

ORIGINAL

UNITED STATES OF AMERICA  
BEFORE THE FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES

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In the Matter of:	:	
	:	
Enrofloxacin for Poultry: Withdrawal	:	FDA DOCKET NO.
of Approval of Bayer Corporation's	:	00N-1571-
New Animal Drug Application (NADA)	:	
140-828 (Baytril)	:	
-----	X	

Food and Drug Administration  
5600 Fishers Lane  
Rockville, Maryland

Friday, May 2, 2003

THE HEARING in the above-entitled matter  
commenced at 9:00 a.m., pursuant to notice.

BEFORE:

DANIEL J. DAVIDSON, Administrative Law Judge

**Diversified Reporting Services, Inc.**  
1101 Sixteenth Street, NW Second Floor  
Washington, DC 20036  
(202) 467-9200

00N-1571

~~FR 5~~  
TR 13

## APPEARANCES:

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Veterinary Medicine (CVM):

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## C O N T E N T S

WITNESSES:	DIRECT	CROSS	REDIRECT	RE CROSS
Heidi Kassenborg	574	576	616	623

RESPONDENT EXHIBITS:	IDENTIFIED	RECEIVED
1930 - French standard		573
1931 - 3 additional pages in '99 report		567
1932 - Table 4E - FoodNet 200 annual report		569
1934 - Report from Minnesota Department of Health		569

## P R O C E E D I N G S

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JUDGE DAVIDSON: Good morning. Come to order.  
We're on the record.

Do we have any preliminary matters to go into?

MR. SPILLER: Yes, Your Honor, a very minor  
one.

JUDGE DAVIDSON: Okay.

MR. SPILLER: May we have your permission to  
bring a small standing podium into the courtroom? And  
it will be available for both parties to use.

JUDGE DAVIDSON: Well, if it doesn't take up  
too much -- too many seats, I have no objection.

MR. SPILLER: If it does, you direct and I'll  
move it immediately.

Thank you, Your Honor.

JUDGE DAVIDSON: All right.

Anything else?

MS. ZUCKERMAN: No, Your Honor.

MR. KRAUSS: Your Honor, I think I made a  
promise to you yesterday that we'd clear up some of the  
exhibits that we --

JUDGE DAVIDSON: Yes.  
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1 MR. KRAUSS: -- had marked.

2 I have marked copies, with the appropriate  
3 stickers on them, for everything that we marked here  
4 during the hearing, and in particular, B1931, which are  
5 the additional pages for the 1999 FoodNet annual report  
6 -- I think I indicated that the version that was  
7 produced in '99 was not a complete document and I had  
8 some additional pages that the witness, Dr. Angulo,  
9 recognized, and so I would like to move into evidence  
10 B1931.

11 JUDGE DAVIDSON: Any objection?

12 MS. ZUCKERMAN: No, Your Honor.

13 JUDGE DAVIDSON: Okay.

14 (Respondent Exhibit 1931 was  
15 received in evidence.)

16 MR. KRAUSS: Additionally, Your Honor, B1932,  
17 which Table 4E, ~~packaging~~ *pathogens* by month collected for  
18 Minnesota, 2000 FoodNet annual report -- I did not see  
19 where the 2000 FoodNet annual report was either on the  
20 docket or in evidence, although that surprises me, to  
21 be honest, but I don't see that. So, I would like to  
22 also move into evidence B1932, which is that table.

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1 JUDGE DAVIDSON: Any more?

2 MR. KRAUSS: Yes, Your Honor. I'd like to  
3 report that B1933 is the same as G749, page 49, and  
4 that's already in evidence, but just to clarify the  
5 record, that matches up, and B1934, which is the report  
6 from the Minnesota Department of Health anti-microbial  
7 susceptibilities of selected pathogens 2000, I'd like  
8 to move into evidence.

9 The witness, Dr. Angulo, identified it, had  
10 seen it before, discussed it at length, and I'd like to  
11 move that into evidence.

12 JUDGE DAVIDSON: Did you provide copies of all  
13 these to the reporter? Because there were a couple you  
14 promised --

15 MR. KRAUSS: Yes, Your Honor, and I have  
16 copies that are now marked with stickers in the format  
17 that we've traditionally been using in this hearing.

18 JUDGE DAVIDSON: Okay. 33 I'm not going to  
19 accept, because it's already in the record as another  
20 number.

21 MR. KRAUSS: Yes, Your Honor.

22 JUDGE DAVIDSON: Any objection to 34? We

1 already moved 31 in.

2 MS. ZUCKERMAN: No, Your Honor.

3 JUDGE DAVIDSON: Okay. So, B1934 is received  
4 in evidence.

5 (Respondent Exhibit 1934 was  
6 received in evidence.)

7 JUDGE DAVIDSON: So, what I've done is receive  
8 31 and 34, correct?

9 MR. KRAUSS: Yes, Your Honor.

10 JUDGE DAVIDSON: Was there another one? 33?

11 MR. KRAUSS: 32, Your Honor. 33 was the one  
12 that's already in.

13 JUDGE DAVIDSON: Okay.

14 MR. KRAUSS: 32 was the -- from the 2000  
15 FoodNet --

16 JUDGE DAVIDSON: Okay. Right.

17 Any objection to that?

18 MS. ZUCKERMAN: No, Your Honor.

19 JUDGE DAVIDSON: Okay.

20 (Respondent Exhibit 1932 was  
21 received in evidence.)

22 MR. KRAUSS: Now, you had particularly  
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1 mentioned B1929.

2 JUDGE DAVIDSON: Yes.

3 MR. KRAUSS: My recollection is that that was  
4 accepted into the docket.

5 JUDGE DAVIDSON: Excuse me. Anything you put  
6 on this record, whether it stays in evidence or not, is  
7 going to be in 1285.

8 MR. KRAUSS: Yes.

9 JUDGE DAVIDSON: Because that's the  
10 administrative record, and the commissioner says he's  
11 going to review the entire administrative record when  
12 he -- if he has to issue his decision. I don't think  
13 he will, because I know whatever I decide you'll all  
14 agree with.

15 MR. KRAUSS: But Your Honor, we would move  
16 B1929 into evidence, as well.

17 JUDGE DAVIDSON: Now, that's the one you  
18 originally put on, then you said you were withdrawing  
19 it, as I recall.

20 MR. KRAUSS: Yes, Your Honor.

21 JUDGE DAVIDSON: 1929 -- let's see what it is.

22 MS. ZUCKERMAN: Your Honor, may we have -- I'm



1 not familiar with 1929. May we have a copy?

2 MR. KRAUSS: Yes, absolutely.

3 This is the response to the FOIA request  
4 regarding Dr. Cray.

5 MS. ZUCKERMAN: Your Honor, we object to the  
6 submission of this document into evidence. May we  
7 request 10 days to respond?

8 JUDGE DAVIDSON: No, you don't need 10 days.  
9 Do you want to state your objections, or do you want to  
10 leave it just like that? Whatever you choose is fine  
11 with me.

12 MS. ZUCKERMAN: I'll leave it just like that.

13 JUDGE DAVIDSON: Okay.

14 MS. ZUCKERMAN: Thank you.

15 JUDGE DAVIDSON: We had a problem with this  
16 before because it's called a completed draft, which is,  
17 as far as I'm concerned, conflicting terms, completed  
18 draft.

19 Secondly, it's offered by -- help me -- Dr.  
20 Cray?

21 MR. KRAUSS: Dr. Fedorka Cray, Your Honor.

22 JUDGE DAVIDSON: Right. Is she a witness in

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1 this proceeding?

2 MR. KRAUSS: She was on <sup>CVM's</sup>~~CBM's~~ witness list,  
3 but she didn't submit written testimony.

4 JUDGE DAVIDSON: I can't accept the document.  
5 It stays in the 1285, but it's not received in  
6 evidence.

7 MR. KRAUSS: Understood, Your Honor. Thank  
8 you.

9 JUDGE DAVIDSON: Okay.  
10 If there's nothing else -- or do you have  
11 something else, Mr. Krauss?

12 MR. KRAUSS: I'm sorry, Your Honor. There was  
13 one other --

14 JUDGE DAVIDSON: Okay. Go ahead.

15 MR. KRAUSS: -- I was remiss.

16 B1930 was the French report regarding MIC  
17 standards and the interpretive criteria that was marked  
18 on Tuesday with Dr. Walker, and I would move that into  
19 evidence, as well, and I have copies, if anybody needs  
20 one. It was referenced in Dr. Walker's testimony.

21 MS. ZUCKERMAN: We would like a copy, Your  
22 Honor.

1 JUDGE DAVIDSON: Is it the first time you've  
2 seen it? No, because it was -- you had a copy the  
3 other day, I'm sure.

4 MR. KRAUSS: And it's a specific reference in  
5 the written draft testimony --

6 JUDGE DAVIDSON: I understand. I understand  
7 that.

8 MR. KRAUSS: Thank you, Your Honor.

9 MS. ZUCKERMAN: We have no objection, Your  
10 Honor.

11 JUDGE DAVIDSON: Okay. 1930 is received in  
12 evidence.

13 (Government Exhibit 1930 was  
14 received in evidence.)

15 MR. KRAUSS: Thank you, Your Honor.

16 JUDGE DAVIDSON: Okay.

17 We can go off the record for a second.

18 (Discussion off the record.)

19 MS. ZUCKERMAN: Your Honor, we'd like to call  
20 Dr. Heidi Kassenborg to the stand.

21 JUDGE DAVIDSON: Dr. Kassenborg, come around  
22 here, please.

1 Whereupon,

2 HEIDI KASSENBERG

3 was called as a witness and, having been first duly  
4 sworn, was examined and testified as follows:

5 JUDGE DAVIDSON: Please be seated. Give your  
6 full name and address for the reporter and then wait  
7 for counsel.

8 THE WITNESS: My name is Dr. Heidi Kassenborg,  
9 Heidi Diane Kassenborg. My address is 14141 44th  
10 Street, South, Afton, Minnesota 55001.

11 JUDGE DAVIDSON: Okay, Ms. Zuckerman.

12 MS. ZUCKERMAN: I'm sorry, Your Honor. One  
13 moment.

14 JUDGE DAVIDSON: Sure.

15 MS. ZUCKERMAN: May I approach the witness,  
16 Your Honor?

17 JUDGE DAVIDSON: Of course.

18 MS. ZUCKERMAN: I'm handing Dr. Kassenborg  
19 what is marked as Exhibit G1460.

20 DIRECT EXAMINATION

21 BY MS. ZUCKERMAN:

22 Q Dr. Kassenborg, do you recognize this  
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1 document?

2 A Yes, I do.

3 Q Would you please identify it?

4 A This is my direct written testimony for this  
5 trial.

6 Q Would you please turn to page 11? Is that a  
7 copy of your signature at the bottom of the page?

8 A Yes, that's correct.

9 Q Have you had an opportunity to review your  
10 testimony after signing it?

11 A Yes.

12 Q Are there any corrections that you would like  
13 to make to your testimony to make it accurate?

14 A Yes. On page 9, line 17, I'd like it to -- to  
15 read -- where it starts "Almost one-half . . .," 38  
16 percent of the domestically acquired instead of one-  
17 half.

18 Q Are there any other corrections?

19 A Yes. Page 3, line 9, it should read -- the  
20 sentence that started with "The final draft," it should  
21 say the final draft of the tables and graphs of this  
22 manuscript is attached to my testimony.

1 Q Are there any other corrections?

2 A No.

3 MS. ZUCKERMAN: Thank you.

4 Dr, Kassenborg is ready for cross examination.

5 JUDGE DAVIDSON: Mr. Krauss.

6 MR. KRAUSS: Good morning, Your Honor.

7 Gregory Krauss on behalf of Bayer Corporation.

8 CROSS EXAMINATION

9 BY MR. KRAUSS:

10 Q Good morning, Dr. Kassenborg.

11 A Good morning.

12 Q With respect to the testimony that you just  
13 identified, did you draft your testimony yourself?

14 A Yes, I did.

15 Q All of it?

16 A Yes.

17 Q Let me just briefly explore your professional  
18 qualifications.

19 You're a veterinarian?

20 A That's correct.

21 Q And you have your Master of Public Health --  
22 you got it in 1997?

1 A Correct.

2 Q Are you a medical doctor?

3 A I'm a veterinary medical doctor, yes.

4 Q Do you have any advanced degrees in  
5 microbiology?

6 A No, I do not.

7 Q Do you have any advanced degrees in veterinary  
8 microbiology?

9 A No, I do not.

10 Q Do you have a Ph.D. in epidemiology?

11 A No, I do not.

12 Q Do you have advanced degrees in biostatistics?

13 A I do not.

14 Q Are you a poultry veterinarian?

15 A I am not.

16 Q Are a diplomate of the American College of  
17 Poultry Veterinarians?

18 A No.

19 Q Are you a member of the American Association  
20 of Avian Pathologists?

21 A No.

22 Q Are you a statistician?

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1 A I'm not considered a statistician, no.

2 Q Are you a member of the American Statistical  
3 Association?

4 A No.

5 Q Your resume mentions a certain case control  
6 study of sporadic e-coli 0157H7 infections at five  
7 FoodNet sites and mentions that that manuscript was  
8 submitted to a journal.

9 A Uh-huh.

10 Q Has that been accepted for publication?

11 A Yes.

12 Q What journal?

13 A Clinical infectious diseases.

14 Q Has it been published yet?

15 A No.

16 Q And do you have any other publications that  
17 have been accepted in -- for publication in a peer-  
18 reviewed journal?

19 A Yes, it should be listed on the -- I don't  
20 recall exactly the other ones, but -- by name, but  
21 there was just one recently that was submitted to the  
22 Journal of Food -- just came out in the Journal of Food



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1 Protection outlining a -- outbreaks of ~~chagella~~<sup>Shigella</sup> in  
2 parsley products, of which I was a co-author.

3 Q And when was that published?

4 A We just received the notice that it was  
5 accepted for publication, so I'm not sure which issue  
6 it will be published in.

7 Q Okay.

8 Now, in terms of the correction you made to  
9 page 3, line 9, of your testimony --

10 A Yes.

11 Q The way I understand it -- and correct me if  
12 I'm wrong -- Exhibit G337 was the -- is a paper of your  
13 case control study, and what you've attached to your  
14 testimony are the final tables and graphs. My question  
15 for you is whether the paper, the manuscript, has  
16 changed compared to Exhibit G337.

17 MS. ZUCKERMAN: Objection, Your Honor. Would  
18 Mr. Krauss please provide the witness with G337 so she  
19 can make the comparison?

20 JUDGE DAVIDSON: That's reasonable.

21 Have you got a copy of it for her?

22 MR. KRAUSS: Yes, Your Honor.

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1 I'm handing the witness Government 337.

2 MS. ZUCKERMAN: Actually, Your Honor, is  
3 Counsel requesting that Dr. Kassenborg compare the two  
4 -- the table or the graph that's attached to her final  
5 testimony?

6 JUDGE DAVIDSON: The question was if they're  
7 the same or there's a change.

8 MR. KRAUSS: That's right, Your Honor. The  
9 question is -- we have Exhibit G337, which is a paper,  
10 with no date on it, and the witness has said the final  
11 tables and graphs to the paper are attached to her  
12 testimony, and my question goes to the substance of the  
13 manuscript, whether that has changed.

14 Obviously, the -- you've got final tables and  
15 graphs. What about the written words in the draft of  
16 the manuscript?

17 MS. ZUCKERMAN: Your Honor, the draft  
18 manuscript from which the tables and graphs came is not  
19 on the record, and moreover, Dr. Kassenborg doesn't  
20 have a copy of that in front of her to decide whether  
21 there were any changes from G337 to the entire  
22 manuscript.

1 JUDGE DAVIDSON: Tell me again what the change  
2 that you made on page 3, Dr. Kassenborg.

3 THE WITNESS: Instead of saying that the final  
4 draft of the manuscript is attached, it's actually the  
5 final tables and graphs of the final manuscript are  
6 attached.

7 JUDGE DAVIDSON: All right. Were they  
8 attached originally to your testimony when you signed  
9 it?

10 THE WITNESS: The tables and graphs? Yes.

11 JUDGE DAVIDSON: So the only change is -- the  
12 only change that you have is the designation of what  
13 was attached and not --

14 THE WITNESS: Yes.

15 JUDGE DAVIDSON: -- what was attached?

16 THE WITNESS: Yes.

17 JUDGE DAVIDSON: Does that answer your  
18 question?

19 MR. KRAUSS: Not really, Your Honor. What the  
20 question is is whether there is an existing additional  
21 document that is different than what's been produced to  
22 us, G337.

1           JUDGE DAVIDSON: I'm sure there are lots of  
2 other documents that exist, but the point is the only  
3 change she made was the label on what was attached.  
4 That's how I understand her testimony as of now. In  
5 other words, she called it one thing and now she's  
6 changing her testimony to call it something else,  
7 including -- in other words, the draft manuscript that  
8 she mentioned in her testimony on page 3 should have  
9 included the words "tables and charts" or "tables and  
10 graphs," whatever it was.

11           Now, the fact that there may or may not have  
12 been other documents in her possession relating to this  
13 -- I don't see how that's relevant at this point in  
14 time.

15           In other words, she -- this is her testimony,  
16 and that's what she's relying on.

17           MR. KRAUSS: Thank you, Your Honor.

18           JUDGE DAVIDSON: Okay.

19           BY MR. KRAUSS:

20           Q    Dr. Kassenborg, Exhibit G337 is a manuscript  
21 entitled "Domestically Acquired Fluoroquinolone-  
22 Resistant Campylobacter Infections Associated with

1 Eating Poultry Outside the Home." Has this been  
2 submitted for publication?

3 A The final draft of that has been submitted for  
4 publication.

5 Q Is Exhibit G337 different than the final draft  
6 that has been submitted for publication?

7 A Yes, the tables and charts are different.

8 Q And is that the only change?

9 A I don't have --

10 MS. ZUCKERMAN: Objection, Your Honor.

11 JUDGE DAVIDSON: She said the tables and  
12 charts are different.

13 That's what your testimony is.

14 I'm confused.

15 THE WITNESS: Could you repeat the question?

16 BY MR. KRAUSS:

17 Q Is the only difference between Exhibit G337  
18 and the document that was submitted for publication the  
19 changes in the tables and charts?

20 MS. ZUCKERMAN: Objection, Your Honor. The  
21 witness doesn't have the entire final draft that was  
22 submitted, so --

1 JUDGE DAVIDSON: Well, she submitted it. She  
2 should know what it is. If she doesn't remember, then  
3 fine, she can say so, but it's a legitimate question.

4 THE WITNESS: There are changes in the tables  
5 and graphs, and associated with that, there would be  
6 changes within the text of the manuscript, as well.

7 BY MR. KRAUSS:

8 Q As you sit here today, Dr. Kassenborg, can you  
9 identify any changes between the Exhibit G337 which has  
10 been produced in this case and the manuscript that has  
11 been submitted for publication?

12 A There are some changes. For me to go through  
13 line by line to tell you what's different between this  
14 and the other -- the other manuscript would be  
15 difficult, not having that other manuscript in front of  
16 me.

17 Q I'd agree. We don't have it, either.

18 Dr. Kassenborg, what's the date of the  
19 manuscript that is Exhibit G337?

20 A I don't recall when this one was.

21 Q And there is nothing on Exhibit G337 that will  
22 refresh your recollection as to about when this

1 manuscript was being prepared?

2 A Sometime before the final draft.

3 Q But you can't give me a year?

4 A Oh, it was within that same year.

5 Q Which would be what year?

6 A These were submitted around December of last  
7 year, so -- it would be in the same year as the final  
8 draft of the manuscript, which was in December a year  
9 ago. No, it was in -- the final draft was December of  
10 last year.

11 Q December of 2002?

12 A Yes.

13 Q Dr. Kassenborg, would you agree with me that a  
14 confounding variable is a third factor that is an  
15 independent risk factor for the outcome that is also  
16 associated with the exposure?

17 A It's associated with both of those.

18 Q All right.

19 So my question is, would you agree with me  
20 that a confounding variable is some third factor that  
21 is an independent risk factor for the outcome and is  
22 also associated with the exposure?

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1 A Yes, it's associated with both of those.

2 Q Is that a way of saying yes?

3 A Uh-huh. Yes. I'm sorry.

4 Q Dr. Kassenborg, directing your attention to  
5 page 2, line 10 to 12, of your testimony, it discusses  
6 campylobacter as the most commonly reported cause of  
7 bacterial gastroenteritis in the United States. Do you  
8 disagree with Government Exhibit G1791, which reports  
9 that salmonella is now the most commonly reported cause  
10 of bacterial gastroenteritis in the United States?

11 MS. ZUCKERMAN: Objection, Your Honor. Would  
12 Counsel please provide Dr. Kassenborg with a copy of  
13 the exhibit to which he is referring?

14 MR. KRAUSS: Yes, I will, Your Honor.

15 I'm handing the witness Government 1791, which  
16 is April 19, 2002, MMWR from CDC.

17 MS. ZUCKERMAN: Your Honor, may I request a  
18 copy?

19 MR. KRAUSS: Yes, you may.

20 THE WITNESS: Could you repeat your question  
21 now that I have the document?

22



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1 BY MR. KRAUSS:

2 Q Do you disagree with this Exhibit G1791, which  
3 reports that salmonella is a more commonly reported  
4 cause of bacterial gastroenteritis in the United States  
5 than campylobacter?

6 A This reports for the year 2001. My testimony  
7 has to do with Paul Mead's analysis, which states --  
8 which was a rather large analysis of food-borne -- the  
9 burden of food-borne illness in the United States.  
10 This is only a year that has more data. This was  
11 merely a year. This is true. This is -- that this  
12 would be the case for 2001, but as you know -- for  
13 2001.

14 I agree that this -- that -- in this document,  
15 for 2001, that salmonella would have been the higher  
16 incidence, but that's just one year, compared to Paul  
17 Mead's analysis of more than just one year.

18 Q I understand, but my question is --

19 JUDGE DAVIDSON: I think that's enough.

20 MR. KRAUSS: Okay. Thank you, Your Honor.

21 All right.

22

1 BY MR. KRAUSS:

2 Q Your testimony at page 2, line 12, states that  
3 campylobacter causes an estimated 2.4 infections  
4 annually.

5 Do you disagree with testimony on the record  
6 that indicates that there were an estimated 1.4 million  
7 campylobacter infections in the United States in 1999?

8 MS. ZUCKERMAN: Objection, Your Honor. Would  
9 Counsel please provide the witness with a copy of that  
10 testimony?

11 JUDGE DAVIDSON: Okay.

12 MR. KRAUSS: Yes.

13 BY MR. KRAUSS:

14 Q Let me point you to Dr. Angulo's testimony,  
15 G1452, page 7, lines 10 through 14.

16 (Witness examines the document.)

17 A And could you repeat your question?

18 Q My question is whether you disagree with that  
19 testimony that reports 1.4 million estimated  
20 campylobacter infections for 1999.

21 A I do not disagree that 1.4 million -- with  
22 this estimate of 1.4 million persons were infected with

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1 campylobacter in 1999.

2 Q Now, as I understand it, Dr. Kassenborg, you  
3 studied the risk factors associated with  
4 fluoroquinolone-resistant campylobacteriosis, right?

5 A Correct.

6 Q And you <sup>lead</sup> ~~read~~ the study that looked at that,  
7 right?

8 A That is correct.

9 Q And you used data from the 1998-1999  
10 campylobacter case control study, right?

11 A Yes.

12 Q And you built a model to examine the risk  
13 factors, right?

14 A That's correct.

15 Q Now, you use a term in your testimony called  
16 population attributable fraction, and in your paper, at  
17 G337, page 10, you refer to population attributable  
18 risk, and the question here do you make any distinction  
19 between those two terms? In your testimony, it's at, I  
20 believe, page 9, line 1.

21 (Witness examines the document.)

22 A And where was it in the G --

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1 Q G337, page 10.

2 Do you understand the question, Dr.  
3 Kassenborg?

4 A Okay. I couldn't find it. It was at the top.  
5 Sorry. Those are used interchangeably.

6 Q For the purposes today, I think I'll refer to  
7 them as population attributable fractions, as it's  
8 written in your testimony, and in shorthand, PAF's. Is  
9 that okay?

10 A Yes.

11 Q And that's a -- PAF's is a term that --

12 A -- that's used --

13 Q -- used in epidemiology?

14 A Yes.

15 Q Now, Dr. Kassenborg, do you agree with me that  
16 PAF's can add up to more than 100 percent?

17 A It depends upon the calculation.

18 JUDGE DAVIDSON: I didn't hear what you said?

19 THE WITNESS: Yes. It would depend upon the  
20 calculation. Yes, they could.

21 JUDGE DAVIDSON: Okay.

22

1 BY MR. KRAUSS:

2 Q Would you agree with me that a population  
3 attributable fraction does not necessarily indicate  
4 anything about causation?

5 A Not anything about causation?

6 Q Not necessarily. In other words, you can have  
7 a population attributable fraction between an exposure  
8 and an outcome and it doesn't mean that the exposure  
9 caused the outcome.

10 A It would add to the body of evidence that  
11 would suggest that the exposure is related to the  
12 outcome.

13 Q But do you agree with me that you can have a  
14 positive population attributable fraction where there's  
15 no causal connection?

16 A If the study is flawed, yes.

17 Q Well, let me explore that just a minute.

18 To calculate a population attributable  
19 fraction, you don't need to understand the biological  
20 causal connection between the exposure and the outcome,  
21 do you?

22 A I'm not sure what you're asking.

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1 Q Isn't it true that, as long as you have an --  
2 a risk factor variable, whatever it is, and an outcome  
3 and you have your case control data set -- as long as  
4 you have the numbers, it's a matter of mathematics to  
5 calculate the PAF.

6 A It is a matter of mathematics to calculate the  
7 PAF.

8 Q And in calculating the PAF between two  
9 variables doesn't necessarily mean that the risk factor  
10 variable caused the outcome variable, does it?

11 A That's correct.

12 Q Okay.

13 For example, if, in the 1998-1999  
14 campylobacter case control study they took data on  
15 males, for example, male persons as a factor and  
16 campylobacteriosis as the outcome and they had the  
17 numbers in their -- in the epidemiological data, you  
18 could calculate a PAF for males as the factor and  
19 campylobacteriosis as the outcome, couldn't you?

20 A I guess I'm not -- I wasn't an author on that  
21 particular campylobacter study, so I -- I'm not going  
22 to comment on that.

1           Q     You used the same data set in your analysis,  
2 didn't you?

3           A     But not the same -- but I wasn't a part of  
4 that analysis.

5           Q     Okay.

6                     Let me take it out of the context of the 1998-  
7 1999 campylobacter case control study and speak more  
8 generally about epidemiological studies.

9                     If, in an epidemiological study, data is taken  
10 on gender, male versus female, along with other risk  
11 factors compared to a disease outcome, if you have the  
12 epidemiological data for the males and the females and  
13 the outcome, could you calculate a PAF with those  
14 numbers for males and the outcome, the disease  
15 condition?

16           A     If males was found to be a risk factor, you  
17 could, potentially. Yeah, you could calculate a PAF  
18 for that.

19           Q     Okay. And in that instance, it wouldn't mean,  
20 would it, that being male caused the disease outcome,  
21 would it?

22           A     You would have to take into account biological

1       plausibility.

2               Q     Okay.

3                       Now, let me ask you, do you agree that you can  
4       have a positive PAF between an exposure and an outcome  
5       where the causal effect would actually be a reduced  
6       risk for the outcome?

7               A     Do you want to restate that?

8               Q     Absolutely, if you need me to. Do you need me  
9       to?

10              A     Yes, I do.

11              Q     Okay. Would you agree with me that a  
12       population attributable fraction can be positive for a  
13       risk factor even if the causal effect of that risk  
14       factor is to reduce risk?

15              A     I'm sorry. I'm not understanding the  
16       question.

17              Q     Do you need, perhaps, an example?

18              A     Yes.

19              Q     Okay. For example, in the instance of, say,  
20       heart attack risk and persons taking baby aspirin, you  
21       could calculate a PAF for persons that have heart  
22       attacks and whether they've had an exposure to baby



1 aspirin, right, and you could have a positive PAF,  
2 persons who have heart attacks, a lot of them, they're  
3 told to take baby aspirin after a heart attack risk,  
4 but the baby aspirin actually is a reduced risk factor  
5 for having a heart attack, right?

6 A I'm not an expert on heart attacks.

7 Q But you're an expert in epidemiology?

8 A But not chronic disease epidemiology, no.

9 Q Well, it's an example, Doctor, okay? It's the  
10 concept of -- that a -- you can have a positive PAF  
11 even though the causal connection between the exposure,  
12 say taking baby aspirin, and the disease outcome, say a  
13 heart attack, could actually be a reduction in risk.

14 A Yes, you could, but that's why you do many  
15 repeated studies, and so, the science is the  
16 accumulation of a body of knowledge, and those things  
17 would be removed or would be found out in future  
18 studies.

19 Q Okay.

20 Is that a long way of saying yes to my  
21 question?

22 A Yes.

1 MS. ZUCKERMAN: Objection, Your Honor.  
2 Counsel is misrepresenting the testimony.

3 JUDGE DAVIDSON: I'll sustain the objection.

4 The problem is -- what do you want? I mean  
5 you've gotten her to say almost what you want, but  
6 you've never asked the question, as I see it. I don't  
7 know what's in your mind. I don't know what's in your  
8 notes. But if you are just trying to get the witness  
9 to admit that the positive -- I mean population  
10 attributable fraction standing alone doesn't show  
11 causation, then why don't you ask that question?  
12 Because that's what it's all beating around to me.  
13 That's what it sounds like.

14 MR. KRAUSS: That's where I'm going, Your  
15 Honor.

16 JUDGE DAVIDSON: Well, then why don't you just  
17 ask the question?

18 MR. KRAUSS: I'll ask it.

19 JUDGE DAVIDSON: You've taken five or 10  
20 minutes to get to that point, and it seems to me, based  
21 on what other witnesses have said in similar -- not  
22 necessarily the population attributable fraction, but

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1 in similar situations, is that there are a lot of  
2 things they take into consideration before they ~~final~~ <sup>find a</sup>  
3 causal relationship, and this is one factor that may or  
4 may not be, according to this witness, is considered  
5 but is not the only one. That's what I think her  
6 testimony was.

7 THE WITNESS: That is correct, Your Honor.

8 JUDGE DAVIDSON: So, if you ask her the direct  
9 question, maybe we can move on.

10 MR. KRAUSS: Thank you, Your Honor.

11 BY MR. KRAUSS:

12 Q A positive population attributable fraction  
13 does not necessarily indicate anything about the causal  
14 connection, does it?

15 JUDGE DAVIDSON: I'm sorry. I want to rule  
16 out that question, because you've already asked it.  
17 The problem, as I see it, is standing alone, by itself,  
18 because her testimony is that it does have an  
19 indication of causal relationship when taken into  
20 consideration with other things. So, you asked her the  
21 same question, it does not have it, but you didn't say  
22 standing alone.

1           So, your answer is going to be starting this  
2 whole line of questioning again. She's going to say,  
3 well, considering other factors -- I mean I can't  
4 testify for her.

5           MR. KRAUSS: So, standing alone.

6           JUDGE DAVIDSON: Thank you.

7           MR. KRAUSS: Thank you, Your Honor.

8           BY MR. KRAUSS:

9           Q     Dr. Kassenborg, standing alone, population  
10 attributable fraction does not necessarily indicate  
11 anything about causation, does it?

12          A     By itself, no.

13          Q     So in your testimony where you state that  
14 eating chicken or turkey -- and this G1460, page 9,  
15 lines 3 to 5 -- that eating chicken or turkey at a  
16 commercial establishment accounted for 38 percent of  
17 the population attributable fraction for domestically  
18 acquired fluoroquinolone-resistant campylobacter  
19 infections doesn't necessarily mean that it was that  
20 the chicken in the commercial establishment or the  
21 poultry in the commercial establishments caused the  
22 fluoroquinolone-resistant campylobacteriosis. Am I

1 right?

2 A Chicken has campylobacter on it. People eat  
3 chicken. There are fluoroquinolone-resistant bacteria  
4 on chickens.

5 People -- there's a large body of evidence  
6 that chicken is a risk factor.

7 JUDGE DAVIDSON: Excuse me.

8 THE WITNESS: I'm sorry.

9 JUDGE DAVIDSON: Doctor, you know, it's  
10 difficult, and I know there's a lot of -- you don't  
11 want to give any wrong answers or wrong impression, but  
12 I think if you pay careful attention to the question,  
13 the answer might not be as complicated.

14 THE WITNESS: Okay.

15 JUDGE DAVIDSON: I'm going to have the  
16 reporter read the question back, and then listen  
17 carefully, and if you still want to give the same  
18 answer, feel free to do so.

19 (The reporter read back the record.)

20 THE WITNESS: By itself, no.

21 BY MR. KRAUSS:

22 Q Now, your population-attributable fractions

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1 were calculated using a multiple logistic regression  
2 model, right?

3 A Uh-huh. I'm sorry. Yes.

4 Q Would you agree that selecting a different  
5 multiple logistic regression model with different  
6 variables could have produced different PAF estimates?

7 A Yes.

8 Q Would you agree that a different multiple  
9 logistic regression model with more interaction terms  
10 might fit the data set better than the one you used?

11 A That's possible, yes.

12 Q Did your multiple logistic regression model  
13 fit the data better than any other logistic regression  
14 model?

15 A That was the best model that we -- I'm sorry.  
16 Would you repeat that again?

17 Q Uh-huh.

18 Did your multiple logistic regression model  
19 fit the data better than any other logistic regression  
20 model that you tested, or did you test any?

21 A When you say "any" --

22 MS. ZUCKERMAN: Objection, Your Honor. It's a  
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1 compound question.

2 JUDGE DAVIDSON: That's all right. I think --  
3 she's having trouble with it, but I'm going to allow  
4 her to answer.

5 THE WITNESS: This fit the best for the models  
6 that we tested.

7 MR. KRAUSS: Okay.

8 BY MR. KRAUSS:

9 Q What other models did you test?

10 A We tested some -- I can't recall the  
11 specifics, but we tested other -- we put other  
12 variables within the model.

13 Q You put other variables within your model.  
14 Did you use any other type -- did you test any other  
15 type of model besides your multiple logistic regression  
16 model?

17 A No.

18 Q Do you know what a non-parametric model is?

19 A I'm not familiar.

20 Q Now, Dr. Kassenborg, in doing your study, you  
21 performed, if I understand this correctly, a step-wise  
22 regression and you found that eating chicken or turkey

1 at a commercial establishment was the only risk factor  
2 that remained independently associated with  
3 fluoroquinolone-resistant campylobacteriosis. Do I  
4 have that right?

5 A That's correct.

6 Q Could your finding -- and here I mean your  
7 finding that eating chicken or turkey at a commercial  
8 establishment was the only risk factor that remained  
9 independently associated with fluoroquinolone-resistant  
10 campylobacteriosis -- depend on the statistical test  
11 used?

12 A Yes.

13 Q And you used backward step-wise regression to  
14 help reach your conclusion. Am I right?

15 A No, I believe this was forward.

16 MR. KRAUSS: Your Honor, may I have one  
17 minute?

18 JUDGE DAVIDSON: Certainly.

19 MR. KRAUSS: All right.

20 BY MR. KRAUSS:

21 Q So, Dr. Kassenborg, your testimony is that you  
22 used forward step-wise regression, right?



1 A Yes.

2 Q Did you try using backward step-wise  
3 regression?

4 A Yes.

5 Q What were the results?

6 A That model did not -- none of the -- I don't  
7 believe anything was statistically -- I believe nothing  
8 was statistically significant in the backwards.

9 Q So, doing the backwards step-wise regression,  
10 there was -- there were no statistically significant  
11 associations between the risk factors you were studying  
12 and the outcome which was fluoroquinolone-resistant  
13 campylobacteriosis.

14 A Correct.

15 Q And did you publish those results?

16 A No.

17 Q Did you mention that in your paper?

18 A No.

19 Q Is there a reason why you didn't report that?

20 A Usually don't publish papers with negative  
21 findings.

22 Q Does your finding -- do I need to repeat what

1 the finding is? Can I just refer to your finding as  
2 your finding? Okay?

3 A Yes.

4 Q Does your finding depend on the model that you  
5 used?

6 A Yes, it would depend upon the model I used.

7 Q And could using a different model have  
8 produced a different result?

9 A Yes, it could.

10 Q I apologize if this is redundant. Did you try  
11 any other models?

12 A No.

13 Q Now, Dr. Kassenborg, in your analysis, was  
14 drinking raw milk a risk factor that was independently  
15 associated with fluoroquinolone-resistant  
16 campylobacteriosis?

17 MS. ZUCKERMAN: Objection, Your Honor. I  
18 think Counsel has already established from Dr.  
19 Kassenborg that the one finding -- that there was one  
20 finding. So, going through any other risk factors  
21 would be irrelevant.

22 MR. KRAUSS: Your Honor, I just want to  
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1 explore other risk factors to confirm with the witness  
2 that those risk factors were not independently  
3 associated with the illness.

4 JUDGE DAVIDSON: Well, you're free to do that,  
5 but I think -- you do it your way, but wouldn't it be -  
6 - would it be better if you asked her if there were  
7 other risk factors considered and then what they were,  
8 instead of asking her ones that you've come up with one  
9 by one?

10 MR. KRAUSS: There is a few that I believe are  
11 significant that I'd like to just explore with her,  
12 Your Honor.

13 JUDGE DAVIDSON: Well, why don't you ask her  
14 first if there were any others, and then you can  
15 explore those. If she says no, you're finished. Okay?

16 MR. KRAUSS: Yes, Your Honor.

17 BY MR. KRAUSS:

18 Q Did you consider any other factors, Dr.  
19 Kassenborg, risk factors?

20 A That's just part of the question. I'm not  
21 sure which question you're asking me now.

22 Q Did you analyze any other risk factors to see

1 whether they were independently associated with the  
2 outcome, fluoroquinolone-resistant campylobacteriosis?

3 A No, the ones that were listed in my testimony  
4 were the ones that were put into the model, those that  
5 achieved a statistical significance of .06 or less, as  
6 is stated in my testimony.

7 Q So -- and here, are you referring to Table  
8 1 --

9 A Yes.

10 Q -- Dr. Kassenborg? Are these the only  
11 exposures or risk factors that you look at, the four  
12 that are listed on page 14 of G1460?

13 A For domestically acquired fluoroquinolone-  
14 resistant cases, matched with well controls, those are  
15 the only ones we looked at in the model, yes.

16 Q So, I take it, then, that you didn't look at  
17 whether drinking raw milk was an independently  
18 associated --

19 JUDGE DAVIDSON: Is that listed?

20 MR. KRAUSS: Excuse me, Your Honor?

21 JUDGE DAVIDSON: Is that listed in the table?

22 MR. KRAUSS: No, Your Honor.

1 JUDGE DAVIDSON: I think the record is already  
2 clear. I don't think you have to enunciate each one  
3 that wasn't considered. She's testified what was  
4 considered.

5 Unless you have information as a foundation  
6 that there were other things that she's not testifying  
7 to, I don't understand why you have to go through that.  
8 I'll listen to what you have to say. Go ahead.

9 MR. KRAUSS: Can I ask about one in  
10 particular, Your Honor?

11 JUDGE DAVIDSON: Just raw milk?

12 MR. KRAUSS: No, I'm going to change the risk  
13 factor, Your Honor.

14 JUDGE DAVIDSON: All right. Go ahead.

15 MR. KRAUSS: Thank you, Your Honor.

16 BY MR. KRAUSS:

17 Q Dr. Kassenborg, did your analysis consider  
18 whether eating non-poultry meat prepared at a  
19 restaurant was a risk factor that remained  
20 independently associated with fluoroquinolone-resistant  
21 campylobacteriosis?

22 A No, that's -- no.

1 Q Now, Dr. Kassenborg, is it possible that two  
2 or more risk factors can interact and produce a risk  
3 that is different than those risk factors when analyzed  
4 individually?

5 A Yes.

6 Q Is being an independently associated risk  
7 factor the same as being a cause?

8 A No.

9 Q On page 8 of your testimony, in paragraph 16,  
10 you mention that you combined individual risk factors.

11 A I'm sorry. I'm not finding that. Could you  
12 repeat where that's found?

13 Q Yes. Page 8, paragraph 16.

14 JUDGE DAVIDSON: Line 9. Starts on line 9.

15 THE WITNESS: Oh, it starts on 9.

16 MR. KRAUSS: I'm sorry.

17 BY MR. KRAUSS:

18 Q Yes, line 9 through 11.

19 (Witness examines the document.)

20 In combining individual risk factors, did you  
21 correct for multiple testing bias?

22 A No, there was no need.

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1 Q Would you agree that campylobacter,  
2 campylobacteriosis risk factors can have interactions  
3 among them?

4 A Yes.

5 Q Now, you used the 1998-1999 ~~EDD~~ <sup>CDC</sup> campylobacter  
6 case control study data for your model, right?

7 A That's correct.

8 Q Would you agree that the data from that study  
9 shows that males have a significantly higher frequency  
10 of campylobacteriosis than females?

11 A Again, I wasn't involved in that analysis.  
12 I'm only testifying on my testimony. I don't know.

13 Q You used the data --

14 A Larger data set, yes. This is a subset of  
15 that data set.

16 Q Okay. So --

17 A I'm not going to comment on the study.

18 Q Does your multiple conditional logistic  
19 regression model include an interaction term to model  
20 potential interactions between factors?

21 A No.

22 MS. ZUCKERMAN: Objection, Your Honor. Asked  
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1 and answered.

2 JUDGE DAVIDSON: She answered it.

3 MR. KRAUSS: Can I have a minute, Your Honor?

4 JUDGE DAVIDSON: Certainly.

5 BY MR. KRAUSS:

6 Q Dr. Kassenborg, in your testimony at page 3,  
7 line 11 to 12, it states that --

8 JUDGE DAVIDSON: We can all see what it  
9 states.

10 MR. KRAUSS: Thank you, Your Honor.

11 JUDGE DAVIDSON: You don't have to read it  
12 unless you want her -- you know --

13 BY MR. KRAUSS:

14 Q There were 20,723,982 people enrolled, and in  
15 your paper, G337, page 5, it says the study area was  
16 comprised of 25,859,311 people. My question is which  
17 was it?

18 MS. ZUCKERMAN: Objection, Your Honor. I know  
19 you asked that Mr. Krauss not read the testimony, but  
20 he did, and he misstated the number on line 12.

21 JUDGE DAVIDSON: He didn't misstate it by  
22 much, but it's okay. There's a difference between this



1 number and the number in the paper. That's the  
2 question. I'll allow the question.

3 MR. KRAUSS: Thank you, Your Honor. That is  
4 the question. Thank you, Your Honor.

5 THE WITNESS: I go with my testimony, the  
6 figure stated on line 12 of page 3.

7 BY MR. KRAUSS:

8 Q The figure stated on page 3, line 12, is the  
9 study area?

10 A Yes.

11 Q Do you know whether your final manuscript that  
12 was submitted for publication uses the 20 million  
13 number or the 25 million number?

14 A It would use the figure in my testimony.

15 Q In your analysis, the study that you did, are  
16 the people in your study population a simple random  
17 sample of the general U.S. population?

18 A No, they are not a random sample of the entire  
19 population, no.

20 Q Does the sample of the U.S. population that  
21 was enrolled in your study have the same statistical  
22 properties as a simple random sample of the general

1 United States population?

2 A No.

3 Q Your study used data from the FoodNet  
4 surveillance area. Isn't that right?

5 A Yes. Correct.

6 Q Do you believe that whatever is true in the  
7 FoodNet surveillance data is also true in the general  
8 United States population?

9 MS. ZUCKERMAN: Objection, vague. "Whatever  
10 is true"?

11 JUDGE DAVIDSON: Rephrase the question.

12 BY MR. KRAUSS:

13 Q Do you believe that whatever is true in terms  
14 of the demographics of the FoodNet surveillance data is  
15 also true in the general United States population?

16 A Again, I'm not a FoodNet expert, I'm an expert  
17 on my testimony, and I'm not going to comment on that.

18 Q Now, Dr. Kassenborg, you mentioned confounding  
19 earlier and what a confounder was. Does your use of a  
20 multi-variant model preclude the possibility of any  
21 residual confounding that might distort its results?

22 A With any study, you can always have a

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1 confounder.

2 Q Would that be a no to the question?

3 A You're using several double negatives, so I'm  
4 not sure what --

5 Q Okay. I'm sorry. I'll try not to do that.

6 Does your use of a multi-variant model  
7 preclude the possibility of any residual confounding  
8 distorting the results of your study?

9 A It does not preclude confounding, that is  
10 correct.

11 Q Would that be any confounding? I'd asked  
12 about residual confounding.

13 A Confounding. I guess I'm not sure what you  
14 mean by residual confounding.

15 Q You don't know the term "residual  
16 confounding"?

17 A I'm not sure what you mean by residual  
18 confounding. It's either confounding or not  
19 confounding.

20 Q Let me ask a different question, since you  
21 answered that one.

22 Does your use of a multi-variant model

1 preclude the possibility of any unmeasured confounders  
2 distorting your results?

3 A As I stated before, there can be unmeasured --  
4 there can be other things that could be confounders.  
5 That's why you don't base everything on one study and  
6 you use the body of medical evidence to make your  
7 decisions.

8 Q And my question was whether your use of the  
9 particular model that you used precludes the effective  
10 confounder.

11 A No, that would not.

12 Q In your analysis, did you perform any formal  
13 statistical test to detect confounders?

14 A We put them within the model to see if there  
15 was any association between them, and the model should  
16 have picked up some of those particular confounders.  
17 It may not have picked up everything, but it should  
18 have picked that up.

19 Q I thought I asked you earlier if your use of  
20 the model precluded the possibility of confounders  
21 distorting your results. I thought you had said no.  
22 Then I asked whether you did any statistical tests, and

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1 you said, well, the model should have picked them up.

2 A You will pick up some, but with any study,  
3 there's always things that you don't ask about, that  
4 may not have been included in the model, that could  
5 have -- that could be a confounder.

6 Q In your analysis, did you use any formal  
7 statistical techniques to adjust for biases that might  
8 be introduced by selection of confounders?

9 A No.

10 Q Did you use any formal statistical techniques  
11 to adjust for biases introduced by the selection of  
12 your variables?

13 A We entered variables that were less than --  
14 that were statistically significant at a value of  
15 confidence interval of .06. So, those individual  
16 statistical analyses were used. So, yes.

17 Q My question was whether you used any formal  
18 statistical techniques.

19 A Yes. We did conditional -- we looked at the  
20 ~~uni-variant~~ <sup>univariate</sup> factors and if they were statistically  
21 significant, so we performed statistical testing on  
22 those, and if they were statistically significant, then

1 we -- then they were entered into the model. So, that  
2 was the statistical test.

3 MR. KRAUSS: Your Honor, would this be a good  
4 place for a break?

5 JUDGE DAVIDSON: If you want.

6 MR. KRAUSS: Thank you, Your Honor.

7 JUDGE DAVIDSON: How much time you think you  
8 want for this break? Just a short one or what?

9 MR. KRAUSS: Just a short one will be fine.

10 JUDGE DAVIDSON: All right. We'll adjourn  
11 till 20 after 10:00.

12 Off the record.

13 (A brief recess was taken.)

14 MR. KRAUSS: Your Honor, I have no further  
15 questions for the witness at this time.

16 JUDGE DAVIDSON: All right.

17 The witness is available for redirect.

18 MS. ZUCKERMAN: Thank you, Your Honor.

19 REDIRECT EXAMINATION

20 BY MS. ZUCKERMAN:

21 Q Dr. Kassenborg, you were asked by Mr. Krauss  
22 whether non-poultry meat was considered in the model,

1 and I believe your answer was that it was not. Would  
2 you explain why it was not considered, please?

3 A Because it was -- it was protective. The  
4 study was looking at risk factors. Oh, I'm sorry. I  
5 was looking at the wrong thing.

6 Why non-poultry meat was -- I'm sorry. I  
7 misunderstood the question.

8 Q Would you explain why non-poultry meat was not  
9 considered in your model?

10 A It was not statistically significant.

11 JUDGE DAVIDSON: I'm sorry. I didn't hear  
12 your answer.

13 THE WITNESS: It was not significant in a  
14 statistical sense.

15 BY MS. ZUCKERMAN:

16 Q When you say it was not significant in the  
17 statistical sense, that means that you considered it --  
18 you considered putting it in the final model but you  
19 did not.

20 So, how did you consider it? What kind of  
21 analysis did you do to consider it?

22 A Anything less than P value of .05 -- of .06 on

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1 the ~~uni-variant~~ <sup>univariate</sup> analysis were included in the final  
2 model.

3 Q So, as I understand it, the ~~uni-variant~~ <sup>univariate</sup>  
4 analysis looked at a number of risk factors so that you  
5 would be able to decide what risk factors to put in a  
6 final ~~multi-variant~~ <sup>multivariate</sup> model. Is that correct?

7 A Yes. There were pages and pages of risk  
8 factors that we looked at, numerous risk factors that  
9 we looked at and analyzed.

10 Q Thank you.

11 Are you the sole author on your paper that  
12 we've been discussing today?

13 A Oh, no, there's others on here. There's  
14 representatives from other state health departments,  
15 being those FoodNet sites, also representatives from  
16 CDC, as well.

17 Q Representatives from any other agency? I'm  
18 sorry. Let me rephrase that.

19 Was your manuscript reviewed?

20 A Oh, yes. It was reviewed by all the authors.  
21 It was reviewed by numerous conference calls with those  
22 authors. It went through a quite rigorous and lengthy

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1 process to get through clearance with CDC. FDA also  
2 looked at it.

3 So, there was many persons within -- not just  
4 the authors but statisticians of the CDC -- many, many  
5 people looked at this particular document.

6 Q Do you know whether anyone suggested adding  
7 interaction terms into the model?

8 A No.

9 Q No --

10 A No, no one did. No one in any of those  
11 reviews and edits suggested that at all. This was a  
12 pretty straightforward analysis, pretty standard  
13 approach.

14 Q Did any of your reviewers suggest using a non-  
15 parametric model?

16 MR. KRAUSS: Objection, Your Honor. Can I get  
17 a clarification as to whether they're talking about the  
18 review for Exhibit G337 versus the --

19 JUDGE DAVIDSON: I thought they were talking  
20 about 337, but okay, that's a legitimate question.

21 BY MS. ZUCKERMAN:

22 Q Were there different reviewers for --

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*Corrected as per OR 46 6/13/02*

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1 JUDGE DAVIDSON: Let's clarify. We are  
2 talking about Exhibit G337 with this line of  
3 questioning as far as submitting to other individuals,  
4 authors. You asked her first about authors --

5 MS. ZUCKERMAN: Yes.

6 JUDGE DAVIDSON: -- and she said there were.  
7 Then you asked her about was it submitted to different  
8 organizations or people for review? I think we're  
9 still talking about 337, but I haven't heard you say  
10 that since the question was asked.

11 MS. ZUCKERMAN: I'm sorry, Your Honor. Yes,  
12 we are talking about G337.

13 JUDGE DAVIDSON: Thank you.

14 MS. ZUCKERMAN: I apologize.

15 JUDGE DAVIDSON: That clarifies it.

16 MR. KRAUSS: Thank you, Your Honor.

17 BY MS. ZUCKERMAN:

18 Q Dr. Kassenborg, did any of the reviewers of  
19 G337 suggest using a non-parametric model?

20 A No.

21 Q Dr. Kassenborg, did any of the reviewers of  
22 G337 suggest using another *multivariate* ~~multi-variant~~ model besides

1 logistic regression?

2 A No.

3 MS. ZUCKERMAN: May I have a moment, Your  
4 Honor, please?

5 JUDGE DAVIDSON: Certainly.

6 MS. ZUCKERMAN: Your Honor, may I have a few  
7 moments to confer with co-counsel?

8 JUDGE DAVIDSON: Certainly.

9 MS. ZUCKERMAN: Thank you, Your Honor. One  
10 final question.

11 JUDGE DAVIDSON: Go ahead.

12 BY MS. ZUCKERMAN:

13 Q Dr. Kassenborg, have any of the reviewers  
14 suggested any changes in the statistical model that you  
15 used between the review of G337 and the paper accepted  
16 for publication?

17 A Yes. There was -- referring to the  
18 statistical model? So, you're asking about between  
19 this particular --

20 Q G337.

21 A Oh. Between the statistical model and this?

22 Q G337 is an earlier draft of the manuscript  
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1 that has been accepted for publication. Is that  
2 correct?

3 A This is a draft for the manuscript, yes.

4 Q Did any of the reviewers who reviewed any  
5 drafts subsequent to G337 suggest a change in the  
6 statistical model that you used?

7 A No, they did not.

8 MR. KRAUSS: Objection, Your Honor.

9 JUDGE DAVIDSON: Sustained.

10 MR. KRAUSS: Thank you, Your Honor.

11 JUDGE DAVIDSON: That's too complicated.

12 MS. ZUCKERMAN: Okay.

13 MR. KRAUSS: Your Honor, thank you for  
14 sustaining my objection, but that wasn't really my  
15 objection. She's asking the witness now to testify  
16 about a later draft of G337 which has not been  
17 produced.

18 JUDGE DAVIDSON: Excuse me. You may think I  
19 didn't understand, but I did.

20 MR. KRAUSS: Oh, I'm sorry.

21 JUDGE DAVIDSON: The problem I saw with the  
22 question was she said any later drafts, and that was

1 what you're objecting to.

2 MR. KRAUSS: Yes, Your Honor. Thank you.

3 JUDGE DAVIDSON: What she really was talking  
4 about, was there any suggested change between the  
5 Exhibit 337 and the final draft that was submitted for  
6 publication. If that's what you're asking, you may ask  
7 it.

8 MR. KRAUSS: And not produced to us.

9 JUDGE DAVIDSON: We'll get to that.

10 MR. KRAUSS: Okay.

11 JUDGE DAVIDSON: If there was. We don't know  
12 that there were.

13 MR. KRAUSS: Thank you, Your Honor.

14 MS. ZUCKERMAN: Thank you, Your Honor.

15 Actually, I have no further questions.

16 JUDGE DAVIDSON: Well, we have about four  
17 possibilities for recross. Go ahead.

18 MR. KRAUSS: Only picking up on one of them,  
19 Your Honor.

20 RE CROSS EXAMINATION

21 BY MR. KRAUSS:

22 Q Dr. Kassenborg, in your answers on redirect,  
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1 when you were referring to the level of review and the  
2 reviewers of your papers, were you limiting your  
3 answers to Exhibit G337 the whole time that you were  
4 answering questions about reviewing?

5 A In part, it would be -- well, if you look at  
6 the tables that I attached to my testimony, that has  
7 that particular model that we're talking about in it,  
8 and so, I was referring to that particular model, which  
9 is the same in my testimony.

10 MR. KRAUSS: Thank you.

11 No further questions, Your Honor.

12 JUDGE DAVIDSON: Okay.

13 MS. ZUCKERMAN: No further questions, Your  
14 Honor.

15 JUDGE DAVIDSON: All right. The witness is  
16 excused.

17 (Witness excused.)

18 JUDGE DAVIDSON: Do you have some papers for  
19 me?

20 MS. ZUCKERMAN: Yes, Your Honor. Yes, Your  
21 Honor.

22 We would like to submit the response to your  
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1 direction to provide information regarding the Sentinel  
2 County study and what information was provided to  
3 Bayer, and we have the document here. We have a  
4 declaration from CDC, CDC's FOIA office, from whom  
5 Bayer requested Sentinel County information, and we  
6 have attached the declaration to a motion that we have  
7 styled as a supplemental motion to reinstate the  
8 documents and written direct testimony in the  
9 evidentiary record that we spoke of Monday morning.

10 JUDGE DAVIDSON: When you say have filed --

11 MS. ZUCKERMAN: I'm sorry. We have not filed  
12 it --

13 JUDGE DAVIDSON: You are filing it now.

14 MS. ZUCKERMAN: I have it here, yes.

15 JUDGE DAVIDSON: Okay. That's fine. I just  
16 didn't want there to be something I didn't have a copy  
17 of somehow.

18 MS. ZUCKERMAN: Your Honor, may I approach?

19 JUDGE DAVIDSON: Certainly. You'll provide a  
20 copy to the dockets branch. You don't have to give it  
21 to the reporter, because it's not going to be marked.  
22 This is a motion.

1 MS. ZUCKERMAN: Yes, Your Honor.

2 JUDGE DAVIDSON: And this is information I  
3 asked for.

4 MS. ZUCKERMAN: Yes, Your Honor.

5 JUDGE DAVIDSON: So it does not get an exhibit  
6 number. Okay?

7 MS. ZUCKERMAN: Yes, Your Honor.

8 JUDGE DAVIDSON: Okay.

9 MR. NICHOLAS: Your Honor, we have a reply to  
10 CBM's motion.

11 Since we were not aware, obviously, that CBM  
12 was going to file a supplemental motion with new  
13 information, we request the right to reply to CBM's  
14 motion to the extent there's anything additional in  
15 there that was not presented to the court.

16 JUDGE DAVIDSON: That's fine.

17 MR. NICHOLAS: You had asked for the protocol,  
18 and that contains a copy of the information that we  
19 received.

20 MS. ZUCKERMAN: Your Honor, I just would like  
21 the record to reflect that I also handed a copy of our  
22 motion to opposing counsel.



1 JUDGE DAVIDSON: Okay.

2 MR. NICHOLAS: And we, as well, have handed  
3 one to opposing counsel.

4 JUDGE DAVIDSON: I need some additional  
5 assistance before I look through this material. Is  
6 there such a thing as a Sentinel County study in the  
7 record?

8 MS. ZUCKERMAN: There was, Your Honor.

9 JUDGE DAVIDSON: Exhibit number?

10 MS. ZUCKERMAN: And it was --

11 JUDGE DAVIDSON: I know I struck something,  
12 but I'm looking for an exhibit number which is entitled  
13 the Sentinel County study, because I reviewed their  
14 motions to strike. They didn't put an exhibit number  
15 on it. They just referred to all the information from  
16 the Sentinel County study.

17 MS. ZUCKERMAN: There are two -- Your Honor,  
18 there is no one exhibit --

19 JUDGE DAVIDSON: That's what I thought.

20 MS. ZUCKERMAN: -- that is entitled Sentinel  
21 County study.

22 JUDGE DAVIDSON: Okay.

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1 Now, that's what I'm asking.

2 I think my order was fairly clear. I struck  
3 the material relating to the Sentinel County study that  
4 is in the record, because you hadn't furnished the  
5 protocol that was requested, and without knowing what  
6 was in the protocol, I felt that that was -- with all  
7 the time you had -- that that was wrong.

8 Now, give me the exhibit numbers that do, in  
9 fact, reflect the Sentinel County study, as opposed to  
10 testimony about the study.

11 MS. ZUCKERMAN: Certainly, Your Honor. One of  
12 those exhibits is attached to the motion I handed you.  
13 It is the protocol to the Sentinel County study.  
14 It's --

15 JUDGE DAVIDSON: That wasn't in previously.

16 MS. ZUCKERMAN: No, it wasn't, Your Honor, and  
17 in fact, <sup>CVM</sup>~~CBM~~ did not have a copy of it.

18 JUDGE DAVIDSON: I understand that part, but  
19 I'm talking about what we have in the record, the  
20 exhibit numbers in the record that reflect the Sentinel  
21 County study, not that refer to it or talk about it  
22 but --

1 MS. ZUCKERMAN: The two -- yes, Your Honor.  
2 The two -- there are two exhibits in the record that  
3 only talk about the Sentinel County study. There is  
4 not one exhibit that is --

5 JUDGE DAVIDSON: Are you telling me there was  
6 no published paper that --

7 MS. ZUCKERMAN: -- dealt solely with the  
8 Sentinel County study.

9 JUDGE DAVIDSON: Or gave the results of the  
10 study or something that was subject to review?

11 MS. ZUCKERMAN: Your Honor, there are two  
12 documents on the record that are published that were  
13 subject to review. One of them does speak to the  
14 Sentinel County study susceptibility test results.

15 JUDGE DAVIDSON: All right. And that exhibit  
16 number is?

17 MS. ZUCKERMAN: That is Exhibit G624.

18 JUDGE DAVIDSON: 624.

19 MS. ZUCKERMAN: Yes.

20 JUDGE DAVIDSON: Anything else?

21 MS. ZUCKERMAN: If I may, to the extent that  
22 you direct, would it be helpful to go through the

1 diagram that has been provided as an attachment to this  
2 motion? The diagram does outline the isolates that  
3 were used in the Sentinel County study.

4 JUDGE DAVIDSON: No, I don't think that would  
5 help me at all. I can see it for myself if it's in the  
6 exhibit -- if it's in the motion, attached to the  
7 motion.

8 MS. ZUCKERMAN: Yes, it is.

9 JUDGE DAVIDSON: All right. I'll look at it.  
10 Let you know on Monday, hopefully, if I can decide by  
11 then.

12 MS. ZUCKERMAN: Thank you, Your Honor.

13 MR. NICHOLAS: Your Honor, is there a time  
14 limit for us to respond?

15 JUDGE DAVIDSON: Well, first of all, we don't  
16 know there's anything here to respond to. You said if  
17 there's something in there that you hadn't previously  
18 seen.

19 MR. NICHOLAS: Yes, Your Honor.

20 JUDGE DAVIDSON: The sooner the better, is all  
21 I can tell you. The rules say 10 days, but we'll be  
22 long gone by then, I hope.

1 I hate to cry poor, but I'm pretty much by  
2 myself, with an occasional assistance from a law  
3 student in these cases, and I've got -- does anybody  
4 have an idea how many thousands and thousands of pages  
5 you people have given me to look at?

6 No one wants to venture a guess? Three  
7 thousand proposed findings of fact? Three thousand?

8 Never in my 30-some years on the bench have I  
9 seen 3,000 proposed findings of fact, and both sides  
10 are guilty, 1,500 or more from each side. There's only  
11 four or five issues in this case. I know they're not  
12 simple issues, but that's ridiculous.

13 Six hundred pages of replies to motions to  
14 strike? A lot of repetition. I don't want to see that  
15 in the brief.

16 I'm going to limit the briefs, and I'm going  
17 to ask you -- I can't require you, but I'm going to ask  
18 you to organize the briefs in a way that will assist me  
19 in going through this record, because up until now, the  
20 organization of your material is all over the place.  
21 You're not helping me.

22 I don't have the staffs you have to prepare

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1 this stuff, and that goes for both sides. General  
2 Counsel's office has quite a few lawyers working on  
3 this. I see them sitting there at the table. And I  
4 know I have more experience than all of you put  
5 together, but that still doesn't enable me to go  
6 through this vast amount of material in the reasonable  
7 amount of time I'd like to be able to do it.

8 So, with that -- as I say, I hate to cry poor,  
9 but that's where I sit and that's where I stand, and  
10 I'd appreciate it if you would attempt to minimize the  
11 verbiage from here on out.

12 And that said, we're adjourned until 9:00  
13 o'clock on Monday morning, same time, same station.

14 (Whereupon, at 10:40 a.m., the hearing was  
15 adjourned, to reconvene Monday, May 5, 2003, at 9:00  
16 a.m.)

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