, VS administrative support staff in Riverdale, MD, to ready the room for use as BSE headquarters.

The Team will begin gathering and assembling information from APHIS and FSIS region and field staff. The Team will pull the draft documents from the third section in the Team leaders' manuals and begin filling in current information as it becomes available.

Public Notification

Should NVSL receive notice from CVL confirming a case of BSE, the next level of notification is activated. Each player will follow the same notification protocol as described above for preliminary notification to confirm the diagnosis of a case of BSE.

BSE Response Team

The BSE Response Team will complete the informational memorandum for the Secretary.

The Team will prepare the letter to the Office of International Epizootics (OIE), the international animal health organization, for signature by the APHIS, VS Deputy Administrator. OIE requires that all countries submit official notification within 24 hours of confirming a diagnosis of BSE.

The BSE Response Team and the office of the APHIS, VS Deputy Administrator would coordinate a teleconference to inform all APHIS regional directors and AVICs.

The BSE Response Team and the office of the FSIS, OPHS Deputy Administrator would coordinate a teleconference to inform all regional and field FSIS offices.

The BSE Response Team would coordinate a teleconference to notify other Federal agencies.

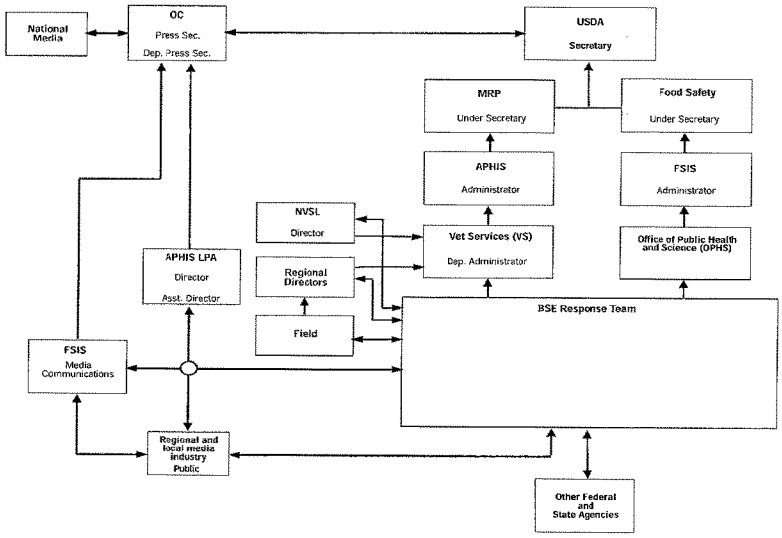
The BSE Response Team would coordinate a teleconference to notify key industry/consumer representatives.

The BSE Response Team and APHIS' International Services would notify foreign embassies.

The BSE Repsonse Team would establish a toll-free 800 telephone line for industry representatives, reporters, and the public.

The BSE Response Team would coordinate with APHIS Legislative and Public Affairs and USDA Office of Communications to issue a press release the day the diagnosis is confirmed. The press release would announce a press conference to be held the morning after the diagnosis is confirmed.

BSE Response Plan Flow Chart



BSE Response Timeline

Presumptive diagnosis of BSE identified (48–96 hours post suspect)		Day 1 Case confirmed	Day 2	Day 3
NVSL Suspect diagnosed	H&E slides prepared and read Immunohistochemistry Hand carried to UK	Diagnosis confirmed in concurrence with CVL, UK		Readiness status to receive and process brain specimens on any herdmates, progeny or other suspects (see BSE Laboratory Testing timeline)
APHIS Field Personnel Routine State Quarantine of herd	Trace progeny Trace adult herdmates Epi-investigation (origoing)	Expand quarantine to include progeny		Complete animal trace out on herdmates and progeny
FSIS ERP, Field Operations Obtain carcass disposition Obtain animal identification/origin information	Trace all food items Trace to rendera	Districts notify all field personnel of confirmation		Complete trace out on brain, spinal cord
BSE Response Team (Riverdale) Assemble BSE Response Team	Update information packet, briefing papers, etc. Obtain funds for depopulation	Confirmation received Statement to Secretary APHIS/FSIS teleconference Government/Industry/ Consumer teleconference Distribute information packet Notify OIE Notify embassies MRP Alert Press Release	Conduct briefings Congressional briefing Press conference	Provide daily/weekly briefing updates as needed Hold daily/weekly conference calls to government agencies and industry Update USDA, APHIS, FSIS homepages Provide daily updates on trade restrictions placed on US Fax updates to APHIS and FSIS field, FAS, NASDA, USTR, and industry groups

BSE Response Plan Checklist

Initial BSE Case

Action	Respnsibility	Date	Progress
Presumptive Dx	NVSL/EP		
Immediate notification to USDA Sec., Undersec., Asst. Secs., Administrators	EP Staff		
Advance notification to key contacts at CDC, FDA, NIH	USDA officials		
If slaughter sample trace to farm of origin	FSIS/APHIS		
Traceout of product if slaughter animal	FSIS, ERP		
Quarantine index herd	VS Area/State	Immediately upon presumptive dx	
Herd epidemiological investigation	VS Area/State	Ongoing while dx confirmed	
Progeny traceouts	VS Area/State	Ongoing	
Movement traceouts	VS Area/State	Ongoing	
Prepare situation room	EP Staff	Immediately after presumptive dx	
Assemble BSE Response Team in Riverdale, MD	EP Staff Chief	Immediately after presumptive dx	
Identify spokespersons and backups	APHIS/FSIS Administrator	During time waiting for confirmation	Completed
Update press releases, info package for APHIS/FSIS offices; info pkg. for industry etc.	EP/BSE Response Team	During time waiting for confirmation	
Designate individual to post and update APHIS home page; designate individual to monitor internet and list servers	EP/BSE Response Team		
Set up phone lines (800 numbers)	EP/BSE Response Team	During time waiting for confirmation	
Confirm Dx	NVSL in concurrence with CVL, England		

After Confirmation

Action	Respnsibility	Date	Progress
Briefing for Sec/Asst. Sec (paper and in person)	Administrators, Communications Liaison		
Provide advance notification to AVIC's/State Vets; NIH, CDC, FDA; Select industry and trading partners (teleconference)	APHIS/FSIS Administrators EP/BSE Response Team	Immediately after confirmation (near end of day)	
Congressional briefing	Asst. Sec., Admin., Spokesperson	After teleconference	
Information pkg. to APHIS, FSIS, State personnel, CSREES, ARS, GIPSA, FAS	EP/BSE Response Team	After teleconference above (at end of day)	
Information to other government, industry contacts —see list (basic info)	EP/BSE Response Team	After teleconference (at end of day)	
MRP Alert	LPA	Day 1	
Information to embassies	EP/BSE Response Team	After teleconference	
Press release to media, press conference, media advisory to APHIS and FSIS employees	LPA/EP/BSE Response Team	Day 2	
Scientific meeting with USDA, CDC, FDA, NIH	EP/BSE Response Team		
Informational meeting for industry, constituent groups	EP/BSE Response Team		
Obtain funds for depopulation	EP Staff		
Disposition of index herd	Area/State personnel		
Disposition of progeny	Area/State personnel		
Notify foreign countries	APHIS, IS/FSIS Int. personnel	Day after confirmation	
Notify all FAS posts	VS prepare for FAS transmission	Day after confirmation	

Ongoing

Action	Respnsibility	Date	Progress
Daily updates on trade restrictions placed on US	APHIS, Chief of Import/Export Staff/ FSIS International		
Prepare daily report of updates current happenings	EP/BSE Response Team		
Prepare daily briefings for Asst. Sec/Sec	EP/BSE Response Team		
Meeting within USDA agencies to examine necessity for further controls	Administrators		