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United States Court Reporter

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8 IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
9 BILLINGS DIVISION

10 RANCHERS-CATTLEMEN ACTION LEGAL FUND,)
UNITED STOCKGROWERS OF AMERICA,)
11 Plaintiff,) CV-05-06-BLG-RFC
vs.)
12) TRANSCRIPT
UNITED STATES DEPARTMENT OF) OF HEARING
13 AGRICULTURE, ANIMAL AND PLANT HEALTH) ON APPLICATION
INSPECTION SERVICE, and MIKE JOHANNNS,) FOR PRELIMINARY
14 IN HIS CAPACITY AS THE SECRETARY OF) INJUNCTION
AGRICULTURE,)
15 Defendants.)
_____)

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17
18 BEFORE THE HONORABLE RICHARD F. CEBULL
UNITED STATES DISTRICT COURT JUDGE
FOR THE DISTRICT OF MONTANA

19
20 James F. Battin United States Courthouse
316 North 26th Street
21 Billings, Montana 59101
Wednesday, March 2, 2005
22 08:17:23 to 11:35:34
23
24

25 Proceedings recorded by machine shorthand
Transcript produced by computer-assisted transcription

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24 REPORTER'S NOTE: "Uh-huh" and "Um-hmm" indicate
affirmative responses. "Huh-uh" and "Hm-umm" indicate
25 negative responses.

4

1 PROCEEDINGS

2 (Open court.)

3 THE COURT: Please be seated.

4 THE CLERK: The Court has set aside this time to
5 hear matter Civil 05-06-BLG-RFC, Ranchers-Cattlemen v. U.S.
6 Department of Agriculture, for an in-court hearing on an
7 application for preliminary injunction.

8 THE COURT: Good morning, ladies and gentlemen.
9 (Counsel and audience responded.)

10 THE COURT: This is the time set for hearing on the
11 preliminary injunction. Under the rules, I did not take the
12 option of, in essence, hearing the case on the merits and
13 taking evidence. This hearing will be limited to a discussion
14 of what was in the briefs. In a case such as this, on a
15 review of an administrative agency, the review is limited to
16 the administrative record.

17 I have advised all counsel this morning that I have
18 reviewed -- I have read every word in every brief that has
19 been filed. I can't say that I've read every word of the
20 entire administrative record that consists, I believe, of
21 around 1,200 pages.

22 What I want to do, keeping in mind that I've read
23 the briefs, I don't want the parties rehashing word for word
24 what was said in the briefs. I'll give both parties an
25 opportunity to make an argument.

1 I have set aside four hours for this this morning.
2 We're in the midst of a criminal jury trial. I have recessed
3 the jury in this case until this afternoon, but I don't expect
4 that the hearing on this preliminary injunction application is
5 going to take four hours. And, of course, I am well
6 acquainted with the law and the requirements of the law, and,
7 in particular, the requirements that are placed on the
8 plaintiffs or the applicants in this case, the people, the
9 group that has applied for the temporary injunction, the
10 showing that has to be made in order for the plaintiff to be
11 entitled to any kind of relief. I am well aware of that law.

12 Having said all that, I will give the applicant, the
13 plaintiff, R-CALF, an opportunity to speak. I'll call on the
14 government. And then the applicant will have a chance to
15 reply.

16 Mr. Edwards, who will speak first on behalf of the
17 applicant?

18 MR. EDWARDS: I will, Your Honor.

19 THE COURT: Very well.

20 MR. EDWARDS: May it please the Court, counsel for
21 the United States.

22 For the record, Clifford Edwards of Billings, along
23 with Taylor Cook and our cocounsel from Washington, D.C., Russ
24 Frye and Will Miller, appear on behalf of the
25 Ranchers-Cattlemen Action Legal Fund, United Stockgrowers of

1 America, R-CALF.

2 We are most mindful, Your Honor, of the Court's
3 admonition that we don't need to devote all four hours to
4 this. We will devote nowhere near that kind of time to our
5 argument. We will be brief and concise.

6 Judge, the importance of issuing this preliminary
7 injunction to the cow/calf-producing industry of the United
8 States cannot be overstated. It cannot be overstressed.

9 We find ourselves confronted with what appears to
10 have been a predetermined result, and the government is
11 stampeding towards opening the gates to the border next
12 Monday, come hell, come high water, come new mad cow disease
13 being discovered.

14 We, for 15 years, as a government, have had a policy
15 of not bringing in cattle from countries that are known to
16 have BSE in their herds. Now we are, next Monday, rolling the
17 trucks. Some 35,000 of them would be required to bring the

18 1.7 million to 2 million head of cattle that are poised to
19 come across the border, poised to enter into our system.
20 We cannot understand -- we implore this Court to
21 stop it with a preliminary injunction, because, Judge, what
22 happened in this country literally on Christmas Eve of 2003
23 when a cow was discovered in the State of Washington to have
24 BSE and that cow was traced back to Canada, it was a sucker
25 punch to the cattle industry in the United States of a

7

1 magnitude that reverberates today.

2 Two of our biggest exporting nations that imported
3 our beef, Japan and South Korea, keep their borders, to this
4 moment, to this day, slammed shut to our beef because of that
5 cow that came from Canada and was discovered to have BSE on
6 Christmas Eve, or the 23rd, I guess it was, of 2003.

7 THE COURT: Have I, have I read somewhere, and I
8 can't say that this is in the administrative record, but have
9 I read somewhere that some kind of an arrangement has been
10 made or is being made that Japan and South Korea are going to
11 reopen their borders for cattle from this country?

12 MR. EDWARDS: I heard -- this isn't in the
13 administrative record, but I did listen to the radio this
14 morning, and, no, they haven't opened them, and there are
15 negotiations going on, but there are absolutely no promises,
16 nor any timetable of opening the borders to either South Korea
17 or Japan.

18 And the very problem is -- and an argument is being
19 made by the United States here that is particularly troubling
20 in logic. We cannot export to Japan, nor to South Korea,
21 because we had BSE, one cow, in our country. Now we're going
22 to open our borders to Canada where we've had two more
23 incidents of mad cow in the last 60 days. It's the 2nd of
24 March. Starting the 2nd of January, we discovered one, and
25 then, a week or ten days later, discovered another.

8

1 THE COURT: How many animals with BSE were
2 discovered prior to the publication of the final rule? And,
3 as I recall, that was in December of 2004.

4 MR. EDWARDS: Yeah, there have been a total of four
5 discovered in Alberta; two after, two before that rule. There
6 then has been the one in Washington additionally.

7 THE COURT: And the one in Washington, that was from
8 Canada in December of 2003?

9 MR. EDWARDS: Yes. Yes.

10 Here is the problem and, under the law, the
11 arbitrary and capricious nature of the government's rule here.
12 We have, with the declaration of Dr. Cox, on pages 5 and 6 of
13 Dr. Cox's declaration, when one examines the situation in
14 Alberta, our neighbor right to the north here, when one looks
15 to the number of head tested, it's about 8,500 head have been
16 tested in Alberta and have come up with four mad cow
17 positives.

18 But what is really significant is in Alberta, they
19 are only testing animals that already show symptoms and signs
20 of BSE. And when we take that out into a general population,
21 Dr. Cox has stated, as a statistician, as a mathematician, we
22 are really translating that result into the type of occurrence
23 or incident occurrence rate like we have seen in countries
24 such as France and Germany which have a significant problem.

25 THE COURT: Doesn't the science indicate that the

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1 tests that are available now to detect this BSE prion are
2 not -- well, it gives false positives if the animal is, in
3 essence, symptom-free? Is that what the science is now?

4 MR. EDWARDS: That it gives false positives?

5 THE COURT: Well, I should say this; that the tests
6 that are available now may not necessarily detect the presence
7 of BSE in an animal if they're symptom-free?

8 MR. EDWARDS: That's correct. That's correct. You
9 may still have the BSE, but it will not detect it in all
10 cases.

11 THE COURT: And the incubation period is long.

12 MR. EDWARDS: A long time. Years.

13 THE COURT: How many years?

14 MR. EDWARDS: I don't know the answer to that.

15 THE COURT: I've seen, in the administrative record
16 and briefs, a figure of ten years. I've seen eight years.
17 I've seen four and a half.

18 MR. EDWARDS: I've seen all of those, too.

19 THE COURT: Is there an established science on, if
20 an animal is exposed to BSE, how long they can have that
21 within them before they develop symptoms?

22 MR. EDWARDS: I don't think that there is an
23 established, scientific answer to that. I think there is
24 disagreement among scientists. And all of the numbers that
25 you described, I have read as well.

10

1 THE COURT: And I'm asking this question because I

2 don't know. I'll be asking some questions today that I think
3 I know the answer to. This one I don't know.

4 Is the science the same when it relates to humans?
5 I mean, can a human consume beef with BSE and not be
6 symptomatic ever, or be asymptomatic, without symptoms, for
7 years --

8 MR. EDWARDS: I think the latter. The latter is
9 correct.

10 THE COURT: -- just as the animals can?

11 MR. EDWARDS: I think that's correct.

12 And the other urgent reason for granting this
13 preliminary injunction and stopping the opening of the gates
14 on Monday, Judge, is once these Canadian cattle come into this
15 country, they disappear into the food chain. We do not, the
16 U.S. government, does not and will not impose a country of
17 origin labeling so that a consumer in America can actually
18 choose, can go to the supermarket and see whether the beef
19 that is in front of them is from the United States of America;
20 grown, raised and slaughtered and fed in the United States
21 versus Canada.

22 So this is why we have such irreparable harm to our
23 industry here. We are not going to know -- no member of the
24 public will have any way to know -- whether their meat in the
25 counter, after this Monday morning rush to open these borders,

11

1 nobody will be able to tell whether they're eating beef that
2 came from Canada, where we have a known problem, or whether it
3 was U.S. beef.

4 The problem that we just cannot stress enough, if
5 you do not enjoin them from opening that border on Tuesday and
6 allow us to have a full evidentiary hearing on the merits of
7 converting it to a permanent injunction, we risk the total
8 devastation of the entire cow/calf, beef-producing industry,
9 because if we open this border and come to a BSE cow or cows
10 in this country, the devastation that we saw to the markets,
11 to the confidence in the public in beef back in December of
12 2003, can never be regained again.

13 THE COURT: Let me interrupt you.

14 You're talking about a full-blown hearing on the
15 merits. Now you don't dispute, do you, that this Court is
16 limited in its review to the administrative record?

17 MR. EDWARDS: No. But what I also think cannot be
18 disputed is it isn't the law, fortunately is not such, that
19 the U.S. can just say, "We are the government. You have to
20 give full deference"; that there is no circumstance, there is

21 no way that any court can stop them. We have cited, of
22 course, the authorities that you can stop them. You have the
23 power, fortunately. That's why we have three branches of
24 government. The Court is the last resort. But you have the
25 power, when you review that record, to stop what was done on

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1 various grounds, arbitrary and capricious.

2 THE COURT: Right, but I think the law is and the
3 case authority is that a Court doesn't have to give deference
4 if, for instance, the final rule is based on unsubstantiated
5 facts, incorrect facts. Now are those the kinds of things
6 that the plaintiff is contemplating as being, in general
7 terms, admissible at what you refer to as a full-blown hearing
8 on the merits?

9 MR. EDWARDS: Yes.

10 THE COURT: Is it a situation where there would be
11 admissible, at such a hearing, evidence other than, oh, say,
12 testimony from competing experts? And when I say "competing
13 experts," I'm talking about government's experts who were used
14 as the basis for the promulgation of the final rule versus
15 yours.

16 MR. EDWARDS: I believe that that -- are you asking
17 me if I am envisioning bringing other witnesses other than our
18 experts?

19 THE COURT: Well, I am just -- I have noticed, in
20 the briefs, a discussion of a full-blown hearing on the
21 merits, and I want to make sure that everybody understands
22 that it is not, it's not a trial where the doors are open and
23 the Court is allowed to make findings of fact and conclusions
24 of law outside the administrative record unless there is a
25 reason that the agency, the USDA, unless there's a reason

13

1 they're not entitled to deference, right?

2 MR. EDWARDS: Right.

3 THE COURT: All right.

4 MR. EDWARDS: That is correct. The --

5 THE COURT: Let me ask you another question before
6 you get there.

7 Is the Court required to consider the economic
8 impact to Canada in making a determination in this matter? Is
9 that an issue for consideration?

10 MR. EDWARDS: I believe not. I think what the Court
11 is to examine is the economic impact and the adverse impact to
12 the beef production industry here in America.

13 THE COURT: Well, let me -- this wasn't covered in
14 the briefs, but under Title 7, United States Code,
15 Section 8301, it states this: "Congress finds that" -- and
16 this is in Chapter 109, Animal Health Protection. It says,
17 "Congress finds that:
18 "(1) the prevention, detection, control, and
19 eradication of diseases and pests of animals are essential to
20 protect:
21 "(A) animal health;
22 "(B) the health and welfare of the people of the
23 United States;
24 "(C) the economic interests of the livestock and
25 related industries of the United States;

14

1 "(D) the environment of the United States; and
2 "(E) interstate commerce and foreign commerce of the
3 United States in animals and other articles."
4 Primarily I want to get the plaintiff view on what
5 (E) means, "interstate commerce and foreign commerce of the
6 United States in animals and other articles." Is it limited
7 to consideration of interests of the United States or
8 countries outside of the United States?

9 MR. EDWARDS: I think certainly you are not required
10 to consider the economic circumstances of Canada. What you
11 have read, I believe, applies to exactly what we're talking
12 about. The commerce, the foreign commerce with South Korea
13 and Japan, has been stopped, and we are risking, by bringing
14 in these cattle from a country with a known BSE problem, we
15 are risking permanently to never be able to open those lines
16 of commerce again.

17 I do not believe that the Court, in any way, has to
18 consider for a moment the economic health of the Canadian
19 industry. The foreign commerce trade is what generates from
20 the United States and goes forward. I believe that's what we
21 are supposed to be considering there. I just cannot imagine
22 that the law would be that somehow a United States federal
23 judge would have to lessen the protection level for United
24 States cattlemen so as to consider Canadian cattlemen.

25 I think this has become a very simple matter, Your

15

1 Honor, and this is --

2 THE COURT: Let me interrupt you for one second.

3 Ms. Olson, as I understand, you'll be speaking on
4 behalf of the government?

5 MS. OLSON: Yes, Your Honor.

6 THE COURT: No, you can sit down. The only reason
7 I'm calling on you is I noticed you're taking notes of some of
8 these questions I ask. Those are some things I'd like you to
9 address, and I'll bet you figured it out, didn't you?

10 MS. OLSON: I did.

11 THE COURT: All right. Good. Thank you.

12 Go ahead.

13 MR. EDWARDS: Okay. I'm going to defer to my
14 cocounsel, Mr. Frye, here in a moment, Your Honor, but this
15 boils down to plain old common sense. I really believe that
16 this injunction must be granted on the basis of common sense.

17 R-CALF has 13,200 direct paying members. There are
18 some 50,000 people with affiliates that are represented before
19 your court today, and these are beef producers, and we beef
20 producers are the lowest rung on the food chain of production
21 in this country.

22 I believe that what has driven this rush to open
23 this border, irrespective of and ignoring the two new BSEs in
24 the last 60 days, is because of the packers, the packers who
25 completely dominate and completely run, in my view, the USDA.

16

1 This is to open up cattle from Canada to cheapen up what the
2 packers have to pay for fed cattle. And with the science that
3 we have now, just using ordinary common sense, it's insane to
4 start bringing in cattle from a country that has got, as
5 recently as 60 days ago and 50 days ago, this type of a
6 problem.

7 We are risking, for the packers to get cheaper
8 cattle, the entire well-being of all cow/calf producers in
9 this country, and that is wrong, and I believe that is why
10 this Court needs to enter this injunction so that this Court
11 can then consider -- and when I say a full-blown hearing, it
12 will be full-blown to hear evidence of experts and cross-exam
13 and direct exams. I think that absolutely has to be done.

14 This is the court of last resort for the cow/calf
15 industry in America, and we ask you to issue that on the basis
16 of what we have put together here, Judge.

17 THE COURT: Does the applicant in this case believe
18 that there is any potential injury to the public interest in
19 granting a preliminary injunction?

20 MR. EDWARDS: No. To the contrary, I think it
21 protects the public enormously, because, like I say, once that
22 Canadian beef gets into the U.S., it disappears. Nobody knows
23 what's Canadian. Nobody knows what's U.S. So I believe it is

24 on behalf of consumers everywhere and the confidence they
25 should have in the meat supply. If this injunction is not

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1 granted, I think legitimately the consuming public is going to
2 be affected adversely because of fears of what might be in the
3 meat, that they don't know where it came from in the counter.

4 THE COURT: Are we accepting today, as we sit here,
5 are we accepting cattle from other countries, foreign
6 countries, with known cases of BSE for import into this
7 country?

8 MR. EDWARDS: I believe we are not.

9 I will ask again that the injunction be granted but
10 would like to turn this over to Mr. Frye.

11 THE COURT: Thank you.

12 MR. FRYE: May it please the Court, I am Russell
13 Frye, also counsel with R-CALF.

14 We're dealing with an unusual kind of problem here,
15 and I think it's important to keep that in mind. The BSE and
16 its human counterpart, vCJD, have no cure. They are
17 invariably fatal. It's an extremely potent, infectious agent.
18 One cow can have 10,000 units of infectivity. That is
19 enough -- a single unit is enough to cause BSE in another cow.

20 THE COURT: Now is that disputed in the science?

21 MR. FRYE: I don't think it's disputed. It's in the
22 government's risk assessment at page 8427. That point is
23 made. It's also not disputed that it's a very persistent
24 infectious agent. You can take a piece of meat, put it up to
25 600 degrees, turn it into charcoal, and it still has

18

1 infectivity in it. So this is a special case, and it demands
2 special precautions.

3 I commend to the Court -- and I know you don't have
4 time for this, but perhaps your clerk will. There is an
5 article that explains very well --

6 THE COURT: I have time.

7 MR. FRYE: -- gives a lot of background, is a very
8 clear summary of all of the science. And the questions you've
9 asked, I think a number of them are answered in that article,
10 and it's an article from the Journal of Food Policy that is at
11 page 1565 of the administrative record.

12 Let me start with the threat of irreparable harm,
13 because I think that's a simpler case, and it's one that
14 Mr. Edwards has covered to some extent already.

15 First of all, I note that the government pointed out

16 that USDA intends to withdraw a portion of the final rule,
17 that which allows imports of beef from cattle that were over
18 30 months of age when they were slaughtered in Canada.

19 THE COURT: That has not -- well, let me ask it this
20 way. It doesn't appear to me that that has officially
21 occurred yet, but to be honest with you, I don't know
22 precisely what needs to be done for it to be official.

23 MR. FRYE: Well, and that was the point I was just
24 going to make, Your Honor. As far as we know, it has not been
25 made official. There needs to be a regulation amending the

19

1 current rule that's signed by the appropriate official at USDA
2 and published in the Federal Register. That has not happened,
3 and, at a minimum, no matter what else you do, Your Honor, you
4 ought to enjoin the portion of the rule that the USDA has
5 already said should not go into effect.

6 But that's just a small piece of the problem. The
7 economic effects are described by the government's own
8 studies, and so there's no question about this. They
9 estimate, if you're just looking at the under-30-month market,
10 about \$2.5 billion worth of damage to the cow/calf producers.

11 On the other hand, they predict about an
12 \$11-million-a-year benefit, and we've got to ask, why are we
13 risking the export markets, the health of the U.S.
14 cow/calf-producing industry, for a projected benefit of only
15 \$11 million a year?

16 Now USDA assumes that there's not going to be any
17 effect on the foreign market, but you can't just explain away,
18 you can't just assume away problems where we have real world
19 experience that is contrary to that, and that's a consistent
20 theme that we have in a number of USDA's answers to R-CALF's
21 position.

22 I'll try to skip over some of this to save some
23 time.

24 Let me mention, we talked about the injury, the
25 economic injury, but there's also a threat of injury to --

20

1 THE COURT: I don't want any of you to feel that
2 you're pressed for time. I've got, I've got all morning.

3 MR. FRYE: Thank you, Your Honor. I appreciate
4 that.

5 THE COURT: I mean, I don't want you rehashing
6 material over and over, but if you feel you need to say
7 something, I don't want, I don't want anybody to think that

8 we're going to be done here in 15 minutes.

9 MR. FRYE: (Nodded head affirmatively.)

10 Well, let me talk a little bit about the risk to
11 health of cattle and health of consumers.

12 The economic impacts that I mentioned just now,
13 Mr. Edwards was talking about, those are really independent of
14 whether there is any future infection of cattle or any future
15 infection of humans. The case we have in Washington State
16 didn't result in any infection in humans or cattle that we
17 know of, but it had devastating effect on our import markets.

18 But there is a real risk to cattle and to humans if
19 we begin importing beef and cattle from a country where there
20 is a BSE problem. It's undeniable. USDA would like to assume
21 it away. They include many statements from their experts
22 saying, "We did a thorough risk assessment, and there is very
23 little chance of BSE entering the United States." Well, it's
24 already happened.

25 They make reference to a -- they say, "We rely on

21

1 the Canadian risk assessment, and we have a lot of faith in
2 what the Canadians did." Well, let me put a quotation up from
3 that Canadian risk assessment.

4 Basically, again, the defendants point out that they
5 relied on this and that the Canadians are reliable. Well, the
6 Canadian risk assessment predicted that there was only a
7 .7 percent chance of BSE even occurring in Canada. But we
8 know that's not true, and saying, "We're therefore relying on
9 that risk assessment to conclude that there is no risk," is
10 illogical. And the Court does not have to give deference to
11 conclusions that are not -- do not make common sense or that
12 are contrary to the facts.

13 The other interesting thing is, the Canadian risk
14 assessment -- this is the part they don't tell us about --
15 also says, "If BSE was introduced," and this is the last line
16 down there, "If BSE was introduced, the consequences would be
17 extreme." So that's the reality, is that we have had BSE
18 introduced in Canada, the consequences have been extreme, and
19 no amount of saying that a sophisticated risk assessment shows
20 that that's not going to happen makes that not true.

21 Mr. Cox, in his supplemental declaration, explained
22 again how the fact that you've already found four cattle when
23 you've only tested 8,500 is a pretty clear indication that
24 there are more out there. So there is a high probability that
25 if we begin importing up to 2 million cattle from Canada in

1 the next year, that BSE will come into the country.

2 Now there are various levels of protection to
3 protect U.S. cattle and protect U.S. consumers. R-CALF
4 doesn't deny that. However, USDA doesn't deny that there are
5 limits to those protections, that they're not complete.

6 Let's just say, for example, what happens if a cow
7 comes into the United States that has BSE, is under 30 months
8 of age. So when it's slaughtered, you don't have to remove
9 the brain, and you don't have to remove the spinal column.
10 Under the USDA's own regulations, those materials can be used
11 for food. So while it's true that most cattle don't show
12 signs of BSE until over 30 months of age, we have pointed out
13 numerous examples where cows have actually had outward signs,
14 had sufficient infectivity that they were falling over when
15 they were under 30 months of age.

16 THE COURT: Now that is not the case, though, in
17 Canada. It's Japan. Was there some other country where there
18 was BSE detected in cattle under 30 months of age?

19 MR. FRYE: Your Honor, there have been about 20
20 cases, I believe. There have been several in Japan, and there
21 have been a number in Europe. The government says, "Well,
22 that's really a special case, because the level of infection
23 is much higher in Europe, and, therefore, the chances are that
24 those animals got a really strong dose when they were young
25 and developed the infection soon."

1 In Japan, on the other hand, we've only found
2 about -- they've only found maybe 14 cases of mad cow disease
3 in Japan, and yet a significant portion of those have been
4 under 30 months.

5 And in any event, we know that the disease is
6 progressing from the time of presumed exposure at an early age
7 until the calf/cow can't stand up any longer, so there is
8 going to be BSE infectivity in the brain, the spinal column,
9 so forth. Those things are not excluded from the food supply,
10 and USDA can't tell us how great the risk is that someone will
11 be infected from that. We do know what the risk is, if
12 someone is infected, of dying. It's 100 percent.

13 The government, the United States, and it's cited in
14 our brief, had a working group with Japan to try to evaluate
15 these issues, and they issued a report that said, "We don't
16 know. We don't have enough information to conclude what the
17 risk is from consuming tissue that has these lower levels of
18 infectivity that aren't yet to the point where there are

19 outward signs in the cattle of being infected with BSE."
20 THE COURT: Let me ask you this. I talked with
21 Mr. Edwards about how long this -- and I think the proper term
22 is "prion"?
23 MR. FRYE: "Prion," I believe.
24 THE COURT: "Prion."
25 If a person ingests material that is

24

1 BSE-contaminated, and I think at least your position is they
2 can be asymptomatic for a long time like a cow.
3 MR. FRYE: (Nodded head affirmatively.)
4 THE COURT: Once a human becomes symptomatic, is
5 there a recognized period of time that they are symptomatic
6 before it is indeed fatal and kills them?
7 MR. FRYE: No, Your Honor.
8 THE COURT: Short period of time? Long period of
9 time? What is it?
10 MR. FRYE: Some experiments are being done right now
11 that show a little promise in Europe for some drugs that may
12 postpone or even cure the disease, but at the present time,
13 there is no cure. Once you have it in your system, you're
14 going to die, and it's just a question of when.
15 In humans, there is a longer period, I think, when
16 you show outward signs before you die, and in cattle it's
17 usually, you know, only a few months or less. In humans, you
18 know, some of the cases have suffered for months and years in
19 a degenerative state.
20 We've talked a little bit about this, and, Your
21 Honor, you pointed out you are limited to the administrative
22 record for the most part. We cited cases in our motion to be
23 allowed to provide testimony today that describe instances
24 where testimony outside of the record may be appropriate to
25 help the Court understand some of the scientific issues or to

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1 help the Court understand what the agency actually did.
2 We also note that -- you asked the question about
3 how many cases were discovered before the final rule. The
4 third Canadian case was discovered, and that's before the
5 final rule was published but after it was signed, and there's
6 some question about what USDA knew at the time the rule was
7 signed. The fourth case was discovered after the rule was
8 signed.
9 The United States has included in the administrative
10 record information about both of those cases and USDA and

11 Canada's response to those cases, even though they were after
12 the rule was signed. I'm not sure whether that's because the
13 rule-making effect is still continuing, because they say
14 they're going to suspend part of it, or not, but we don't
15 contest inclusion of that information in the administrative
16 record even though it's after January 4, 2005.

17 THE COURT: It would certainly seem relevant.

18 MR. FRYE: It certainly seems relevant to us, Your
19 Honor. And, in fact, we think it's more relevant than the
20 government does.

21 We've also included in the record the inspector
22 general's report which we believe the Court can and should
23 take judicial notice of. It's an official document. It's an
24 agency record. It's also an admission against interest,
25 because it describes how USDA, in this whole question of how

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1 to handle Canadian imports in light of BSE in Canada, was
2 driven by concerns about responding to industry concerns and
3 increasing trade and ignoring its own internal risk
4 assessments or not performing risk assessments before acting
5 to increase imports. And we think in light of that, and we've
6 provided cases that suggest this, the Court doesn't have to
7 give deference to USDA's judgments on these issues because
8 there's evidence that it was considering factors inappropriate
9 under the statute.

10 Let me --

11 THE COURT: Are you going to talk about the OIE
12 standards?

13 MR. FRYE: I will if you would like, Your Honor,
14 sure.

15 THE COURT: I've got some questions that I have, in
16 my reading, I have tried to sort out, and what I need to know
17 is this. It appears to me that there are standards that the
18 USDA follows. Now what I have a question about, at least I
19 want to hear your discussion on it, is were any OIE standards
20 either changed or amended in this final rule? And, if so, I
21 am at a complete -- I don't know what the process is for
22 changing an OIE standard, because I am not -- I don't have the
23 knowledge that I need on how OIE standards are promulgated in
24 the first place.

25 MR. FRYE: I will try to provide a partial answer.

27

1 It is an arcane area that, I confess, I don't completely
2 understand.

3 THE COURT: Then I don't feel near as bad.

4 MR. FRYE: And I hope that we explained it as best
5 we could and that your confusion doesn't stem from the way we
6 presented it.

7 But there is -- first of all, I think we agree with
8 a number of the things that the United States has said about
9 the OIE standards. They are guidelines, but they're
10 guidelines that are accepted around the world, and they are
11 guidelines for what countries believe are appropriate measures
12 to take with respect to trade in meat and animals from
13 countries that have BSE.

14 The OIE guidelines specify maybe like five criteria
15 for what is necessary for a country to be considered minimal
16 risk. The United States doesn't have a native case of BSE, so
17 we're not in this position, but Canada can't be no risk. It's
18 at least got to be a minimal risk BSE country. And the
19 criterion include things like whether they conduct thorough
20 epidemiological studies when they have cases of BSE to try to
21 figure out what the cause was, whether they have surveillance
22 testing of the animals to see if there is BSE in the herd.
23 The criterion that everyone, I think, agrees is not met --
24 well, you also have to have fewer than two or five cattle per
25 year with BSE, and Canada has met that so far.

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1 THE COURT: I guess, in particular, the one that is
2 discussed in the briefs is it appears to me that there may
3 either be or there was an OIE standard that indicated that you
4 had to wait, in essence, eight years after the last case of
5 BSE was confirmed before you could allow importation of cattle
6 from the country that had confirmed cases of BSE. Now was
7 that, was that changed or what?

8 MR. FRYE: No, Your Honor, and you've focused on the
9 key difference between something we well agree on but the
10 difference between what is proposed for Canada and what the
11 rest of the world applies to every other country, and that is
12 that the feed ban has to have been in place and effective for
13 at least eight years, and the reason for that is so that you
14 can get the BSE out of the system, if you will, so the cattle
15 who became infected before there was a feed ban can get out of
16 the system, so that the feed that was contaminated can get
17 used up and out of the system.

18 And the United States proposed to the OIE that that
19 rule should be changed from eight years to five years. And,
20 in fact, I will show you in a moment from the record where
21 they did that. The OIE said, "No, we're not going to change.

22 We're not going to decrease it from eight years to five years.
23 We think it's scientifically justified to keep that rule at
24 eight years."
25 And so we have now USDA saying, "Well, Canada

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1 doesn't meet the OIE guidelines for minimal risk region, but
2 those are just guidelines, and we think because of these other
3 measures that Canada has in place, that there is sufficient
4 protections overall with the entire program that Canada has
5 that we don't really need the eight-year feed ban."

6 Well, there are a lot of responses to that. Number
7 one is, until the rest of the world agrees, we're going to be
8 the ones saddled with Canadian beef and cattle that nobody
9 else wants because it doesn't comply with the OIE guidelines.
10 The second answer is, we've got recent experience to show that
11 eight years is necessary. We have a Canadian cow born after
12 the feed ban with BSE.

13 THE COURT: Which was 1997?

14 MR. FRYE: It was August of 1997, is when it was
15 enacted, but when we look at the explanations for this latest
16 Canadian cow, it's clear that the government doesn't believe
17 it was effective then because the government believes there
18 was still feed in the system available for cattle that had
19 potential to be infected with BSE.

20 Let me show the Court and everyone else something
21 else here. Your Honor, you asked about how long is the
22 incubation period in animals, and there is a lot of confusion
23 about that. Some of it is because scientists are still
24 uncertain. You have to speculate to some extent when a cow
25 first got exposed to guess how long it took for it to develop

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1 outward symptoms.

2 But what the United States said in this Federal
3 Register notice is that the mean value is 4.2 years; and 7.5
4 years, which is the time back to August of 1997, that ought to
5 be the 97th percentile of the incubation period. So pretty
6 much anybody exposed prior to the feed ban in August 1997,
7 those cattle ought to have shown clinical signs by now.

8 So that's, that's their explanation. Now they don't
9 really explain why it was okay to go to five years for the OIE
10 guidelines, but they say, "Well, okay. Canada has had seven
11 and a half years. That ought to be sufficient because of the
12 gestation period." And you can see other examples here from
13 the Federal Register or from the defendants' opposition where

14 they say it's about four years, is how long it takes for a cow
15 to get BSE.

16 And if we could move the document up on the page
17 just a little bit?

18 THE CLERK: (Complied with request.)

19 MR. FRYE: The very last paragraph is the citation
20 that talks about what I explained earlier, that APHIS asked
21 OIE to change their guideline from eight years to five years,
22 and the OIE refused to do so. Now that's what they say when
23 they're trying to say, "We don't really need a whole eight
24 years for the feed ban."

25 However, when USDA is trying to explain why we don't

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1 need to worry about cattle that are under 30 months of age, or
2 when we pointed out that every single animal that's been shown
3 to have BSE from Canada had been alive a lot longer than 4.2
4 years when it first showed clinical signs, well, then they
5 come back and say, "Well, 4.2 years, that's the average for
6 other countries. That's not the average for Canada. In
7 Canada, we think the incubation period could be much longer.
8 There, it's generally seven to eight years. So don't worry
9 about the fact that it took six years for the Canadian cattle
10 to get BSE, because that's consistent. It still suggests that
11 they could have gotten BSE exposure prior to the feed ban and
12 it just took them longer to develop outward signs. It didn't
13 take them four years."

14 Well, that is precisely the kind of inconsistent
15 statement that makes a rule-making arbitrary and capricious.
16 When it suits their purpose, they say, "Oh, it really only
17 takes four years, and so the BSE ought to be out of the system
18 in Canada. It's okay to begin importing Canadian cattle."
19 When we point out the facts don't support that, then they say,
20 "Well, that's because the incubation period is really a lot
21 longer than four years." I can't think of a clearer example
22 of arbitrary and capricious rule-making.

23 Now we've heard about the fact that, "Well, Canada
24 has a lot of protections in place, and we're not just looking
25 at the feed ban. We're looking at all of the protections that

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1 they have in place."

2 Well, let's take a look at that. This is -- I'm
3 going to put something up that is information that's all
4 contained in the administrative record and described in our
5 papers about how Canada compares with what the rest of the

6 world is doing.

7 So one of the key things is this SRM removal,
8 removal of specified risk materials. Well, in the European
9 Union, they remove at least the brain, the skull, the eyes,
10 the spinal cord, all of that, on any animal over 12 months.
11 In Canada -- they remove that from all animals they slaughter,
12 all of the cattle they slaughter. Well, in Canada, it's any
13 cattle over 30 months. So clearly that's not a greater
14 protection than the rest of the world.

15 How about testing? In the EU, whenever they have
16 any high risk cattle that can't stand up or that die for
17 suspicious reasons or whatever, they test them if they're over
18 24 months old; not over 30, but over 24 months. Canada,
19 again -- Japan is looking. They're testing every one of
20 those. In Canada, they test -- it's voluntary, but they test
21 some of the cattle that show these signs if they're over 30
22 months of age. Again, this isn't a greater level of
23 protection than the rest of the world.

24 How about testing just of animals to see if there is
25 infection that we haven't -- that hasn't caused outward signs?

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1 And even USDA acknowledges that the available tests now can
2 identify BSE three months before you can see any outward signs
3 of it.

4 THE COURT: Has anybody done any computation of what
5 the percentage of success is in testing cattle that don't have
6 outward symptoms of BSE?

7 MR. FRYE: USDA makes reference to some estimates.
8 I don't think we've ever seen the calculational basis for
9 that, but it all assumes -- there are so many assumptions you
10 have to make because, because of the nature of this, because
11 you're predicting what the chances are of finding an animal
12 you can't see outwardly. But it is -- I think most
13 authorities suggest that if you are focusing on the downers,
14 the cattle that can't walk straight and that kind of thing,
15 that you're 60 to 100 times more likely to find BSE in that
16 animal than in one that doesn't have outward signs of disease.
17 If you just test apparently healthy animals, then how many you
18 find with the disease depends on what percentage are infected;
19 the course of the disease, whether they've got a high exposure
20 recently or a low exposure long ago. And we can't predict
21 those things. All we can say is, you know, if, if it's going
22 to appear sick three months from now, you may be able to find
23 that cow and keep it out of the food chain if you test it
24 today.

25 THE COURT: Now let me ask you this. In the briefs,

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1 there's discussion on the part of both parties about not only
2 the efficacy of testing before an animal becomes symptomatic,
3 but in the discussion, I think, on alternatives under the
4 registry act or something like that, there is the discussion
5 of COOL, or the country of origin labeling, and then there's
6 discussion about allowing private citizens to test cattle.
7 And there's even a mention of, for instance, countries like
8 Japan allegedly agreeing to take or accept cattle for import
9 that have been tested to be BSE-free. Well, it doesn't make a
10 whole lot of sense if the available state-of-the-art tests
11 aren't going to show anything until, at best, three months
12 before symptoms become apparent. Explain that to me.

13 MR. FRYE: I think there are probably several
14 elements to the explanation.

15 One is it's a very serious disease, and we ought to
16 do whatever we can to prevent it and eradicate it, and the
17 tests, the cost of the tests is relatively little compared to
18 the price of the cattle, and so it's a precaution that ought
19 to be taken.

20 Even if only 10 percent of the time you find
21 infected animals and 90 percent of the infected ones pass the
22 test, you've still kept 10 percent of the infected animals out
23 of the food chain, whereas otherwise it would have been
24 100 percent going into the food chain.

25 I think the other thing is, if we're talking about

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1 Canada, is -- I'm sorry. Japan also, according to the
2 published reports, has been talking about only accepting
3 younger animals, younger than 30 months, like 14 to 24 months
4 or something like that. At that point, three months is a
5 significant portion of the progress of the disease, and so it
6 would provide perhaps a more meaningful indication for them,
7 for those cattle.

8 Also, the question of whether to test a target
9 animal, one that you believe has a problem, is a very
10 discretionary, a discretionary question. Somebody has to say,
11 "My cow is not going through the gate right. He seems, she
12 seems to have trouble going through the gate," or, "She seems
13 to have trouble walking." These discretionary judgments are
14 being made by a lot of different people and sometimes under
15 conditions that make it hard to judge some of these things.

16 And so I think -- I can't speak for the Japanese,

17 but I think one rationale for testing all of them and one
18 reason that these other countries test all or many of them is
19 that it eliminates these discretionary judgments about, "Is
20 this really a potentially infected animal or not?" and just
21 says, "Test all of them." And as this chart shows and our
22 documents show, in the EU they test every animal over 30
23 months. In Germany, it's over 24 months.

24 THE COURT: Let me ask. Is the science such, the
25 state of the art such that if you test every animal less than

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1 30 months of age with the state-of-the-art, accepted BSE test,
2 and you remove, at the time of slaughter, all SRMs, is the
3 science such that then you can say there's virtually no risk
4 to consumers, or not?

5 MR. FRYE: We believe that the science doesn't allow
6 you to say that at this stage. We believe that there are
7 still unanswered questions about the risks to consumers.

8 I mentioned earlier that joint U.S./Japan working
9 group that concluded that they couldn't tell what the risk is
10 from subclinical animals affected with levels of prions that
11 can't be detected by current tests.

12 We have relatively recent discoveries of the
13 potential of BSE transmission through blood. They've
14 identified transmission of the human version through blood in
15 transfusions.

16 THE COURT: Is that one of the reasons, or perhaps
17 the reason, why, if you travel, for instance, to Europe, to
18 Great Britain, that if you go in to a blood bank in the United
19 States, they won't accept your blood for transfusion, a
20 donation?

21 MR. FRYE: Yes, Your Honor. You're absolutely
22 right.

23 THE COURT: No, is that the reason or just one of
24 the reasons?

25 MR. FRYE: I'm not a doctor, and I don't know if

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1 it's the only reason, but I know it is a reason.

2 THE COURT: I see.

3 MR. FRYE: I know that your blood is not accepted
4 for donations here in the United States if you've spent time
5 in the UK.

6 And the declaration of Dr. Ferguson also
7 acknowledges that there's additional evidence of possible risk
8 via blood transfusion. It's been demonstrated previously

9 experimentally in sheep. That's at page 11423 of the
10 administrative record.

11 So we know that it's possible to transmit through
12 blood, and, therefore, I think it's just not logical to assume
13 that the only place it can be in the body, in the body of
14 cattle, is in these central nervous system tissues.

15 There's also a problem that we've described briefly,
16 that the removal of the SRMs doesn't completely remove the
17 central nervous system tissue and doesn't eliminate
18 possibility of cross-contamination of the meat.

19 THE COURT: Do we, in this country, allow ruminant
20 blood in ruminant feed now?

21 MR. FRYE: Yes, we do, Your Honor, but the Food and
22 Drug Administration has said we should not and that they're
23 going to do a rule to prohibit that. We pointed that out in
24 our papers. Canada, I think I saw some, some reference that
25 one of the USDA experts said that Canada intends to do the

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1 same thing, but they do not presently. Presently they allow
2 ruminant blood in feed.

3 They also only exclude ruminant protein material
4 from ruminant feed, whereas in these other countries, they
5 keep it out of all animal feed so there is no potential of
6 misfeeding on the farm or of cross-contamination of the
7 equipment used to make the feed.

8 So just to dispose, to finish with this chart for a
9 moment, although Canada -- USDA says we don't have to worry
10 about the fact that it's been less than eight years that
11 they've had a feed ban and much less than that that the feed
12 ban has been effective, apparently, because Canada has all
13 these other, more robust protections against BSE, if you look
14 at what they're doing, it's less than what the rest of the
15 world is doing, and to suggest that now we're going to pave
16 the way and convince the OIE and the rest of the world that
17 that's okay is just speculation and not an appropriate basis
18 for rule-making.

19 Let me return to a question you were asking, or you
20 mentioned comments about voluntary testing as a possible means
21 to mitigate some of these economic impacts from concern about
22 BSE in meat from Canadian cattle. Mr. Edwards mentioned
23 country of origin labeling as another way of allowing
24 consumers, if they're worried about BSE-contaminated meat from
25 Canada, to deal with that problem.

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1 We believe those are appropriate. We believe it's
2 un-American to tell the U.S. industry that they can't test for
3 BSE if that's what the customers want. And, most importantly,
4 for these purposes, USDA's response to those comments was
5 either insufficient or nonsensical, because in response to
6 country of origin labeling, without disputing that it's a
7 mechanism that might mitigate some of these economic impacts
8 on small businesses, the answer is just, "Well, it's not a
9 food safety measure. It's a consumer preference measure."

10 Well, of course. That's the point. It's a consumer
11 preference measure that USDA could require that has a
12 potential to mitigate these economic impacts, and yet it was
13 not even considered in the regulatory flexibility analysis.

14 Similarly with testing. Okay. Testing doesn't
15 catch a whole lot of the cases. It catches some, but the
16 important thing is, if the customers want that, it's illogical
17 for USDA to say, "We're not even going to consider that as a
18 measure to mitigate the economic impact of this rule."

19 THE COURT: Isn't it on the books for September of
20 next year?

21 MR. FRYE: The country of origin labeling
22 supposedly, they say, is going to go into effect in September
23 of 2006. There is some history behind that whole issue that
24 Your Honor may be aware of that makes it unclear whether
25 Congress will actually let that happen as scheduled or whether

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1 the Administration will do it, but, in any event, to say we're
2 going to suffer huge losses for the next year and a half but
3 it's okay because we'll do country of origin labeling in a
4 year and a half, that isn't logical. That's not -- that's
5 arbitrary and capricious action.

6 Let me say one more thing about the feed ban,
7 because I think it's such a central issue and one in which
8 USDA's responses are so contradictory, and that is the stated
9 basis for assuming, in the risk assessment, that the feed ban
10 is going to prevent Canadian cattle from infecting U.S. cattle
11 and it's going to prevent the current BSE cases of cattle in
12 Canada from spreading to other cattle in Canada in the future,
13 the basis for that is the UK experience, and there is, in the
14 Federal Register, a graph that the United States refers to in
15 explaining why it is that the UK experience shows us,
16 demonstrates that the feed ban is effective.

17 And here is a copy of that graph from the Federal
18 Register. But if you look closely at what that graph shows,
19 the X axis at the bottom is year of birth of BSE cases. In

20 1989 is when the UK implemented its feed ban, a comparable
21 feed ban to what we have in Canada and the United States now.
22 I said 1989. I think it's 1988.
23 But in any event, these are all of the cases of BSE
24 in cattle in UK that were born after the feed ban. So, for
25 example, if you look at, let's say, 1990, they had 5,000 cases

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1 of BSE in cattle born two years after the feed ban. Now how
2 does that demonstrate that once you have the feed ban in
3 place, you don't have to worry about BSE in any cattle that
4 are born after the feed ban?

5 And, in fact, it's hard to tell from this chart
6 because the scale is so huge. There are so many cases in the
7 UK. But if we increase the scale, even five, eight, ten years
8 after the feed ban went into effect, they're still finding
9 hundreds or thousands of cases of BSE, in some cases, in the
10 UK from cattle that were born five or more years after the
11 feed ban went into effect.

12 So this doesn't demonstrate that the feed ban
13 removes the risk. Certainly it stops the epidemic from
14 spreading, but it doesn't remove the risk. It doesn't mean
15 that you won't have many animals potentially infected after
16 the feed ban goes into place. And that's logical. We've seen
17 it in this case in Canada most recently. The government says,
18 "Well, you know, there may have been contaminated feed left
19 around from earlier." They acknowledged elsewhere that, you
20 know, inspections, when they inspect feed in Canada, "Well,
21 not much, but maybe 10 percent of the feed samples have meat
22 and bonemeal or have animal protein in them." So the feed ban
23 isn't an automatic, an immediate stop on BSE cases, and it's
24 not a fail-safe on it. It continues.

25 And if we can push the graph up a little?

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1 THE CLERK: (Complied with request.)

2 MR. FRYE: This is just another chart that's in the
3 administrative record, and, in fact, it's in that article I
4 commended to the Court's attention at the beginning from food
5 policy. But this shows just a little more clearly that you
6 have the lower line, the blue line, the BAB, as born after the
7 feed ban, those are all cases of BSE in cattle born after the
8 feed ban. So it's not just an anomaly that we have Canadian
9 cattle born after the feed ban with BSE. It's a likelihood
10 under the very set of data that the USDA says supports its
11 position.

12 I think what I'd like to do is go back and provide
13 maybe a little more answer to a couple of questions that Your
14 Honor asked Mr. Edwards.

15 You asked about whether you're required to consider
16 economic impact to Canada and what the language of the statute
17 means that talks about interstate commerce and foreign
18 commerce in animals and other articles.

19 We contend that Congress intended for USDA to
20 consider the effect on the U.S. industry, the domestic
21 livestock industry, of trade, both incoming trade in animals
22 and products and our ability to trade with our neighbors.
23 That's the congressional intent behind the statute.

24 That doesn't mean that a rule should be based on
25 what's good for the Canadian economy. No matter how much

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1 Prime Minister Martin comes and beats on President Bush,
2 that's not an appropriate consideration for USDA. We think
3 there are some things in the record that indicate, as we
4 pointed out, that that was the type of consideration that was
5 going on, but that is not appropriate consideration under the
6 statute and therefore renders the rule arbitrary and
7 capricious.

8 The verified complaint at paragraph 45 did quote
9 from a portion of Section 8301 and pointed out that it talks
10 about the economic interest of the livestock and related
11 industries of the United States, not the economic interests of
12 the livestock industry in Canada.

13 I've talked about some of the irreparable harm, and
14 Mr. Edwards has as well, that is likely to occur if we
15 suddenly allow the border to be opened to this backlog of
16 Canadian cattle, opened to beef from Canadian cattle, despite
17 the clear incidence of BSE in Canada.

18 They've tested about 8,500 animals in Alberta and
19 found four cases. We've tested about 300,000 in the United
20 States and found zero. There's clearly a difference, and for
21 USDA to act as if that difference doesn't occur, doesn't
22 exist, is, again, arbitrary and capricious.

23 Much of this discussion really has gone to our
24 likelihood of success on the merits, but as the Court is
25 aware, there is an alternative standard for granting a

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1 preliminary injunction in the Ninth Circuit. Where the
2 balance of harm strongly tips in R-CALF's favor, it is not
3 necessary for the Court to conclude that we're likely to

4 succeed on the merits, and I submit, as we've described, the
5 injury to the United States cattle market that will occur on
6 March 7 will be immediate. It can't be undone. You can't
7 close the barn door later, get all of the meat and cattle back
8 up to Canada.

9 And, more importantly, you can't change the
10 perception of our trading partners and of our U.S. consumers
11 that we are letting in meat and cattle from a country that has
12 a BSE problem. And I think the fact that the courtroom is
13 filled with interested parties and reporters and we have TV
14 crews outside, the Court obviously is aware of the fact that
15 this is an issue of public interest.

16 THE COURT: Yeah, it's come to my attention.

17 (Laughter.)

18 MR. FRYE: And again, it's illogical for the
19 government to assume that U.S. consumers will be indifferent
20 to or unaware of the fact that we're now importing animals
21 from Canada, and most of their statements to that effect
22 actually predate the discovery of the two animals in the last
23 60 days with BSE in Canada, which have been widely publicized.

24 So that risk is real. The consequences are
25 irreparable. And the harm from delaying the rule, for the

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1 defendants or for the public at large, is insignificant. The
2 industry, the meat packers, have been dealing with this
3 situation for almost two years now. Nothing precipitous is
4 going to happen on March 7 that we've heard about. Delaying
5 the import of animals and meat from a country known to have
6 BSE for a few more weeks will present insignificant harm and
7 prevent an immediate and irreparable injury, and, therefore,
8 the balance strongly tips in our favor.

9 THE COURT: Let me ask you. When you say "a few
10 more weeks," where do you come up with "a few more weeks"? If
11 I were to grant a preliminary injunction, where do you get "a
12 few more weeks," "a couple weeks," whatever you said?

13 MR. FRYE: I am not sure what I said, but --

14 THE COURT: Well, I'll be able to tell you exactly.

15 MR. EDWARDS: Take it back.

16 MR. FRYE: I will take it back, Your Honor. I
17 should have said "a few weeks or months."

18 THE COURT: You said, "from a country known to have
19 BSE for a few more weeks." What does that mean?

20 MR. FRYE: I'm sorry; I hadn't turned to the last
21 page of my notes, because it did say, "a few weeks or months."
22 We recognize that the Court both will attempt to schedule a

23 hearing on the permanent injunction promptly but also has a
24 very busy schedule, so I didn't mean to suggest it would be
25 resolved in a few weeks, but it certainly will be resolved

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1 promptly, and I don't imagine the Court is expecting it will
2 be anywhere near to another two years before this issue is
3 resolved.

4 And a number of your questions, Your Honor, to
5 Mr. Edwards I took to be inquiring about how full-blown we
6 really expected this hearing to be, and I want to assure you
7 we would be conscious of the Court's time. And as the
8 government suggested, the vast majority of the information is
9 in the administrative record and can be dealt with on papers,
10 and we would just need enough time to help explain some of
11 these highly technical issues to the Court.

12 Thank you.

13 THE COURT: Thank you.

14 Let's take a brief recess, about ten, 15 minutes.

15 THE LAW CLERK: All rise.

16 (Recess taken from 09:32:46 to 09:47:46.)

17 (Open court.)

18 THE COURT: Please be seated.

19 Ms. Olson.

20 I think the plaintiff was done, correct?

21 MR. EDWARDS: Yes, Your Honor.

22 THE COURT: Ms. Olson, you may speak on behalf of
23 the government.

24 MS. OLSON: Thank you, Your Honor. May it please
25 the Court.

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1 I represent the defendants in this case. I'd like
2 to make a few general points and then respond to the many
3 points that plaintiff's counsel raised.

4 The plaintiff is asking defendants here to ignore 20
5 years of scientific research and findings. They are, in
6 essence, saying that they're right and the rest of the world
7 is wrong, that the governments in the rest of the world,
8 including our government, don't care about the health of their
9 citizens.

10 But this rule rests on a bedrock of epidemiological
11 evidence that is derived from consensus of the international
12 scientific community. The agency here is but the handmaiden
13 of science, and it should not be required to turn its back on
14 20 years of scientific literature, data, investigations, and

15 research.

16 The plaintiff doesn't tell us, doesn't tell USDA,
17 anything new. They've already raised, I think, every one of
18 their objections in the comments to the proposed rule, and
19 teams of experts at USDA and elsewhere in the federal
20 government have seriously considered and carefully analyzed
21 those comments, as well as a vast body of all relevant
22 scientific information in the field, and they've reached a
23 scientifically sound conclusion based on that information.

24 The plaintiff would have us rely on a few isolated
25 studies that they've selected that go against the scientific

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1 consensus.

2 THE COURT: Let's talk about the conclusion first.

3 In reading at least the parts of the administrative
4 record that I read and the briefs -- and, of course, in
5 reading the briefs, I made notes. And it seems like the
6 whiter your hair gets, the more notes that you make, for one
7 reason or another.

8 MS. OLSON: I'm sorry; the whiter the what?

9 THE COURT: The whiter the hair gets.

10 MS. OLSON: Oh.

11 THE COURT: The more white the hair gets --

12 MS. OLSON: Oh, the whiter the hair.

13 THE COURT: -- the more notes you need to take.

14 Throughout the material, the government, or the USDA
15 experts, and the studies, like the Harvard-Tuskegee, or
16 whatever it is --

17 MS. OLSON: Right.

18 THE COURT: -- study that was talked about, in
19 formulating or developing this risk analysis, here are the
20 terms that I saw:

21 Very low risk of BSE becoming established or
22 spreading if it's introduced into the United States;

23 Likelihood to be, quote, negligible;

24 Infectious levels of BSE are highly unlikely to
25 develop in Canadian cows under 30 months;

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1 The slight possibility of infection developing in
2 cattle less than 30 months of age.

3 Nowhere did I see a conclusion by an expert, either
4 for the USDA and certainly not for the plaintiff, but nowhere
5 did I see an expert say there's no risk. Did I miss
6 something?

7 MS. OLSON: No, you didn't, because --
8 THE COURT: It looks like there is a risk. Now if
9 it's a slight risk, very low, negligible, highly unlikely,
10 there's a risk, right?
11 MS. OLSON: Right.
12 THE COURT: Well, I remember -- let me ask you this.
13 Do any of the USDA, the APHIS experts, opine that there are no
14 risks, virtually no risks?
15 MS. OLSON: Virtually no -- there is virtually no
16 risk. But zero risk, perfection, is impossible to achieve.
17 THE COURT: I guess that's where I get confused. I
18 haven't made the distinction between "virtually no risk" and
19 "no risk."
20 MS. OLSON: The risk here is so negligible. If we
21 were to adopt zero risk as our standard, not only would all
22 trade stop, I think all beef-eating would stop. If we were to
23 adopt no risk for the standard in our lives, we wouldn't get
24 into the car and drive to work in the morning.
25 The goal of this rule is to stamp out the risk.

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1 There is not zero risk, but there is zero tolerance of risk.
2 And the rule embodies risk mitigation measures, a series. As
3 we've said in the briefs, they're interlocking, reinforcing,
4 risk mitigation measures which taken by themselves are highly
5 effective but taken together do create a virtually
6 impenetrable barrier. I'm not going to say there's
7 perfection, because there always will be imperfections, but
8 the risk here to the public health is negligible.
9 THE COURT: I know that in your briefs, or in your
10 brief and the briefs of the USDA, the point is that you don't
11 have to quantitatively --
12 MS. OLSON: Right.
13 THE COURT: -- assess the risk; in other words, put
14 a number on it. Right?
15 MS. OLSON: Right.
16 THE COURT: But there are portions of the
17 administrative record where a quantitative number was set.
18 For instance, I recall, even with the white hair, I recall
19 .36 --
20 MS. OLSON: Prevalence rate.
21 THE COURT: -- prevalence rate per million head.
22 MS. OLSON: Right.
23 THE COURT: Am I understanding that?
24 MS. OLSON: Yes, you are. You're referring to the
25 prevalence rate that Dr. Cox conjured up, which -- it's a

1 number that's fictional. His number was 5.5 cases per
2 million. And the reason --

3 THE COURT: Did the USDA, or the APHIS, did their
4 experts attempt to conjure up, as you say, a quantitative
5 number?

6 MS. OLSON: I don't know if individuals did that,
7 but the rule embodies their conclusion and their consensus
8 after examining this question and looking at, as you know,
9 reams of studies and scientific information that is the
10 consensus of the international community, and their conclusion
11 is that the risk in Canada is well below the standard for a
12 minimal risk region set by OIE.

13 THE COURT: Okay. Now that raises this question.
14 The final rule was published, if that's a correct term,
15 December of 2004, correct?

16 MS. OLSON: This final rule?

17 THE COURT: Yeah.

18 MS. OLSON: January 4 was the --

19 THE COURT: January 4. Of this year?

20 MS. OLSON: Of this year.

21 THE COURT: Okay.

22 MS. OLSON: 2005.

23 THE COURT: Okay. I thought it was a month before.
24 I don't know why that sticks in my mind.

25 Was there a BSE cow detected in December of 2004?

1 MS. OLSON: In January, on January 2 and 11, these
2 discoveries were confirmed, but neither those cows nor the
3 other two that were discovered would be allowed into the
4 country under this rule, because they're all over 30 months of
5 age.

6 THE COURT: Here is the main question I have. The
7 studies that APHIS experts did that are part of the
8 administrative record, that's part of the science in this
9 case. Did those experts take into account --

10 MS. OLSON: Yes.

11 THE COURT: -- all five head of cattle that have
12 been detected from Canada as having BSE?

13 MS. OLSON: Yes, they did. There are four: May and
14 December of 2003 and then the two this January.

15 THE COURT: Oh, okay. Four. Did these experts take
16 into account the two that were discovered after -- or two days
17 before the final rule was published and nine days afterward?

18 MS. OLSON: Yes. Indeed, the secretary, as a result
19 of these findings, dispatched an investigative team
20 immediately to Canada, and he has delayed the portion of the
21 rule which would allow beef in from cattle 30 months of age
22 and older.
23 THE COURT: I know he said that, but what procedural
24 steps, if any, is the USDA required to take in order to
25 implement that rule? I mean, I haven't seen anything other

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1 than the secretary's comments.

2 MS. OLSON: Yes, Your Honor. Today, I believe, it
3 is being officially announced, or I'm not sure if it's
4 published or announced. I have it written here somewhere, but
5 it is today being officially delayed.

6 THE COURT: That's good enough for me, then.

7 MS. OLSON: (Nodded head affirmatively.)

8 THE COURT: Five or four cases? And the plaintiffs
9 were saying five. Is it four or five? I had it fixed in my
10 mind it was five --

11 MR. EDWARDS: (Nodded head affirmatively.)

12 THE COURT: -- but it's four?

13 MS. OLSON: I think in their reply brief they talked
14 about a Canadian cow that was discovered in 1993, but this was
15 a cow that was imported from Great Britain, and it never
16 entered the feed chain or the food chain. It was destroyed.
17 It can't be considered a cow indigenous to Canada, so it
18 doesn't factor into the risk calculation under any standard.

19 THE COURT: Well, the plaintiff's statistics were,
20 that I heard a moment ago -- and then I will let you talk.

21 MS. OLSON: Oh, no, I'm happy to . . .

22 THE COURT: -- were four cases in 8,500 animals
23 tested. Is that about accurate?

24 MS. OLSON: (No response.)

25 THE COURT: Four cases of BSE in 8,500 animals

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1 tested. Is that about accurate, or is that wrong?

2 MS. OLSON: I have the exact numbers.

3 In 2003, Canada tested 5,727 cows. In 2004, it
4 tested 15,800 cows. And its goal in 2005 is to test 30,000
5 cows. This is way over the OIE recommended level of testing,
6 and, in fact, for the past seven years Canada has exceeded
7 OIE's recommended level of testing, which is 300 tests per
8 5 million adult cattle in the age group of 30 months and
9 older. And I believe Canada tested a broader age group, a

10 higher risk age group, 24 months and older. And this is, I
11 might also add, proportionate to the testing, the surveillance
12 we do in the United States. We have a much bigger cattle
13 population.

14 THE COURT: Right. I understand that.

15 How many BSE cows were -- and is it appropriate for
16 me to use the word "diagnosed"?

17 MS. OLSON: Yes. I think when they manifest these
18 clinical signs --

19 THE COURT: And then they have the test that
20 confirms it. I am going to use the word "diagnosed."

21 MS. OLSON: "Discovered."

22 THE COURT: Okay.

23 MS. OLSON: "Discovered," I guess, is a word that's
24 commonly used.

25 THE COURT: How many BSE-infected cattle were

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1 discovered in 2003?

2 MS. OLSON: Two, in May and December.

3 THE COURT: And then in 2004?

4 MS. OLSON: None.

5 THE COURT: None. And then so far in 2005?

6 MS. OLSON: Two in January, and --

7 THE COURT: How many were tested to give rise to
8 that two? And I know the projection is they want -- "they,"
9 the Canadian government -- want to test 30,000. That's their
10 goal. How many were tested before the two were found?

11 MS. OLSON: Your Honor, may I confer with --

12 THE COURT: Certainly.

13 MS. OLSON: -- USDA and get an accurate number for
14 you?

15 THE COURT: Certainly.

16 (Discussion off the record at counsel table.)

17 MS. OLSON: Thank you, Your Honor.

18 These samples were taken in December, and we don't
19 know how many were tested in 2005. I believe they were --
20 well, because they were samples in December. The number
21 tested in the last 12-month period, from when these were
22 discovered or when these were tested, is 23,000.

23 THE COURT: You mean the last 12-month period
24 from --

25 MS. OLSON: That's what I, yes, that's what I've

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1 been told.

2 THE COURT: In essence, in 2004 up through January
3 of 2005? Or, say, February --

4 MS. OLSON: Right.

5 THE COURT: -- February of 2004 through February of
6 2005? Something like that?

7 MS. OLSON: Right.

8 THE COURT: Well, it seems to me that the plaintiff
9 is arguing that if you quantitate the risk on the basis of the
10 number of animals that have been discovered with BSE on the
11 total number of tests, the incidence is much higher.

12 MS. OLSON: But that's not the way the OIE -- that's
13 not the way it's done under international standards. You base
14 your incidence rate on the four previous 12-month periods. So
15 for Canada, that would run from January 2005 back to
16 January 2004, and you'd have two.

17 THE COURT: Okay. Then let me stop you there. Two
18 out of, let's say, 15,000 or 20,000.

19 MS. OLSON: But these --

20 THE COURT: Is that correct?

21 MS. OLSON: But these are high -- it's a targeted
22 population, and it has been determined -- and these are,
23 again, I'll reiterate, 30 months -- they're more than 30
24 months old, so it's really not relevant to this case because
25 they wouldn't have been allowed in. Their assertion that

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1 these cows pose a risk, they don't pose any risk. They
2 wouldn't ever be here. They wouldn't ever cross the border.

3 THE COURT: I understand, but if, for instance, if
4 you say the quantitative incidence could be two in 2 million,
5 wouldn't that indicate that it's a gut cinch we'd have BSE in
6 this country if the borders were open?

7 MS. OLSON: Well, no. What their expert did, and
8 why I say his numbers are fictional, is he extrapolates the
9 prevalence rate in Alberta, which is a high risk population,
10 and he extrapolates it to the whole population, cattle
11 population, of Canada where there is no BSE. And that's where
12 the difference comes between his number of 5.5 per million
13 versus under OIE standards it would be .36 cattle, cases per
14 million. It's this -- no, I guess --

15 THE COURT: That's the figure that I asked you
16 about.

17 MS. OLSON: Right.

18 THE COURT: That .36 is not the plaintiff's. Theirs
19 is 5.5.

20 MS. OLSON: Right.

21 THE COURT: The .36 is the OIE standard.
22 MS. OLSON: Right.
23 THE COURT: Does that mean that --
24 MS. OLSON: And it has to be over a given year, and
25 they're lumping all four together; or, well, there are two for

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1 a 12-month period, for the last 12 months.
2 THE COURT: And here is the question I had reading
3 it from in both briefs. I saw their 5.5. I saw the OIE which
4 was .36. And I'm asking this question because I really don't
5 know the answer to it. Does that mean that in 3 million head,
6 there's going to be one BSE?
7 MS. OLSON: No.
8 THE COURT: If it's .36 incident rate per a million
9 head, does that mean that in 3 million head, that there's
10 going to be BSE?
11 MS. OLSON: No, because among other things, he's
12 completely -- aside from the fact that none of these cows are
13 in the category that can be imported, he is ignoring all of
14 the other safeguards here which will prevent BSE from becoming
15 established in this country or spreading.
16 THE COURT: Well, I was under the impression that
17 the -- and I may be wrong, and you can correct me if I'm
18 wrong. I'm under the impression that the OIE standard is
19 considered by or was considered by the OIE when this .36
20 incident rate per million was promulgated. I mean, they're
21 saying that that is the incident rate if you follow OIE
22 standards, and I assume that's one of the reasons that most
23 all of the experts say we can't guarantee no risk. Am I
24 wrong?
25 MS. OLSON: You can't guarantee no risk, but OIE

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1 doesn't -- the guidelines do not say that we should not import
2 beef from countries that have BSE. It's the opposite. They
3 say that we should import beef from countries that have BSE,
4 applying their standards under the conditions set forth in
5 their -- I shouldn't say "standards" -- their guidelines. And
6 the guidelines for a minimal risk region say that if you have
7 an incidence rate of fewer than -- it's like -- it amounts to
8 about ten cattle per year, ten infected cattle per 12-month
9 period, for four period -- for four 12 -- consecutive
10 four-month periods, then you come within the minimal risk
11 standard, and then it is safe to import this beef under the
12 conditions that we have set out in the rule. All these other

13 safeguards are in place.

14 THE COURT: But one of the safeguards is this
15 eight-year period where, in essence, you shouldn't import
16 cattle for a period of eight years after the last animal's
17 discovered that had BSE after or subsequent to the feed ban,
18 right?

19 MS. OLSON: Right, and I want to point out that USDA
20 has never said that the mean incubation period for all cattle
21 is 4.2 years. That is the mean incubation period for cattle
22 in the United Kingdom which had a huge epidemic compared to
23 the four isolated instances in Canada. And Dr. Cox improperly
24 applied that 4.2-year incubation period to conclude that these
25 four cows were infected when, in fact, the incubation period

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1 is usually seven to eight years, and animals are typically
2 infected before they're 1 year old.

3 There's a chart in the administrative record at 8341
4 which shows the precipitous decline in the infection rate of
5 cows when they get beyond 1 year. And where a cow with BSE is
6 older, like all four of these, that indicates low initial
7 exposure, and the incubation period would be longer. So that
8 means they would have been infected more than 4.2 years
9 before. And their assumption in applying this mean rate of
10 incubation to determine the date of exposure to BSE in the
11 four cows is scientifically unsound. There is, there is no
12 basis for his method of calculating this, reaching this
13 conclusion.

14 THE COURT: When did the feed ban in Canada go into
15 effect? 1997?

16 MS. OLSON: Yes.

17 THE COURT: Wasn't there an animal discovered with
18 BSE that was born at some period of time after 1977? Wasn't
19 that one of the recent animals?

20 MS. OLSON: Yes. And the feed was, when the feed
21 ban first went into effect, the feed was not destroyed in
22 1997, because at that time there was no BSE in North America,
23 and no need was seen -- there didn't appear to be a risk. So
24 there was a slight lag time, and this cow that was -- the
25 fourth cow that was discovered in late January was born in, I

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1 believe it is, March of 1998. So he's 81 months old.

2 And the plaintiff was talking about how OIE
3 recommends eight years. The feed ban in Canada has been in
4 effect almost for eight years, 7.5, but under OIE standards,

5 it would be inappropriate for us or any country to rigidly
6 apply its eight-year criterion like an item on a checklist to
7 conclude that the exporting country fails to qualify for a
8 particular status just because it doesn't meet that criterion.

9 You're supposed to, OIE says you're supposed to
10 assess whether alternative risk management measures could
11 achieve the same level of protection. And here we have
12 addressed it by lowering the age or preventing cows which are
13 30 months of age and older from coming into the country.

14 So that deficiency in length of the feed ban is
15 addressed through restrictions on the age of the live cattle
16 imported. And seven years actually represents the 96th
17 percentile of the incubation period distribution. I think we
18 pointed that out in the brief. So there is a rational basis
19 for thinking, "Well, maybe we can find some other measure to
20 compensate here." And again, cattle, again, before, that were
21 exposed to feed prior to the ban, are now too old to be
22 imported. All four of these would have been too old to be
23 imported.

24 I wanted to make a second point in my just opening
25 remark, which was -- that was to follow my opening remark.

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1 THE COURT: Before I interrupted you.

2 MS. OLSON: Which, I am perfectly happy to answer
3 questions.

4 But despite all of the doubt that the plaintiff
5 tries to sow here, I think the proof is in the pudding that
6 these risk mitigation measures have been effective because
7 there has never been an indigenous case of BSE in the United
8 States. There has never been an indigenous case of vCJD in
9 the United States or Canada, and we're talking about 25 years
10 here because the first outbreak of BSE was in 1986 during a
11 virtual epidemic in Europe where it was estimated that a
12 million cattle could have been exposed. And through this, up
13 until May 2003, there weren't any restrictions on the imports
14 of Canadian cattle or beef because of BSE, and, nevertheless,
15 throughout this entire period, the safeguards that we had in
16 place here and that Canada had in place have kept these
17 regions disease-free.

18 THE COURT: Let me ask you.

19 MS. OLSON: Um-hmm.

20 THE COURT: I know you say there's never been an
21 indigenous cow discovered. There has been a cow discovered in
22 the United States with BSE in the State of Washington, but it
23 came from Canada, right?

24 MS. OLSON: Right, and it wasn't infected here in
25 the United States. It was infected in Canada, and that's what

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1 I mean --

2 THE COURT: When you say "indigenous," you mean one
3 born and raised here that would have had to have been infected
4 here.

5 MS. OLSON: Right, through our feed chain.

6 THE COURT: Right.

7 MS. OLSON: I'll just address -- they raised a
8 number of points. We talked about Dr. Cox's quantifications,
9 and in that regard, in regard to his prediction that vCJD will
10 come into this country, I also just want to point out that all
11 of the evidence says you don't get vCJD from eating beef. You
12 just get it from eating SRMs, and humans need about 10,000
13 times the level of exposure. There's no -- all the evidence
14 shows that humans need about 10,000 times the level of
15 exposure to get vCJD from a BSE-infected cow. Dr. Cox is
16 assuming a 1-to-1 correspondence, and the scientific evidence
17 does not at all agree with that.

18 THE COURT: Is it established that we have to eat
19 SRMs that are contaminated with BSE before you, as a human,
20 contract BSE, or can the BSE, the meat, be contaminated by
21 BSE, for instance, in removal of the SRMs?

22 MS. OLSON: The only known means of transmission to
23 humans is through SRMs, and that's why SRMs are an effective
24 mitigation measure because --

25 THE COURT: How about -- go ahead, ma'am. I'm

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1 sorry.

2 MS. OLSON: Oh, no.

3 -- because they are the only repository of BSE in
4 cattle, and there is no scientific basis for plaintiff's
5 assertion that muscles and blood and saliva of cattle can
6 transmit BSE.

7 THE COURT: I have to ask, then, this. Why, if -- I
8 have never been to Europe, but if I were to go, I don't know
9 if I would have to spend a certain period of time. I don't
10 know the answer to this. But if I were to go to Europe, go to
11 England, and then -- it's my understanding that -- as I say, I
12 have no idea if there's a standard, how long I have to be
13 there, but if I stay however long their standard says, then
14 when I come back here, I can't donate blood. Is there any
15 truth to that? I mean, I've had people tell me that, that

16 they go in to donate blood, and once it's learned that they've
17 either lived, for instance, for a while in the UK, they're
18 asked that question when they give blood or go in to donate
19 blood and they can't. Is that true?

20 MS. OLSON: No. I believe, and I'm going to look
21 over here for a nod to make sure I'm correct, but if you've
22 visited there for some period of time, I think several months
23 or more between 1980 and 1996, which was the height of the
24 epidemic in the United Kingdom, then you can't give blood.
25 But if you go over now --

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1 THE COURT: Is that --

2 MR. WALSH: I think that's correct. I think there's
3 a time limit, Your Honor --

4 THE COURT: I see.

5 MR. WALSH: -- within which they ask that question.

6 THE COURT: I see. Okay. Well, but it still gives
7 rise to this question. If it's a gut cinch you can't get BSE
8 from blood, why do they have that prohibition in this country
9 of donating blood if you've been over there during that period
10 of time?

11 MS. OLSON: Because what we're saying when we say
12 BSE can't be transmitted through blood is we're talking about
13 the blood of cattle or the muscles of cattle. If you eat, I
14 guess it is, filet mignon or something, you can't get BSE from
15 that, or if you ingest cattle blood. Or I guess they also
16 talk about saliva, that it can be transmitted from cow to cow
17 or from cows to humans through those tissues, through muscle,
18 saliva, or blood. It can't. Cows can't give it to each other
19 that way, and there is no evidence that cattle blood transmits
20 BSE to other cows. There is also no evidence that humans
21 contract vCJD from eating muscle or any other part of the cow
22 other than the SRMs.

23 THE COURT: Well, and, Mr. Walsh, you can answer
24 this. It's fine with me. But is the reason that if you're
25 over in the UK for a certain period of time, and I think

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1 Mr. Walsh indicates from the mid '80s to the mid '90s, is the
2 reason that the blood donation is not taken because of a risk
3 of transmitting BSE?

4 MS. OLSON: Because the person who lived in England
5 might have eaten cow brains or -- you know, they used to eat
6 those things.

7 THE COURT: Okay. But that means, then, that there

8 is at least some scientific evidence somewhere to the extent
9 that has given rise to, I assume, knowledgeable people worrying
10 about the risk where they say if you have been exposed to BSE,
11 if you've, if you've eaten, if you've consumed, during this
12 period of time in the UK, SRMs, then there is a risk of that
13 person transmitting BSE through a donation of blood and a
14 subsequent transfusion?

15 MS. OLSON: That's very possible, but the risk that
16 this rule encompasses is the risk of cows spreading it to each
17 other or humans contracting it from cows, and what you're
18 talking about is human to human, and that would be an entirely
19 different risk assessment. It's just outside the scope of
20 this rule.

21 THE COURT: I'm talking about catastrophic harm if,
22 for instance, BSE got loose in this country.

23 Go ahead, Mr. Walsh.

24 MR. WALSH: Well, Your Honor, the difference is, I
25 think, whatever risk there is in transferring it, the

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1 difference is in the manner of transmission. The blood
2 donation problem is one where that blood is going to be
3 injected directly into the blood vessels of an individual.

4 THE COURT: It's going to be transfused.

5 MR. WALSH: Transfused as opposed to the normal
6 process of ingestion. So I think that's where the scientific
7 studies dealing with blood transmission have focused on the
8 risk of transmission through transfusion.

9 THE COURT: Gotcha.

10 MR. WALSH: It's entirely different.

11 MS. OLSON: And, in fact, it's the same with sheep.
12 These studies -- well, I think the transfusion studies have
13 involved sheep, and there is no evidence that these can be
14 extrapolated to cattle.

15 THE COURT: Gotcha.

16 (Pause.)

17 MS. OLSON: I'm sorry, Your Honor. I just want to
18 figure out what I haven't addressed.

19 THE COURT: No, I've been interrupting you. I know,
20 from when I used to have to stand down there behind that
21 podium, that it breaks your train of thought when some judge
22 interrupts you.

23 MS. OLSON: Well, it's the comments that were made
24 that I'm responding to as well.

25 I've addressed their quantitative -- the points

1 about the quantitative and the quantification.

2 I think we've talked about the feed ban.

3 And they made a few points about surveillance that I
4 would like to respond to. I've pointed out that Canada's
5 surveillance level exceeds the OIE recommended level of
6 testing and has done so for the past seven years.

7 I also want to talk about the fact that they urge
8 the notion that all cattle should be tested, including
9 apparently healthy ones, and you had a number of questions
10 about that. The international scientific community says this
11 is not scientifically justified, and there are two reasons for
12 this. First, the high risk population, testing the high risk
13 population is the most likely to disclose BSE in a herd.
14 Testing of cattle that are healthy is the least likely to
15 produce results. And then, secondly, the testing, mandatory
16 testing of all cattle would produce false negative results,
17 and we do have some numbers on that.

18 The Harvard model did this calculation, and the
19 testing of cattle that don't have any outward symptoms would
20 produce 92 percent false negatives in adults and 99 percent
21 false negatives in young clinically normal cattle. And those
22 are the ones where the infectivity is typically found only
23 in -- well, it is only found in the distal ilium and the
24 tonsils.

25 THE COURT: Now let me interrupt you again.

1 MS. OLSON: Don't ask me what distal ilium is.

2 THE COURT: Well, I know what a distal ilium is.

3 (Laughter.)

4 THE COURT: I used to defend medical malpractice
5 cases. I know exactly what it is. However, I'm not going to
6 ask you that.

7 And maybe you don't know the answer to this
8 question. I'm asking because I don't know. When you talk
9 about 92 percent false negatives, I'm not sure -- I mean, I
10 know what a false negative is, but when, for instance, when
11 the two cattle were discovered that had BSE January 2 and
12 January 11, I think you told me, two days before the final
13 rule and nine days after, or seven, I remember reading they
14 think they have a case of BSE in an animal in Canada. And
15 then there's a certain period of time that goes by before they
16 can either confirm it or deny it.

17 Now was the, as far as you know -- maybe you don't
18 know -- was the preliminary diagnosis made on the basis of

19 clinical symptoms of the animal --
20 MS. OLSON: (Nodded head affirmatively.)
21 THE COURT: -- and then the test, a test, was run,
22 or was it a situation where a test was run on a symptom-free
23 animal, it gave perhaps a false positive, and then some other
24 test or the same test was run that confirmed it or not?
25 MS. OLSON: I believe these were animals that were

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1 displaying clinical signs. Is that --
2 MR. WALSH: I don't know whether they were
3 displaying clinical signs, Your Honor. They were in the
4 targeted population, and they were tested using what is called
5 a quick test or a Bio-Rad test --
6 THE REPORTER: Bio-Rad?
7 MR. WALSH: Bio-Rad, B-i-o hyphen R-a-d.
8 And that gave the preliminary indication that the
9 animals might be positive for BSE.
10 The tissue samples were taken, and then they were
11 run by the Canadian authorities using the IHC test, the
12 immunohistochemistry test, which is the international standard
13 essentially for confirming BSE.
14 THE COURT: Well, we have a lot of drug cases that
15 go to trial in this court. And, of course, I hear testimony
16 about they suspect somebody -- for instance, if they're on
17 supervised release or probation, one of the conditions is that
18 you can't use drugs. And the U.S. probation office is a great
19 operation, and, of course, they do random tests, urinalysis
20 testing, and they use a dip stick. And then if it -- I don't
21 know what color, if it glows or turns red or blue, but then if
22 this preliminary test does something, shows a preliminary
23 positive result, then they have a laboratory test done on the
24 sample. Is that similar to what we're talking about here?
25 MR. WALSH: Yes, sir, it is.

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1 THE COURT: Is there only one recognized definitive
2 test for BSE?
3 MR. WALSH: I think there's a gold standard test. I
4 am not really sure whether it's the only recognized test, but
5 the gold standard test is the IHC test, the
6 immunohistochemistry.
7 THE COURT: And then what test, then, is it -- you
8 know, in the briefs there is discussion about -- and I have no
9 idea of the name of the either private feedlot or the private
10 business of some kind who wanted to run their own BSE tests in

11 their own, apparently, approved laboratories, and the
12 USDA/APHIS said, "No, you can't do it." Now do you know what
13 I'm speaking about?

14 MR. WALSH: (Nodded head affirmatively.)

15 THE COURT: Ma'am? Ms. Olson?

16 MS. OLSON: Oh, I'm sorry, Your Honor.

17 THE COURT: Do you know what I'm speaking about? Or
18 Mr. Walsh, do you know what I'm talking about?

19 MR. WALSH: Yes, sir, I do.

20 THE COURT: Was the test that concern wanted to run,
21 was that test this gold standard?

22 MR. WALSH: I think it was both of the tests,
23 actually. I think it included the gold standard test as well;
24 that they wanted to have, to create a laboratory. It was one
25 plant that I'm familiar with that wanted to create its own

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1 laboratory, and it would run the IHC -- just the screening
2 test. Just the screening test, not the IHC. So they would
3 use this quick test.

4 THE COURT: That the USDA uses, itself?

5 MR. WALSH: The USDA uses it. That test is actually
6 licensed. It's called a veterinary diagnostic test, and it is
7 licensed by USDA under the Virus-Serum-Toxin Act. And in
8 licensing veterinary diagnostic tests of that sort, the USDA
9 can attach conditions to them as well --

10 THE COURT: Are there --

11 MR. WALSH: -- to that license, under which
12 conditions they may be used. That test is licensed for the
13 purpose of surveillance. It's not licensed as a food safety
14 test or as a test to be used on every animal that runs through
15 a slaughter land. So it's licensed for official use as a
16 surveillance and monitoring test.

17 THE COURT: Are there private citizens -- and when I
18 use the term "citizens," I am including feedlots, meat
19 packers, whatever. Are there private citizens or groups of
20 private citizens in the United States who are permitted by
21 APHIS, the USDA, to perform these tests?

22 MR. WALSH: No, sir. No. The tests are not
23 licensed for private use.

24 THE COURT: Why not?

25 MR. WALSH: It's used by USDA in a surveillance

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1 program, in a series of federal and state laboratories that
2 have been, you know, accredited for the tests.

3 THE COURT: Does it take special laboratories?

4 MR. WALSH: Yes, sir, it does. Well, it takes
5 special skill and expertise to run even the quick test and to
6 interpret the results correctly. Absolutely.

7 THE COURT: If a private citizen has the expertise
8 and knows how to use the test, the question is why aren't they
9 allowed to do it? I mean, why aren't they -- why isn't the
10 person, for instance, allowed to test his own cattle?

11 MR. WALSH: Their own cattle? You mean after the
12 slaughter. There is no live animal test, so there is no test
13 available for that.

14 THE COURT: I see.

15 MR. WALSH: I mean, the basic -- there are several
16 reasons why. First, the test is not a food safety test, so
17 it's not -- and it produces -- if it's used on targeted
18 animals, it has a useful and effective purpose. In other
19 words, if the animals are showing signs that are consistent
20 with BSE, if they are animals that are generally older animals
21 or they're actually showing signs of central nervous system
22 disease or have other factors that are consistent, it makes
23 sense to use that test as a screening test on those animals.
24 When that same test is used on younger animals, say fed steers
25 and heifers that may be 18 to 20 months of age, you're going

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1 to produce an exceptionally high false negative rate, or at
2 least a negative rate. You're not going to get any useful
3 information from that test because the animals simply don't
4 have enough time to develop any level of infectivity.

5 You know, when an animal begins to show some signs
6 of clinical disease, then you can expect to find some BSE. So
7 using that test at a point in time when the animal is
8 extremely unlikely, in any population, to exhibit signs of BSE
9 or to have BSE infectivity, you're not using the test for any
10 effective purpose.

11 THE COURT: Okay.

12 MR. WALSH: And it's not yielding any useful
13 information with respect to animal health.

14 THE COURT: Okay. The gold standard is used after
15 an animal is slaughtered.

16 MR. WALSH: (Nodded head affirmatively.) Well, even
17 the rapid test is used after an animal is slaughtered.

18 THE COURT: Yes. Okay. But getting to the gold
19 standard, after they're slaughtered, is the test run on just
20 the SRM or what?

21 MR. WALSH: I think it's usually run on a brain

22 sample.
23 THE COURT: Actually a brain biopsy?
24 MR. WALSH: I think they take a brain stem sample
25 with some sort of a probe that I could not describe for you.

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1 THE COURT: Well, yeah. I am sure it's not as
2 delicate --
3 MR. WALSH: I'm sorry?
4 THE COURT: -- as what I consider to be a biopsy,
5 but will the gold standard detect the presence of BSE in the
6 brain if the animal is asymptomatic?
7 MR. WALSH: If the infectivity is there, I believe
8 it will detect the infectivity; I mean, it would detect the
9 BSE. I can't -- you know, there are animals, I believe, that
10 may not show clinical signs. They may have -- you know, I
11 think there's a certain amount of expertise in whether the
12 clinical signs suggest there is some problem.
13 THE COURT: Right.
14 MR. WALSH: But normally if the infectivity is there
15 in the sample, the gold standard test will detect it. I don't
16 know what the correlation, then, is back to what other signs
17 might have been there to suggest the animal actually had the
18 disease, physical signs.
19 THE COURT: I gotcha. And the point is that the
20 infectivity can be there and not even show up on the gold
21 standard?
22 MS. OLSON: (Nodded head affirmatively.)
23 MR. WALSH: That, I don't know the answer to. I
24 think that --
25 THE COURT: I mean, the prion can be there

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1 without -- or is that wrong?
2 MS. OLSON: When cows are younger, it's there, but
3 it's not at an infectious level, I think.
4 MR. WALSH: I guess it depends on how much
5 infectivity is there --
6 THE COURT: I gotcha.
7 MR. WALSH: -- in the sample as to how much that IHC
8 test will . . .
9 THE COURT: Now is there any difference in the risk
10 level? If an animal has BSE, it has BSE? Is that right or
11 not?
12 MS. OLSON: Not until it starts manifesting the
13 signs. Or I guess two to three months before it starts

14 manifesting the signs is when the BSE reaches levels that are
15 a health risk. So that's the problem with the tests, that it
16 comes up -- it actually leads to a false sense of complacency.

17 THE COURT: And the animal doesn't become a health
18 risk until it starts to exhibit actual clinical signs of
19 infection?

20 MS. OLSON: Yes, it doesn't pose the risk of
21 spreading it to other animals or obviously ultimately to human
22 beings.

23 THE COURT: Thank you.

24 MS. OLSON: Your Honor, the plaintiff produced a
25 chart showing the decline in the rate of BSE in Great Britain

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1 after the feed ban was imposed, and I would like to explain
2 that chart. Because so little was known about BSE at the
3 time, the United Kingdom didn't impose a feed ban when it
4 first discovered BSE. Instead, it did so in 1988 after a huge
5 level of infectivity had begun to circulate. About a million
6 animals were exposed or could have been exposed during this
7 epidemic, so it is very reasonable to expect that infected
8 animals would be born after the feed ban in Great Britain.

9 The key question here is not whether animals were
10 born after the feed ban and contracted BSE, but, rather, what
11 happened after the feed ban was fully implemented. And the
12 dramatic effect of the feed ban is apparent from this chart,
13 and there's another point in the administrative record where
14 we have numbers. It declined from approximately 30,000 cases
15 of BSE in 1988, when the feed ban was implemented, steadily to
16 fewer than 100 cases in 2004. And BSE declined by 90 percent
17 in Great Britain between 1992 and 1997, and the decline would
18 even have been faster except that at the beginning, this was
19 an ineffective feed ban because the United Kingdom was
20 pioneering it. It was an experiment that clearly worked, and
21 as time has gone on, the feed ban has become more and more
22 effective in preventing cross-contamination.

23 THE COURT: Do we accept imports of cattle from the
24 UK?

25 MS. OLSON: No, I don't think we do, cattle or beef.

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1 We do, though, and I want to bring this up, that we
2 have been importing boneless beef from Canada since August of
3 2003 and prior to May 2003. So there is just a window there
4 where we didn't. But, and I think we pointed this out in our
5 briefs, since May 2003 we have been importing boneless beef,

6 and if Canada is considered a BSE country, we have been
7 importing beef from Canada.

8 THE COURT: You know, and I noticed that, and I have
9 to say -- of course, I was the person involved in the
10 temporary restraining order in 2004. I think it was in April.

11 MS. OLSON: Yes.

12 THE COURT: May 5, in essence, the USDA and the
13 plaintiffs stipulated to the imposition of a preliminary
14 injunction that would stay in effect during this rule-making
15 process.

16 But I was not aware of this. I was not aware of
17 this fact. Now I knew that boxed beef was going to continue
18 to come in from Canada, and there's a statement in your brief
19 that says this. This is something that I did not know: "In
20 fact, the United States has continued to import nearly as much
21 Canadian beef since the discovery of BSE in North America as
22 it did before, 96 percent of average beef imports, and there
23 has been no resulting loss of consumer confidence." Now is
24 that, I mean, is that true?

25 MS. OLSON: Yes, it is.

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1 THE COURT: Has the USDA tried to determine, for
2 instance, what percentage of the folks in this country know
3 that there's this much Canadian beef coming in in boxes,
4 96 percent of the total amount that was imported before BSE?

5 MS. OLSON: Well, it's a matter of public record.
6 USDA has complied with all of the public notification
7 requirements, and groups like R-CALF and other interested
8 groups are certainly aware of it. And to the extent the
9 public is in the supermarket, we don't have a labeling
10 requirement yet, but Congress has established that as well.

11 THE COURT: Well, you know, that, that gives rise to
12 this question. If that's, if that -- and I believe you when
13 you tell me, and I believed it in the brief. As I have just
14 indicated, I was taken aback by it because I didn't realize.
15 I didn't realize that the impact on the Canadian beef market
16 was so negligible simply because in reading newspapers and
17 listening to TV and radio, at least from the Canadians, it
18 sounds to be a whole lot worse. But apparently if you are
19 importing -- if we are importing nearly as much Canadian beef
20 since the discovery of BSE in North America as we did before,
21 what's the rush? I mean, what is the rush to get this final
22 rule to implementation? I mean, I have to say that I have
23 difficulty with that question. And when I was reading the
24 brief, I made notes of -- when I saw that, I have an arrow

25 drawn from a note stuck here on the brief saying, "What's the

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1 rush?"

2 MS. OLSON: Well, there isn't a rush, and the fact
3 that we are importing some Canadian beef doesn't mean that we
4 are importing as much as it would be safe to import. There is
5 no reason -- I think the more important question is why delay
6 a rule which is scientifically sound on the basis of
7 speculation and on the basis of the interests of a narrow
8 sector of the domestic -- the economic interests of a narrow
9 sector of the domestic beef industry?

10 THE COURT: Well, you know, I know that's one of the
11 considerations under the statute I cited, the economic
12 interests of the livestock and related industries in the
13 United States. I'm focusing on primarily the health and
14 welfare of the people of the United States.

15 If there is a risk, for instance, and we know there
16 is, however slight it may be, we know that it's not a, we know
17 that it's not a situation where the world's recognized experts
18 can say, "There is no risk. Sit back. Relax." We know
19 that's the situation. For instance, if country of origin
20 labeling is -- and I said "on the books." I probably
21 misspoke. I am thinking in terms of at least it's in the
22 hopper for September of 2006. I know it's the government's
23 position that COOL is not a food safety issue, but what is
24 wrong with giving the private citizens of this country, who
25 this agency is mandated to protect the health and welfare of,

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1 what's the risk of -- I don't know how you mark beef, but
2 putting a stamp on meat saying, "This is Canadian beef," "This
3 is U.S. beef," and allowing the folks, the American consumers
4 in this country, to decide in the grocery store if they're
5 going to buy Canadian beef or U.S. beef?

6 MS. OLSON: Well, the narrower issue or the labeling
7 requirement has been taken care of by Congress, and Congress
8 has mandated a September 1996 effective date.

9 But the larger interest here is that if we abandon a
10 scientifically sound rule, it will give other countries the
11 chance to back off, and it will take all of the pressure off
12 them to reopen their markets. We have an exceptionally strong
13 interest in implementing this rule because it is
14 scientifically sound. It is validly issued. And it is in
15 compliance with the USDA's authority and its international
16 obligations to rely on sound science and not speculation and

17 not the search for economic advantage.

18 THE COURT: Well, if it poses a risk, however
19 slight, to American consumers, what is the exceptionally
20 strong interest in implementing the rule, at least as far as
21 the interests concerning the health and the welfare of the
22 folks in the United States?

23 MS. OLSON: Because, Your Honor, I think I can
24 safely say there will never be a time when there is zero risk
25 of contracting a disease from eating any food and from

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1 contracting BSE from eating beef.

2 The rule is as safe as it could possibly be, and to
3 delay now would, as was referred to earlier, likely impair and
4 interfere with our efforts, which are showing progress, to
5 reopen our markets in Japan. And if the USDA doesn't comply
6 with sound science -- if the United States doesn't comply with
7 sound science, why should Japan? Why should Korea? U.S.
8 exports of animals and products will be more vulnerable to the
9 imposition of scientifically unjustified restrictions, and how
10 can we challenge those restrictions if we don't rely on good
11 science ourselves?

12 THE COURT: Well, in the brief, it's stated thusly,
13 Quote, "The injury to the public interest in granting
14 plaintiff's request to enjoin the rule far outweighs any
15 purely conjectural harm to the plaintiff." What is the
16 interest to the public -- what is the injury to the public
17 interest, at least as far as you're concerned?

18 MS. OLSON: The injury to the public is that there
19 is no health risk here, and it is in the interests of
20 plaintiff and the cattle industry to have a scientifically
21 sound rule in place and to have a middle ground from a
22 previous black and white regime where, if a country had BSE,
23 we didn't import. If a country didn't have -- if a country
24 had BSE, we would not import. If it didn't have BSE, we would
25 import.

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1 This rule represents a middle ground, which
2 hopefully the United States will be seen as also fitting into,
3 just as we would see Canada as fitting into. The middle
4 ground is the minimal risk region. And OIE guidelines, I'll
5 reiterate, they do not prohibit or discourage the import of
6 beef from countries with BSE. It's simply -- those guidelines
7 simply provide that those imports must come under certain
8 conditions which this rule fully complies with.

9 And we have -- it's been 15 or 20 years of
10 scientific research around the world that has led to this
11 solid scientific consensus on the evidence on which this rule
12 is based. And our understanding of this disease is now at a
13 point where we understand the safeguards that are necessary to
14 eliminate it and to keep it out of the United States and to
15 prevent it from jeopardizing health.

16 I don't see any risk, any harm to the public from a
17 health standpoint here. I mean, obviously there's a risk.
18 I've overstated that. There is a minimal risk.

19 THE COURT: If a person gets BSE, they're going to
20 die.

21 MS. OLSON: But the series of safeguards in place
22 here ensure that that is highly, highly unlikely to happen.

23 I think a reasonable question to ask might be what
24 more could USDA do? It has hired teams of experts in zoology,
25 microbiology, veterinary medicine, every relevant scientific

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1 and medical area of expertise. They have studied a vast body
2 of information. I think the sheer breadth of the
3 administrative record speaks for itself, and they have reached
4 a scientifically sound conclusion which is completely
5 consistent with international standards.

6 To invalidate this rule would be a departure from
7 those international standards, and it would also jeopardize
8 interests like the plaintiff's in seeing that their beef is
9 perceived as safe by foreign markets, and perhaps other
10 countries will follow suit, and that is the objective here, to
11 protect the health of the American people. We've reached a
12 point now where we can contemplate this middle ground because
13 it doesn't endanger the health of citizens, but it also
14 provides a huge benefit in terms of opening up our products to
15 foreign markets.

16 THE COURT: Well, I assume that BSE could possibly
17 be in this country already because of the nature of its
18 infectivity, the difficulties in detecting it until the
19 infectivity reaches a certain stage.

20 MS. OLSON: It could, Your Honor.

21 THE COURT: It could be. But --

22 MS. OLSON: And I will point out that if the feed
23 ban is as flawed as the plaintiffs make it out to be, then we
24 shouldn't be eating beef. But our position is that the feed
25 ban is highly effective in preventing the spread of BSE. So

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1 if it is in this country, it's going to be detected. It's not
2 going to spread. And there is no evidence that there is any
3 BSE in the United States, but --

4 THE COURT: Isn't it significant that two animals
5 from Canada have been discovered with BSE, one two days before
6 the final rule was announced and one the week after?

7 MS. OLSON: These are a cluster. They have been
8 investigated rigorously. They have been traced back to a feed
9 source produced prior to the feed ban, in Alberta, and all of
10 these cows, all four of them, came from the same area of
11 Canada and --

12 THE COURT: That's the area right north of us, isn't
13 it?

14 (Laughter.)

15 MS. OLSON: -- and were infected by feed.

16 The point is responsible investigations have been
17 conducted to trace it, and the secretary, there is no -- we're
18 talking about cows 30 months of age and older. All four of
19 them are banned by this rule. To the extent there is any
20 risk, the secretary has taken care of it by delaying the
21 implementation of the rule.

22 THE COURT: Let me ask this now.

23 MS. OLSON: On the basis of these four cows, there
24 would be no reason for delaying the rule.

25 THE COURT: Is the OIE guideline, or standard, is it

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1 different for removal of SRMs? Is it different than what the
2 USDA has in the final rule? It sticks in the back of my mind
3 that -- and I may be wrong -- the OIE guideline requires
4 removal of SRMs from anything over 6 months, and we're talking
5 about 30 months. Am I wrong?

6 MS. OLSON: The OIE -- we require the removal of all
7 SRMs from beef. I don't know; I can find out what the OIE
8 rule is, if I may confer.

9 THE COURT: Do you know, Mr. Walsh?

10 MR. WALSH: Yes, sir. The OIE recommendations with
11 respect to SRM removal vary with the risk of classification of
12 the country.

13 THE COURT: I'm talking about minimal risk. Minimal
14 risk country, what is it? Thirty months.

15 MR. WALSH: Our requirements are consistent with the
16 OIE recommendations in that regard, and the SRMs vary by the
17 age of the animal as well.

18 THE COURT: Well, I know there are -- for instance,
19 I have in my notes -- 17 European countries require removal of

20 SRMs from animals 6 months of age, not 30 months, and Japan
21 requires them all, as, I think, one of the plaintiff's charts
22 showed. Is that wrong?

23 MS. OLSON: The -- I'm sorry; that they showed
24 the -- forgive me.

25 THE COURT: I think this chart showed that -- one of

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1 the charts the plaintiff had up here a moment ago talked
2 about, in Japan, they require removal of SRMs from all cattle.

3 MS. OLSON: Right.

4 THE COURT: And at least in some, like 17, I think,
5 European countries, I have in my notes they require, I have,
6 removal from cattle over 6 months of age, 17 European
7 countries. Is that true?

8 MS. OLSON: It may, it may be, because the
9 infectivity experience in Europe and in Japan is completely
10 different from the experience here. They have perhaps
11 measures in effect that are not scientifically called for in
12 our situation. There was an epidemic in Europe.

13 THE COURT: I assume that epidemic started with one
14 animal.

15 MS. OLSON: I don't know if it's known how it
16 started. That's part of the mystery of the disease.

17 But while you raise Japan, I want to point out that
18 there are these apparently two animals, but those cases have
19 not been fully documented. Their test results have not been
20 validated by international reference labs, and the Japanese
21 have not been able to demonstrate that it is, in fact, BSE.
22 So there are just things going on in Japan that are not --
23 that are different from our experience here, and the same goes
24 for the European Union countries.

25 So, Your Honor, if this rule is invalidated, the

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1 Court will, in effect, be telling all of our international
2 trading partners that the science we base this rule on isn't
3 reliable and that they don't have to rely on sound science.

4 THE COURT: Does this statutory mandate require this
5 Court, or any other U.S. District Court, to worry about what
6 our international trading partners are concerned with? It
7 seems to me like the basic, the basic mission is to protect
8 the health and welfare of the people in this country. That's
9 this subparagraph (E) of Title 7, Section 8301, "interstate
10 commerce and foreign commerce of the United States in animals
11 and other articles." Is that, in your mind -- it goes on to

12 say "regulation by the Secretary." This is in subparagraph
13 (B), "regulation by the Secretary and cooperation by the
14 Secretary with foreign countries, States or other
15 jurisdictions, or persons are necessary to prevent and
16 eliminate burdens on interstate commerce and foreign
17 commerce." Is it the burden that is imposed on a foreign
18 nation that they're talking about or the burden that is
19 imposed on this country in exporting meat? Because in that
20 same sub (B) paragraph, the second one is, "to regulate
21 effectively interstate commerce and foreign commerce," and,
22 three, "to protect the agriculture, environment, economy, and
23 health and welfare of the people of the United States."
24 MS. OLSON: Well, we consider the interests of
25 Canada and other trading partners, because if we don't

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1 consider those interests, those countries will have no reason
2 to consider trade with the United States.

3 THE COURT: And I agree. I agree with that. But
4 what's most important?

5 MS. OLSON: Health is number one, and that rule, the
6 law, the statute says that the secretary is authorized to
7 prevent disease, and the result of that will be the protection
8 of these other interests, among which, I might add, is the
9 entire livestock industry of the United States, not merely
10 cattle producers.

11 Slaughter houses in this country are closing. Meat
12 processing companies have laid off employees. They have
13 suffered concrete, devastating harm compared to the
14 plaintiffs, who are -- apparently the returns in 2004 are at a
15 30-year high, and their own expert, Dr. VanSickle, concedes
16 that they are going to get a \$66 to \$74 million net benefit
17 through 2009. So if we're talking about harm, we're talking
18 about some very speculative harm to the plaintiffs, and the
19 fact that we have been importing beef from Canada all along
20 suggests that there isn't going to be this flood onto the
21 market that they're anticipating.

22 And they've talked -- the harm that they speak of is
23 in terms of harm to health, and here we have a series of
24 highly effective measures. We have surveillance, which is --
25 there's been a very high compliance level. We have a feed ban

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1 which is shown to be extraordinarily effective in Great
2 Britain and, indeed, throughout this period has kept us
3 BSE-free. We have import restrictions. We have various

4 slaughter protections that prevent SRMs and other infective
5 material from entering the food supply. And these, taken
6 together, are a virtual insurance policy against the infection
7 of beef in this country and the infection of people with vCJD.

8 And again, Your Honor, I remind you that for 26
9 years, there has never been a case of vCJD here. There has
10 never been a case of vCJD in Canada from indigenous cattle
11 from either of those regions. These measures have worked, and
12 now we're ready to move beyond that. We know what it takes to
13 keep health in this country from being threatened, from there
14 being any unreasonable risk to public health. We have reached
15 that point. We know how to mitigate those risks.

16 And now it is safe to import that beef and with the
17 restrictions in the rule and the additional protections that
18 Secretary Johanns has put into effect by keeping out any of
19 the materials that might have any risk whatsoever from cattle
20 30 months of age and older, and for that reason, we ask that
21 this preliminary injunction be denied.

22 Your Honor, may I have one brief moment to confer
23 and make sure that I --

24 THE COURT: Yeah. Let's take a brief, another brief
25 recess.

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1 THE LAW CLERK: All rise.
2 (Recess taken from 11:00:17 to 11:21:50.)
3 (Open court.)

4 THE COURT: Please be seated.

5 Ladies and gentlemen, it has come to my attention
6 that there have been -- along with the white hair comes a
7 little hearing deficit. I didn't hear inappropriate remarks
8 from the audience. I don't want to hear any more. Apparently
9 some have occurred. I don't want to hear any more. If I hear
10 any more, I'll have you removed.

11 Now is there anything else that the government wants
12 to present?

13 MS. OLSON: Your Honor, I wanted to point out that
14 Donna Fitzgerald is here to address any issues that the Court
15 might wish to address, to discuss on the NEPA claim, and I
16 wanted to ask the Court if Mr. Walsh could have the
17 opportunity to clear up just a couple of points.

18 THE COURT: Certainly.

19 MR. WALSH: Thank you, Your Honor.

20 There were just a couple of questions, I think. I'm
21 not sure that we answered them as fully as we might have.

22 You had asked whether we had considered the two most

23 recent cases in Canada in January of this year in the
24 administrative record. Of course, we didn't have those cases
25 before us at the time the rule was signed, and it was issued a

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1 week later, published a week later in the Federal Register.
2 But throughout the process of the rule development in this
3 case, the possibility of additional cases was considered at
4 every step of the way, and it's for that reason that the
5 agency has said, in the documents in the records themselves
6 and in the public statements issued since then, that, in fact,
7 it was not unexpected that there would be additional cases but
8 that overall, you wouldn't expect, you wouldn't expect to take
9 any different action.

10 However, with each case that came, the agency has
11 committed itself and it announced that it would take those
12 things into consideration with respect to whatever rule was in
13 place at that time. So they were considered in the sense that
14 additional cases were expected, or at least not unexpected,
15 and were factored into the risk analysis.

16 With respect to the country of origin labeling, in
17 the context of rule-making I would like to make one point.
18 You know, the secretary's authority under the Animal Health
19 Protection Act to issue this rule is the authority to issue
20 regulations that the secretary finds necessary to prevent the
21 introduction of disease. The question of country of origin
22 labeling has been raised sort of in the context of how could
23 you have mitigated the potential effects of this rule? I
24 think there's a substantial question, and I quite frankly
25 don't think that the Animal and Plant Health Inspection

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1 Service would have the authority to impose country of origin
2 labeling simply to mitigate the potential economic effects
3 that are suggested by the implementation of this rule.

4 THE COURT: Yeah, and I did not mean to either
5 indicate or suggest that I thought the USDA or APHIS really
6 had that kind of authority. The only --

7 MR. WALSH: Under the Animal Health Protection.
8 That would be my point. But the department and the
9 agricultural marketing service in the department has worked
10 for a number of years on country of origin labeling, you know,
11 work, in attempting to see whether it would work. Is there an
12 interest in the livestock and meat industry for country of
13 origin labeling? What are the costs and so on associated with
14 it? They have proposed voluntary programs for country of

15 origin labeling which have not been styled up. Those
16 opportunities have not been accepted. Now we have mandatory
17 country of origin labeling prescribed by statute, and there's
18 a good bit of rule-making that has gone on for that --

19 THE COURT: Right.

20 MR. WALSH: -- so there is a substantial record in
21 that regard.

22 THE COURT: And the only reason I brought it up is I
23 am not, of course, an expert like, for instance, you folks
24 obviously are, or the plaintiffs are, but I have lived with
25 this case. I know the importance of it. And I tried to

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1 educate myself with the assistance of my smart law clerk as to
2 not only the science, and I've just dabbled a little bit in
3 the science, but as to the process that a government agency
4 goes through in promulgating rules and making rules.

5 It struck me as just a matter of common sense, and
6 that's why I raised it, when I said I was surprised at the
7 amount of Canadian beef, boxed beef, coming into the country
8 as revealed in the government statistics, the 96 percent. And
9 I have no idea -- of course, I've never taken a poll. I am
10 not a real big believer in polls. I suppose some scientific
11 polls might be, quote, scientific. But, for instance, if one
12 were taken that asked a simple question -- and maybe some have
13 been. In the rule-making process after Congress has said COOL
14 is going to become a reality in September 2006, maybe there
15 have been some polls -- I have no idea -- where consumers have
16 been asked, "Do you want it? Do you want to be able to tell
17 what meat is in your grocery stores from Canada as opposed to
18 what meat in your grocery store is born and raised and
19 produced right here in the United States?"

20 I would think, and just common sense tells me that
21 in view of the amount of beef that's coming in, there probably
22 are a number of consumers who'd like to know at the meat
23 counter, for instance, at Costco, or wherever, where did the
24 beef come from? Did it come from Canada or from the United
25 States? That's the only reason that I brought it up. I

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1 didn't mean to indicate that I thought that the government
2 agency had the power to actually enact that requirement. Now
3 I would think that it's going to affect the price of beef.

4 MR. WALSH: Um-hmm.

5 THE COURT: It will, most likely or probably, I
6 would think, go up, because that's going to cost some money.

7 But having said that, I would think that if, in this poll, the
8 second question was asked to consumers, "Would you be willing
9 to pay the increased price?" I wouldn't be surprised if a big
10 majority replied, "Sure."

11 MR. WALSH: Well, we'll find out. I'm sure that
12 those questions have been asked. I think the industry,
13 various sectors of the industry have done some surveys about
14 country of origin labeling, confidence in beef, Canadian
15 imports and things. I, quite frankly, don't know what the
16 results are.

17 But the point is that the Animal and Plant Health
18 Inspection Service did give careful consideration to all of
19 those comments and suggested different sorts of remedies for
20 perceived economic effects, and, in the end, chose not to do
21 it for a variety of reasons, including, under our statute,
22 under the statute which we're talking about today, you know,
23 the authority is measures that are necessary to prevent the
24 introduction of disease. And that particular thought, that
25 country of origin labeling would be helpful, would really not

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1 be related to the prevention of disease, which brings me to
2 the last point, I guess.

3 It's obvious everybody is wrestling with this
4 concept of extremely low risk, very low risk, minimal risk,
5 negligible risk. The fact of the matter, Your Honor, is that
6 under the Animal Health Protection Act, every effort is made
7 by the agency to produce zero risk. They have designed a rule
8 that will prevent the introduction of BSE into this country
9 and the infection of an American animal. They have designed
10 other rules, the SRM removal rules and SRM requirements and
11 this, to prevent the SRMs from any infected animal, in the
12 unlikely event it did come into this country, from getting
13 into the human food supply.

14 So there is no doubt, it seems to me, in my
15 experience with this agency, that they have achieved what is
16 absolutely humanly possible to achieve zero risk. The problem
17 comes is that you are not going to find a scientist or you're
18 not going to find a veterinarian or a public health official
19 who will stand up at this podium and say any rule that we have
20 issued will produce zero risk.

21 So, I mean, that is the purpose of the rule, and
22 that is what the agency thinks this rule has achieved. They
23 think it's achieved zero risk. But there's no way in this
24 world that anyone could stand up here and legitimately say to
25 this Court, "We can guarantee that there's a zero risk." But

1 let there be no mistake about it. That's what they want to
2 achieve, and that's what they think they have achieved in this
3 room.

4 Thank you, Your Honor.

5 THE COURT: Thank you.

6 I do not need further comments. The application of
7 the plaintiff for a preliminary injunction is hereby granted.

8 It is further ordered that the implementation of the
9 final rule published January 4, 2005, entitled "Bovine
10 Spongiform Encephalopathy, Minimal Risk Regions and
11 Importation of Commodities; Final Rule and Notice," published
12 at 70 Federal Register 460, is hereby preliminarily enjoined.

13 Now I want the parties, since everybody is here, I
14 want the parties to meet and discuss a schedule and propose to
15 me, within ten days, a schedule for a trial on the merits of
16 this matter for a permanent injunction.

17 As I have indicated to counsel in chambers before we
18 started, I believe that such an order is appealable under
19 Title 28, Section 1292, and I am aware of the fact that --
20 well, here is what I think. I don't think that either party
21 will want a stay. If a stay is granted, it has to be granted
22 by the Ninth Circuit Court of Appeals, if an appeal is
23 followed. A stay, under a stay, even if the Ninth Circuit
24 were to issue a stay, because, for instance, the government
25 applied for one, that would not affect this preliminary

1 injunction. The order in the preliminary injunction will stay
2 in place until either I or the Ninth Circuit Court of Appeals
3 lifts it or reverses it.

4 And so I want this proposed schedule within ten days
5 as to when we are going to hold the trial on the merits to
6 decide on the permanent injunction. And I would appreciate if
7 counsel would also, if you can so stipulate, set some kind of
8 parameters or limits. I know that the law sets parameters or
9 limits on what this Court can consider, and I think that
10 testimony from experts, for instance, at the hearing on the
11 permanent injunction will clear up some significant issues
12 that I have.

13 I will file an opinion setting forth my reasons for
14 granting the plaintiff's application for preliminary
15 injunction either this afternoon, no later than tomorrow.

16 We'll be in recess. Thank you.

17 THE LAW CLERK: All rise.

18 (Proceedings were concluded at 11:35:34.)
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1 REPORTER'S CERTIFICATE
2 I, JoAnn C. Bacheller, a Registered Diplomate
3 Reporter and Certified Realtime Reporter, certify that the
4 foregoing transcript is a true and correct record of the
5 proceedings given at the time and place hereinbefore
6 mentioned; that the proceedings were reported by me in machine
7 shorthand and thereafter reduced to typewriting using
8 computer-assisted transcription; that after being reduced to
9 typewriting, the original of this transcript was delivered to
10 the Clerk of Court.
11 I further certify that I am not attorney for, nor
12 employed by, nor related to any of the parties or attorneys to
13 this action, nor financially interested in this action.
14 IN WITNESS WHEREOF, I have set my hand at Billings,
15 Montana this ____ day of _____, 2005.
16
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JoAnn C. Bacheller
United States Court Reporter
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