

ORIGINAL

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

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

Food and Drug Administration  
5600 Fishers Lane  
Rockville, Maryland

Tuesday, May 6, 2003

THE HEARING in the above-entitled matter  
commenced at 9:30 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

## APPEARANCES:

On behalf of the Center for  
Veterinary Medicine (CVM):

NADINE R. STEINBERG, ESQ.  
ROBERT M. SPILLER, JR., ESQ.  
CLAUDIA J. ZUCKERMAN, ESQ.  
CANDACE C. AMBROSE, ESQ.  
U.S. Food and Drug Administration  
Department of Health and Human Services  
Office of the General Counsel  
Office of the Chief Counsel  
5600 Fishers Lane, GCF-1  
Rockville, Maryland 20857  
(301) 827-5050

On behalf of Respondent Bayer Corporation:

GREGORY A. KRAUSS, ESQ.  
ROBERT B. NICHOLAS, ESQ.  
JEFFREY C. BATES, ESQ.  
McDermott, Will & Emery  
600 13th Street, N.W.  
Washington, D.C. 20005-3096  
(202) 756-8263

Also present:

Dennis D. Copeland, D.V.M., Director  
Stewardship - Government/Industry Relations  
Research & Development  
Bayer HealthCare Animal Health Division  
Bayer HealthCare, LLC  
P.O. Box 390  
Shawnee Mission, Kansas 66201-0390  
(913) 268-2522

## C O N T E N T S

WITNESSES:	DIRECT	CROSS	REDIRECT	RE CROSS
Mary Bartholomew	731	734		
Louie Cox, Jr.	835	836		

  

RESPONDENT EXHIBITS:	IDENTIFIED	RECEIVED
1924 - Attachment to motion	915	915
1925 - Unidentified document	915	915
1926 - Unidentified document	915	915
1927 - Granoff, et al. study	915	915
1942 - Study on Restaurant Spending	759	
1943 - Today's Special: Nutrition Information	766	

  

GOVERNMENT EXHIBITS:		
1806 - MIT transcript of Cox	852	
1807 - Harvard transcript of Cox	855	
1808 - Letter from ASA to Cox	858	
1809 - 4/99 Cox letter to Voxe	866	
1810 - Second day of transcript	873	877
1811 - Cox paper	885	

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

2 JUDGE DAVIDSON: Okay. Are there any  
3 preliminary matters?

4 MR. SPILLER: The Center has no preliminary  
5 matters, Your Honor.

6 MR. NICHOLAS: I do, Your Honor. Bob  
7 Nicholas.

8 First off, we attempted to hand-deliver to you  
9 yesterday the docket, our reply. I'm not sure whether  
10 you got it or not.

11 JUDGE DAVIDSON: I got it.

12 MR. NICHOLAS: Secondly --

13 JUDGE DAVIDSON: It was not just a reply; was  
14 it?

15 MR. NICHOLAS: No. It was a reply to the  
16 motion and in addition --

17 JUDGE DAVIDSON: Another motion. Come on.  
18 It's not your fault. You're all doing it.

19 MR. NICHOLAS: And Mr. Krauss has one or two  
20 matters.

21 JUDGE DAVIDSON: All right. Mr. Krauss.

22 MR. KRAUSS: Good morning, Your Honor.

1 Gregory Krauss on behalf of Bayer.

2 Yesterday I promised just to give you an  
3 update on the "B" documents that I used and whether  
4 they were in evidence. In fact, they are all in  
5 evidence. B-44, B-881 and B-934 are all in evidence.

6 JUDGE DAVIDSON: Thank you.

7 All right. Here's what I have for you. I  
8 received admittedly confusing e-mail and then I managed  
9 to figure out what was involved in and look at the  
10 material. Correct me if I'm wrong. What it's talking  
11 about is correspondence back and forth concerning  
12 Freedom of Information Act requests and other requests  
13 from Bayer to CVM and other government agencies, I  
14 guess, and there appears to be some disagreement as to  
15 what was happening, what did happen, what did not  
16 happen, et cetera, et cetera.

17 But the latest motion from Bayer indicates  
18 that they have no objection to government's G-1801  
19 coming in and Bayer 34, 36, 37 -- I forget.

20 MR. NICHOLAS: It's 1937 to 41, Your Honor.

21 JUDGE DAVIDSON: "B." 37 to 41 comes in,  
22 because it all deals with the same subject matter.

1 Well, I'm going to let you decide.

2 First of all, if you want them all in, which I  
3 don't see the need to, but if you want them all in,  
4 including 1804, which I did not allow in yesterday,  
5 which deals with the same kind of thing -- okay.

6 If you don't want them in, that's fine with  
7 me, too. They stay in the administrative record and if  
8 there becomes a particular issue as to what was or  
9 wasn't then maybe that will rise to the level of  
10 evidence.

11 As far as I'm concerned, it's just procedural  
12 correspondence which may or may not affect the evidence  
13 in this proceeding.

14 So by the close of business today, you can  
15 tell me what you've decided during one of the recesses.  
16 If you want extra, I will let you get together and  
17 confer whether you want them in or out. Personally, I  
18 would just as soon leave them out. It would be the  
19 same for everybody and they would be in 1285, as I  
20 said.

21 Okay. Now we have another appearance ready?

22 MR. BATES: Good morning, Your Honor.

1 JUDGE DAVIDSON: State your name, address, and  
2 capacity in which you appear and the long list of bars  
3 in different states and the United States Government  
4 you've been admitted to.

5 MR. BATES: My name is Jeffrey Bates. I'm  
6 with McDermott, Will & Emery. I can be reached at the  
7 firm in Washington address as well as 28 State Street,  
8 Boston, Massachusetts, which is our Boston office,  
9 02109.

10 I'm admitted to practice law in the State of  
11 Massachusetts or, as we like to say, the Commonwealth  
12 of Massachusetts, as well as a number of courts,  
13 including in the federal courts, Registry of  
14 Commonwealth.

15 JUDGE DAVIDSON: Okay. Thank you.

16 MR. BATES: And oh, one last point. I'm  
17 appearing on behalf of Bayer.

18 JUDGE DAVIDSON: Oh, I did not know that.

19 Okay. We're ready for Dr. Bartholomew.

20 MR. SPILLER: The Center calls Mary  
21 Bartholomew.

22

1 Whereupon,

2

MARY BARTHOLOMEW

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

5

JUDGE DAVIDSON: All right. Please be seated.

6

Give your full name and address to the reporter and

7

then await counsel's additional questions.

8

THE WITNESS: My name is Mary Joann

9

Bartholomew. My address is, Center for Veterinary

10

Medicine, HFV 105, 7500 Standish Place, Rockville,

11

20855.

12

MR. SPILLER: May I approach the witness, Your

13

Honor?

14

JUDGE DAVIDSON: Certainly.

15

DIRECT EXAMINATION

16

BY MR. SPILLER:

17

Q Dr. Bartholomew, I'm handing you a document.

18

Can you identify that, please, for the record?

19

A Yes. That's my witness testimony with my CV

20

attached at the back.

21

Q And is your testimony Exhibit G, like "Golf,"

22

1454?

1 A Yes, it is.

2 Q And is your CV Exhibit --

3 JUDGE DAVIDSON: 1404.

4 MR. SPILLER: Thank you, Your Honor.

5 BY MR. SPILLER:

6 Q G-1404?

7 A Yes, it is.

8 Q And referring to Exhibit G-1454 and page 20,  
9 is that a copy of your signature?

10 A Yes, it is.

11 Q Since the date that you signed this, have you  
12 had the opportunity to look through it to see whether  
13 or not there are errors that require correction?

14 A Yes, I have.

15 Q And did you find any?

16 A I found one that I would like to correct at  
17 this time.

18 Q All right. Tell us what page that's on.

19 A It's page eight, line 16.

20 Q All right. I have page eight, line 16, and I  
21 notice that material is double indented. Is that a  
22 quote of something else?

1           A     Yes.  That's a quote from a book chapter  
2     that --

3           Q     All right.  So am I correct that the  
4     correction you're offering today is to your testimony -  
5     - we're not presuming to go back and change the book.  
6     Is that right?

7           A     That's right.

8           Q     Okay.  Tell us what that correction is.

9           A     The fraction of 45.2 percent should be 48.2  
10    percent and the fraction 70 percent should be 66.7  
11    percent.

12          Q     All right.  And do these figures also appear  
13    in the Center's Risk Assessment that's G-953 in this  
14    record?

15          A     The corrected numbers I gave you appear in the  
16    risk assessment document.

17                   MR. SPILLER:  Thank you, ma'am.

18                   No further questions, Your Honor.

19                   JUDGE DAVIDSON:  The witness is ready for  
20    cross.

21                   MR. BATES:  Thank you, Your Honor.

22

## 1 CROSS EXAMINATION

2 BY MR. BATES:

3 Q Good morning, Dr. Bartholomew.

4 A Good morning.

5 Q Have you testified or been qualified as an  
6 expert witness before?

7 A I have not testified as an expert witness; no.

8 Q And your field of expertise is biostatistics;  
9 is that correct?10 A That's correct. I'm a biostatistician at the  
11 Center.12 Q Could you tell us what that field is, what  
13 your expertise involves?14 A Statistics involves the analysis of data,  
15 looking at what are appropriate methods for analyzing  
16 and interpreting what data are telling you and --17 Q And where do you get the data for the work  
18 that you do?

19 A Data come from many places.

20 Q Maybe you could give me some examples.

21 A Well, are you talking about my work as a  
22 reviewer at the Center or --

1 Q Let's talk about that.

2 A As a reviewer at the Center for Veterinary  
3 Medicine, I review new animal drug applications, and  
4 the data received are data presented by drug sponsors  
5 with drug applications. It appears as studies that  
6 they have conducted for the purposes of demonstrating  
7 the efficacy or safety in some way, shape or form.

8 Q Thank you. Now, let's shift a little bit.  
9 You are joint author of what we will call the CVM risk  
10 assessment. I think that's G-953. Is that what that  
11 is?

12 A I believe that's the exhibit number.

13 Q And you were joint author of that?

14 A Yes, I was a joint author. It was a team  
15 effort. There were many people at the Center and  
16 outside the Center also involved in the team effort of  
17 constructing, gathering data, constructing risk  
18 assessment, and then writing the risk assessment  
19 document.

20 Q There was a lot of statistical data in that  
21 document, as I recall.

22 A There's a fair amount of data; yes.

1 Q And the data, let's talk about where you got  
2 some of that. For example, did you get some of that  
3 from census data?

4 A Census data were used; yes.

5 Q And did you get some from data published by  
6 non-governmental organizations?

7 A There were literature data that were used for  
8 the risk assessment.

9 Q I see. And whether or not it was in the  
10 model, is it also true the FDA, Food and Drug  
11 Administration is trying to get information on  
12 restaurant use and so on and trying to get that through  
13 the National Restaurant Association?

14 A As far as I know, the FDA is not gathering  
15 information from the Restaurant Association.

16 Q So you've been at CVM since 1990?

17 A Yes, I have.

18 Q And you have already said you were joint  
19 author of the risk assessment, CVM risk assessment.  
20 When I use risk assessment I mean CVM risk assessment.  
21 And so you know why and how and when that assessment  
22 was performed?

1 A Most of that information I am aware of; yes.

2 Q And you are also, as I recall from CV, on a  
3 EPA Office of Water panel that's evaluating microbial  
4 risk assessments for water?

5 A That's correct.

6 Q So you know something about the microbial  
7 contamination of water?

8 A To the extent that it was discussed at the  
9 workshop panel, yes.

10 Q And something about EPA's efforts to regulate  
11 that problem?

12 A Somewhat; yes.

13 Q Just a few last preliminary questions. Do you  
14 have any degrees in microbiology?

15 A No, I don't.

16 Q In that field, microbiology, any professional  
17 certifications?

18 A No, I do not.

19 Q And let's switch now to risk assessment. Any  
20 degree in risk assessment?

21 A No. I have certificates from a couple of  
22 short courses that I have taken.

1 Q Thank you.

2 Let's speak a little bit more directly about  
3 the risk assessment. Can you tell us when that risk  
4 assessment was begun, when work on it was begun?

5 A Yes, I can. It was in the summer of 1998.

6 Q And can you tell me when it was finished?

7 A I would say that we put the final version with  
8 correction on our website on January 5th of 2001. I  
9 would consider that a completion date.

10 Q And you said, with corrections. Can you  
11 explain what you mean by that?

12 A Yes. We had put the final version on the  
13 website in October and when it was up on the web, it  
14 was noted that there had been an error in the  
15 spreadsheet. There were a couple of places where the  
16 sales were pointing between a data  
17 point from 1998 and connecting to a data point for  
18 1999, and that was found through the efforts of one of  
19 our stateholders, and when we found that out we  
20 corrected it and put the revised version up on the web.

21 Q Do you recall if you also deleted a study?

22 A I do recall that there was a study deleted but

1 that was not at that time. That was deleted between  
2 the December, '99 which was called the draft risk  
3 assessment.

4 We had a public meeting and after the public  
5 meeting, we went back and did revisions and worked on  
6 it and we dropped one of the case control studies; yes.

7 Q Which study was that?

8 A It was a study by Hopkins from Colorado.

9 Q Now, is it correct that when you did the risk  
10 assessment, you used data from the 1998, 1999 CVM case  
11 control study?

12 A Yes, we did use data from the KPK case control  
13 study; yes.

14 Q And from the point of view of relevance and  
15 quality as biostatistics, how would you evaluate this  
16 study?

17 A I would say that the CDC study was a large,  
18 well conducted study and that you will need to look at  
19 what you're using it for with respect to how it was  
20 collected.

21 Q So with that background, let's talk about what  
22 you were trying to accomplish with this study. Was

1 your purpose to try to quantify the likelihood that  
2 humans in the United States might be impacted by  
3 domestically acquired fluoroquinolone  
4 campylobacteriosis which is attributable to use of  
5 Baytril in chickens?

6 A Yes.

7 Q And did you try to accomplish that purpose by  
8 seeking to quantify the number of persons in the U.S.  
9 population who in 1998 or 1999 got campylobacterial  
10 infections from eating chickens that were resistant to  
11 fluoroquinolone campylobacterial infection that were  
12 domestically acquired, that were not due to prior  
13 fluoroquinolone treatment in people who sought care  
14 from a health care provider and were prescribed the  
15 fluoroquinolone? If you want that read back in parts,  
16 we can do that.

17 JUDGE DAVIDSON: We can?

18 MR. BATES: I will repeat it or perhaps we can  
19 get the --

20 JUDGE DAVIDSON: Well, how about breaking it  
21 down? There's just too many things in there.

22 MR. BATES: All right.

1           Your Honor, perhaps if I just put some bullets  
2 on the board.

3           JUDGE DAVIDSON: Only if you remember that  
4 that is not going to go into the record and when you  
5 refer to it you can't say, "this here" or "that." You  
6 have to state what it says.

7           MR. BATES: I understand. Okay. I'm just  
8 going to do it for the convenience of the witness and  
9 myself.

10          JUDGE DAVIDSON: Okay.

11          MR. BATES: So we know exactly what we're  
12 talking about.

13          BY MR. BATES:

14          Q       So the first part is, we talked about what the  
15 purpose of the study was.

16                 What I'm trying to see if we both can agree on  
17 is how you tried to accomplish that purpose.

18                 So first seeking to quantify -- pardon my  
19 writing -- the number of persons in the U.S. who in  
20 1998 and 1999 got campylobacter infections from eating  
21 chicken that were resistant to fluoroquinolone, not to  
22 the prior treatment of fluoroquinolone, sought care

1 from a health care provider and were prescribed  
2 fluoroquinolone.

3 I'm not trying to confuse. I'm just trying to  
4 make sure I have all the pieces.

5 A Would you go back to the first part of your  
6 question? Are you asking specifically about the use of  
7 the 1998, 1999 campylobacter case control study and  
8 efforts --

9 Q No. I'm sorry. We talked about what the  
10 purpose of the study was and now I'm trying to  
11 understand the means that you were trying to use to  
12 accomplish that purpose quantitatively.

13 So I'm just trying to take the various sort of  
14 interlocking steps to see if I'm understanding how you  
15 tried to accomplish that purpose.

16 So my question is, in trying to accomplish the  
17 purpose we just discussed, were the steps I just  
18 covered in m questions accurately describe the way in  
19 which you tried to accomplish this?

20 A There is one step, basic step that I think you  
21 left out and that is that you have fluoroquinolone  
22 resistance that's not attributed to prior treatment and

1 it was also not attributed to foreign travel.

2 Q Okay. So we are on the same page here, more  
3 or less.

4 A More or less, yes; and I think that one that -  
5 - you are only going down the path of looking at the  
6 human aspect of this and this is a risk assessment  
7 model that has two parts and there was what was the  
8 human health part and then there was the exposure part.

9 Q That is right. Thank you. That's exactly  
10 right.

11 So with that in mind, I'm going to talk with  
12 you a little bit about the model itself and the risk  
13 assessment itself. And would you like to have a copy  
14 in front of you?

15 A That would be very helpful. Thank you.

16 MR. BATES: May I approach, Your Honor?

17 JUDGE DAVIDSON: Yes.

18 MR. BATES: This is Exhibit G-953.

19 JUDGE DAVIDSON: Okay.

20 BY MR. BATES:

21 Q There you are. Why don't you have a quick  
22 look at that just to make sure.

1 (The witness examined the document.)

2 A Yes.

3 Q That's it?

4 A Yes, that's it.

5 Q Just so we're clear on what we're talking  
6 about, the risk assessment, the analysis stops with the  
7 quantification of the number of these people that were  
8 prescribed fluoroquinolone. It does not go on to ask  
9 how many of those people did or did not respond to  
10 treatment. Is that correct?

11 MR. SPILLER: Objection. The question assumes  
12 a fact not in evidence. We should let the witness say  
13 when it stops.

14 MR. BATES: I have no objection.

15 JUDGE DAVIDSON: Okay.

16 THE WITNESS: I'm sorry. I didn't understand  
17 the objection. Would you explain?

18 MR. BATES: I'll do my best to; and if I get  
19 it wrong, I'm sure my colleague will help me.

20 BY MR. BATES:

21 Q Am I right that the last step in the  
22 qualification, risk assessment, was the number of these

1 cases where people were prescribed fluoroquinolone; am  
2 I correct?

3 A Yes.

4 Q So you didn't take the next step, which might  
5 have said how many of those people might have  
6 responded, did or didn't respond to treatment?

7 A No. We describe that in the risk assessment,  
8 why we didn't do that.

9 Q Okay.

10 MR. BATES: Your Honor, if I may draw some  
11 pictures here. I would like to do that.

12 BY MR. BATES:

13 Q So is it fair to say that at least logically,  
14 if not chronologically, the first step in the process  
15 was to try to estimate the number of cases of  
16 campylobacteriosis in the entire U.S. population?

17 A That's correct.

18 Q So we can just sort of draw this over here.  
19 We're trying to get the universe of campy cases in the  
20 U.S. population. We don't actually have a study of the  
21 whole U.S. population that gives us the number of  
22 cases?

1 A That's right.

2 Q So am I right that what you did was to take  
3 the FoodNet attachment data on a number of cases and  
4 then extrapolate that to come up with the number of  
5 cases for the U.S. population?

6 A Yes. We do that. CDC does that, also.

7 Q And so, when we are working with many things  
8 but certainly with diseases, it is correct, isn't it,  
9 that when one wants to sample from which one  
10 extrapolates to be representative of the population  
11 that it is trying to investigate?

12 A Yes, that's a general principle.

13 Q Especially in diseases.

14 So let's say, for example, one wanted to know  
15 whether the sample which had a lung cancer rate --  
16 whether that rate was similar to be extrapolated to the  
17 U.S. population, you would want to know whether  
18 consumption of cigarettes, for example, was similar to  
19 consumption of cigarettes for each population? Is that  
20 fair?

21 A Yes.

22 Q So that's why you said on page 32 -- and

1 you're welcomed to look at this if you like.

2 A Page 32?

3 Q Well, I want to give you the pages in the  
4 model, the exhibit pages in the record.

5 A I see. Okay.

6 Q And on that page it says the ideal  
7 extrapolation of FoodNet data incident rates to the  
8 U.S. population would require knowledge and  
9 distribution of risk factors that affect the rates of  
10 diseases.

11 A Right.

12 Q And that's another way of saying what I just  
13 said about lung cancer and smoking?

14 A Yes.

15 Q And you did an analysis of the representatives  
16 of the sample; is that correct?

17 A Yes, we did.

18 Q And you used some basic demographic factors,  
19 rural versus urban, age, sex and race. Is that  
20 correct?

21 A Yes.

22 Q You came up with more or less, 177 million

1 cases in 1998 and 104 million cases in '99 -- 1.7  
2 million in '98 and 1.4 in '99?

3 A I'm sorry. You're asking two questions there.  
4 You're asking about the representativeness of the  
5 samples and we did display in Table 1.1 that detachment  
6 area is fairly consistent with the U.S. population.

7 Q On that basis, you then extrapolated? I'm not  
8 trying to write down of course how big this big circle  
9 is.

10 And in 1998, you estimated about 177 million  
11 cases --

12 MR. SPILLER: The form of the question.

13 BY MR. BATES:

14 Q I'm sorry. 1.77 million.

15 MR. SPILLER: Can you specify? We request  
16 that counsel identify the page and part where that  
17 occurs.

18 MR. BATES: I'm sorry, Your Honor. These were  
19 about the only two numbers I could remember without  
20 looking them up.

21 Well, let's see if I've got the right place.

22 BY MR. BATES:

1 Q If you would please turn to page 44 of Exhibit  
2 G-953; and at the bottom of that page you will see that  
3 there is a -- call it a small table. Do you see that  
4 table?

5 A Yes.

6 Q And it gives a mean estimate for 1998 at about  
7 1.77 million. Is that mean estimate for what is  
8 calculated that would be the number of cases in that  
9 big circle here for 1998?

10 A Yes; that would be the number.

11 Q And just below that, the line that starts,  
12 "1999," the mean for that one is one million, three  
13 hundred seventy-six and so on?

14 A Yes.

15 Q And that's the guesstimate for the total  
16 number of cases that you developed for 1999?

17 A Yes.

18 Q So for '98, 1.77; '99, 1.4, more or less? Is  
19 that a fair statement?

20 A Those are the means; yes.

21 Q Now, we talked a moment ago about the use of  
22 the 1998, 1999 CDC case control study. At page 103 of

1 your risk assessment, in the carryover paragraph, the  
2 last sentence, that says that the data from this study  
3 -- and this study here means the 1998, 1999 CDC case  
4 control study? Is that correct?

5 (The witness examined the document.)

6 THE WITNESS: That's correct.

7 BY MR. BATES:

8 Q And it says the data from this study will  
9 provide "updated risk factor information from which  
10 etiological fractions would be identified," is that  
11 correct?

12 JUDGE DAVIDSON: If that's what it says. I'm  
13 waiting for something to come out of all of these  
14 questions. You're repeating what is already in my  
15 record.

16 MR. BATES: I understand.

17 BY MR. BATES:

18 Q So if we had risk factors from this study, we  
19 could then use those as we talked about a moment ago to  
20 test whether our sample is representative or not?

21 A I don't see how that would be possible because  
22 it implies that you know what the distribution of risk

1 factors is in the entire population if you are trying  
2 to do the test that's representative of, and I don't  
3 see how we could possibly know that.

4 Q Well, I don't want to be too hard here. I  
5 talked a little bit about cigarette consumption versus  
6 lung cancer.

7 If the CDC study that we're talking about said  
8 that eating chickens or other meats in restaurants was  
9 a risk factor, wouldn't we want to know whether the --  
10 the frequency with which people ate in restaurants and  
11 the sample was similar to the frequency of the U.S.  
12 population overall?

13 A I'm not sure that I agree with that, because I  
14 don't know the details of that, whether or not  
15 restaurant chicken consumption is the sole determinate  
16 of what we would be looking for.

17 We were concerned about exposure to chicken  
18 through various sorts, not just through restaurant  
19 consumption of chicken.

20 Q Do you know whether the CDC study that you  
21 refer to now has been completed?

22 MR. SPILLER: Object to the form of the

1 question. Can you specify which CDC study that you are  
2 referring to?

3 MR. BATES: I'm sorry. I will be glad to do  
4 that.

5 BY MR. BATES:

6 Q We're talking about the 1998 CDC study that  
7 you said in the risk assessment is going to be looking  
8 at risk factors.

9 A Yes.

10 Q Has that been completed?

11 A I don't know for sure whether that has been  
12 completed. I have not seen a published article based  
13 on that study to date.

14 Q Well, let me show you attachment three to  
15 Exhibit G-1452 and ask if you recognize that.

16 A Yes. I see that this is a CDC draft article.

17 MR. BATES: May I approach, Your Honor?

18 JUDGE DAVIDSON: Yes.

19 BY MR. BATES:

20 Q And if you turn to the back of the study,  
21 you'll see a table near the end, and that is table  
22 four, is it not?

1 JUDGE DAVIDSON: Page number?

2 MR. BATES: That is Exhibit page number 101.

3 JUDGE DAVIDSON: Thank you.

4 BY MR. BATES:

5 Q That is a table attempting to show risk  
6 factors; is that right?

7 A It says, "multi-varied analysis and derived  
8 population, attributable fractions, Campylobacteriosis,  
9 case control study, 1998, 1999."

10 Q And population, attributable fractions, is  
11 that the same thing as etiological fractions we're  
12 talking about?

13 A Yes.

14 Q So in that document from CDC there's a table  
15 which tries to identify the risk factors that we were  
16 just talking about?

17 A Yes. They are analyzing risk factors.

18 Q All right. And one of those for chicken is  
19 eating in restaurants; is that correct?

20 A Yes.

21 Q And then that is the only one for chicken; is  
22 that correct?

1 MR. SPILLER: I object to the form of the  
2 question. It states as a fact something not in the  
3 record and contrary to the cite of the table.

4 BY MR. BATES:

5 Q Pink chicken. Undercooked. I'm sorry. I'm  
6 looking for population, attributable fraction,  
7 etiological fraction for chicken. The only one here --  
8 am I right?

9 A No. There's "A," undercooked or pink chicken.

10 JUDGE DAVIDSON: "A" chicken prepared at home  
11 is another factor.

12 BY MR. BATES:

13 Q I'm sorry. I'm talking about the etiological  
14 fraction. So we have "A," undercooked or pink chicken,  
15 and we have chicken at a restaurant?

16 A Yes.

17 Q Just by way of comparison, the chicken at a  
18 restaurant fraction is said to be 24 percent and the  
19 pink is 3 percent; is that right?

20 A Yes.

21 Q So why wouldn't we want to know, when we're  
22 trying to do with this extrapolation, whether the

1 sample was a good basis from which to extrapolate  
2 whether people throughout the U.S. were eating at  
3 restaurants at a similar rate to the people in the  
4 sample?

5 MR. SPILLER: Your Honor, I object to the form  
6 of the question, why wouldn't we want to know. The  
7 "we" isn't defined. I don't believe there has been any  
8 testimony that we wouldn't want to know anything.

9 JUDGE DAVIDSON: Sustained.

10 BY MR. BATES:

11 Q If you want to know whether the sample that  
12 you're using accurately predicts for the whole in one  
13 of the risk factors, in fact the largest for chicken,  
14 quite a lot, is eating chicken in a restaurant,  
15 wouldn't you want to know whether the frequency of  
16 eating out in restaurants in the sample was similar to  
17 the frequency of eating out at restaurants for the  
18 whole U.S. population?

19 A If you were interested specifically in  
20 restaurant chicken consumption, perhaps; but I think  
21 that we established with Dr. Angulo that the FoodNet in  
22 the case control study would be representative of the

1 U.S. population.

2 Q I'm not challenging whether it is  
3 demographically now. I'm referring back to the  
4 statement involved.

5 If you knew about the risk factors, you would  
6 want to use those to help us understand whether the  
7 sample is representative?

8 MR. SPILLER: I object to the form. It's not  
9 a question.

10 JUDGE DAVIDSON: Overruled.

11 You're going back to one of your first  
12 question, when you read from the witness' testimony or  
13 from the -- I can't remember at this point.

14 MR. BATES: This was from the model.

15 JUDGE DAVIDSON: From the model. Ideally you  
16 started? Is that it?

17 MR. BATES: That's correct.

18 JUDGE DAVIDSON: It took us a long time to get  
19 there; didn't it?

20 Why don't you refresh your recollection of  
21 that and then ask her the question?

22 MR. BATES: I'll be glad to, Your Honor.

1 BY MR. BATES:

2 Q So if you go to page 103. I'm sorry. I'm  
3 sorry.

4 JUDGE DAVIDSON: Back in G-953.

5 BY MR. BATES:

6 Q Yes. It's page 32. Sorry.

7 MR. SPILLER: I'm sorry, Mr. Bates.

8 MR. BATES: Exhibit 953.

9 MR. SPILLER: Okay.

10 THE WITNESS: Page 32. Yes.

11 BY MR. BATES:

12 Q And the first full paragraph, the point that  
13 says, "The ideal extrapolation of FoodNet incidence  
14 rates to the U.S. population would require knowledge of  
15 the distribution of risk factors that affect the rate  
16 of disease."

17 And my question is, in light of that  
18 observation, would you agree with me that we would want  
19 to examine whether the rate of eating at a restaurant  
20 in the sample is similar to the rate in the U.S.  
21 population?

22 A I would agree that that would probably be one

1 of many.

2 Q Fine. So let's see if we can do that.

3 Now, Dr. Bartholomew, what I have just done is  
4 clip up a map of the United States. Now, I wonder if  
5 you could tell me which states were in the FoodNet  
6 sample for the 1998, 1999 time period, the example in  
7 your study?

8 A I would have to look them up in the risk  
9 assessment. I cannot spew them off.

10 Q All right.

11 A It says -- and I'm reading at the bottom of  
12 page 34, in Table 1.3 or Table 1.4, the State of  
13 California; Connecticut.

14 Q State of California. Connecticut.

15 A Georgia.

16 Q Georgia. Now, as for Georgia, is that the  
17 whole state, or just part of it, or both?

18 A I don't recall.

19 Q Okay. Go ahead.

20 A Maryland. Did I say that?

21 Q Maryland. No. Okay. Maryland.

22 A Minnesota.

1 Q Minnesota.

2 A New York.

3 Q New York.

4 A And Oregon.

5 Q Oregon.

6 So at least geographically speaking, it's a  
7 big part of the center of the country here that is not  
8 represented in the FoodNet; correct?

9 A Yes.

10 MR. BATES: Your Honor, I would like to mark  
11 for the record Exhibit B-1942.

12 JUDGE DAVIDSON: Copy for the witness. Copy  
13 for myself. Copy for counsel.

14 MR. BATES: Can you reach that? I'm sorry.

15 (Respondent Exhibit 1942 was  
16 marked for identification.)

17 MR. BATES: Your Honor, this is a study on  
18 restaurant spending that we obtained from the National  
19 Restaurant Association.

20 MR. SPILLER: Excuse me. Form of the  
21 question. Can we ask the witness if she recognizes it  
22 and let her characterize it if she is --

1 MR. BATES: I will be glad to.

2 BY MR. BATES:

3 Q Dr. Bartholomew, I am handing you a copy of  
4 what has been marked as B-1942. Do you recognize that  
5 document?

6 (The witness examined the document.)

7 A No, I don't.

8 Q Can you tell me what it says it is?

9 A It says it is a Restaurant Spending, Consumer  
10 Expenditure Survey in 1998.

11 Q Can you tell me who did it?

12 A National Restaurant Association.

13 Q And a moment ago you testified, if I recall,  
14 that you didn't know if the FDA relied on such studies  
15 by the National Restaurant Association; is that right?

16 A Yes.

17 Q I wonder if I could show you a document and  
18 see if that might refresh your recollection.

19 JUDGE DAVIDSON: Do you have copies?

20 MR. BATES: I do.

21 (The witness examined the document.)

22

1 BY MR. BATES:

2 Q Can you tell us what that is?

3 A I can tell you that it says it's from  
4 www.fda.gov, and I'm not sure what it is. They  
5 specialize in nutrition information. I am not sure  
6 what this is.

7 Q Go to the last page and look at the bottom of  
8 the page. What does that tell us about the --

9 MR. SPILLER: Objection to the question. The  
10 witness has already said that she doesn't recognize it,  
11 and there's no testimony that it is within the scope of  
12 her direct.

13 MR. BATES: Your Honor, I take counsel's  
14 point. I would like to move the restaurant study on  
15 the grounds that as it shows in this document from the  
16 FDA, the FDA does rely on studies such as this from the  
17 National Restaurant Association on how Americans spent  
18 their food dollars.

19 JUDGE DAVIDSON: Well, I'm not the FDA, but  
20 it's a pretty large organization, and the Consumer  
21 Magazine is certainly not the kind of thing we rely on  
22 in my cases as far as factual information.

1 I get a copy of the Consumer Magazine every  
2 time it comes out. It's got a lot of interesting  
3 tidbits in it, but it's nothing that qualifies as  
4 evidence.

5 MR. BATES: With all due respect, Your Honor,  
6 I believe this is a study of restaurants in the United  
7 States. It was not just in a magazine.

8 JUDGE DAVIDSON: I know. Who did that?

9 MR. BATES: I beg your pardon?

10 JUDGE DAVIDSON: You tell me the Restaurant  
11 Association of America did that. Does that qualify as  
12 evidence in my case? And if it is, why didn't you  
13 introduce it? This witness certainly didn't rely on  
14 it.

15 You're cross-examining a witness and you're  
16 trying to put evidence in the record which I don't even  
17 think qualifies as evidence. Now, I could be wrong, if  
18 you show me where it does qualify as evidence; but you  
19 should submit it yourself, not through this witness.

20 MR. SPILLER: Your Honor, since there has been  
21 a motion, if it's going to be in evidence, if it's  
22 going to be entertained, could I have voir dire on this

1 document?

2 JUDGE DAVIDSON: Well, let's wait and see what  
3 he has to say.

4 MR. BATES: I would like to move the  
5 introduction of this document.

6 JUDGE DAVIDSON: You did that already.

7 MR. BATES: Let me state the grounds. One of  
8 the kinds of evidence that is admissible as evidence is  
9 evidence by market studies that people in the industry  
10 and people in the public rely upon. That is a fairly,  
11 I think, straightforward proposition on the evidence  
12 cause.

13 Secondly, the document we're talking about  
14 here is in fact a study of restaurant spending.

15 Thirdly, in issuing regulations, that is what  
16 this document pulled from the website does -- issuing  
17 regulations, effective May 2, published August, 1996,  
18 in the Federal Registrar.

19 In explaining those regulations in this  
20 document that I handed you, Your Honor, it says: "This  
21 is important considering more and more Americans are  
22 spending their meals outside home."

1           "According to the National Restaurant  
2 Association, Americans are spending 44 percent of their  
3 dollars outside the home in 1996." And so on.

4           So this is the kind of evidence that is  
5 admissible. It is also the kind of thing that FDA has  
6 itself relied upon; and certainly if there are  
7 questions about the weight of the evidence, we can have  
8 argument about those.

9           But this is, as I say, evidence from a market  
10 study, from a business source that the public and the  
11 industry rely. It is something that the FDA in the  
12 past has relied on and I believe it would help the  
13 trier of fact in considering this case.

14           JUDGE DAVIDSON: You still haven't answered my  
15 question about why you introduce that with this witness  
16 when she says she doesn't recognize it. She didn't  
17 testify about it, and it's cross-examination.

18           You have a case in chief that you presented.  
19 You presented me with all evidence. If this was  
20 reliable evidence that you wanted put in your case, why  
21 wasn't it put in earlier?

22           MR. BATES: I think the reason I'm trying to

1 examine on it now is the discussion in the case so far  
2 about the --

3 JUDGE DAVIDSON: I understand your reasoning  
4 for putting it in. I don't understand why it wasn't in  
5 before.

6 If you bring it in at the last minute that you  
7 claim is viable and interesting -- and I might glean  
8 something from it if I were to review it but it has  
9 nothing to do with this witness, per se, and should  
10 have been put in, if you thought it was important,  
11 evidence right at the outset.

12 MR. BATES: Well, it does have to do with this  
13 witness.

14 JUDGE DAVIDSON: Only because you want to get  
15 to the representativeness aspect.

16 MR. BATES: We need to do that in order to  
17 understand whether this universe is correctly defined.

18 JUDGE DAVIDSON: That's what you need to do,  
19 you think; but I'm not satisfied that this is where  
20 this belongs at this time. I will let counsel for CVM  
21 respond to your motion.

22 MR. SPILLER: Your Honor, we oppose the

1 motion. The witness has testified she didn't rely on  
2 this. She didn't even recall it. It is clearly not in  
3 her written direct testimony. It is clearly beyond the  
4 scope of her written direct testimony and therefore not  
5 fair cross, anyway; and a ludicrous standard that this  
6 is a document of a kind relied upon by FDA would enable  
7 truckloads of documents to come in if that were  
8 allowed.

9 FDA properly as a scientific agency relies on  
10 millions of documents every year.

11 There is no indication that this witness, the  
12 testimony that we are cross examining today, relied on  
13 this.

14 It should not be received in evidence.

15 JUDGE DAVIDSON: You want to mark the second  
16 one 1943?

17 MR. BATES: Yes, sir.

18 (Respondent Exhibit 1943 was  
19 marked for identification.)

20 JUDGE DAVIDSON: It will stay in the  
21 administrative record, but it's not going to be in my  
22 evidentiary record.

1 MR. BATES: Thank you, sir.

2 JUDGE DAVIDSON: All right. That's my ruling.  
3 B-1942 and B-1943 are not received in evidence.

4 MR. BATES: Just to resume, could I ask the  
5 reporter to read back the witness' answer to the  
6 question that I was given to whether restaurant data  
7 would or wouldn't be relevant? I'm trying to move on.

8 JUDGE DAVIDSON: All right. Off the record.

9 (A discussion was held off the record.)

10 JUDGE DAVIDSON: Okay.

11 MR. BATES: Ready to proceed?

12 BY MR. BATES:

13 Q So we talked, Dr. Bartholomew, you and I did,  
14 about the first step in the model, trying to estimate  
15 the total number of Campylobacteriosis cases in the  
16 United States for these two years.

17 Was the next step in the model to try to  
18 estimate the portion of those cases that was  
19 attributable to chicken?

20 A Yes.

21 Q And that is what we were talking about a  
22 moment ago when we spoke about attributable risks and

1 etiological fraction; is that right?

2 A Yes.

3 Q Okay. We are going from total numbers to  
4 somewhat smaller numbers this time, percentage of cases  
5 out of the whole which are attributable to the  
6 chickens; is that right?

7 A Yes.

8 Q I gather from a biostatistical point of view  
9 this is a little bit complicated and rather than me  
10 trying to say it myself, let me just refer you to  
11 something in your testimony. I'm sorry. The model.  
12 This is at page 102 of the model. And when I say the  
13 model, I'm referring to Exhibit G-953.

14 If you look at the point under assumption one,  
15 it says, "Discussion Number One." There's a statement  
16 that says, "One limitation is epidemiological tools  
17 used to determine the attributable risks or etiological  
18 fraction."

19 Is it those cases that were exposed to the  
20 risk factor of interest even though the exposure may  
21 not have been a cause of the disease, could be  
22 included in the calculated level of risk thereby

1 potentially overestimating the actual level of risk?

2           So with that statement in mind, it's possible,  
3 isn't it, that some of the cases in my attributable  
4 risk circle may not actually have been caused by  
5 exposure to chickens?

6           A     Yes. Exposure to chickens. I would agree that  
7 there may be some that are miscalculated.

8           Q     And with regard to this particular part of the  
9 model and its significance, am I right that you all did  
10 a sensitivity analysis to get some sense as to which  
11 variables were likely to affect the outcome analysis?

12           A     We did sensitivity analysis and I can't speak  
13 to the results without looking at them because I don't  
14 recall.

15           Q     Okay. Let's do that.

16                     Actually, I'm going to move on, because that's  
17 in the record.

18                     JUDGE DAVIDSON: Thank you.

19                     BY MR. BATES:

20           Q     So based on what we just said, we could  
21 multiply the total by this percentage, the etiological  
22 fraction but we're not actually following a true causal

1 change; is that correct?

2 A I thought about this question some and what we  
3 had established ACRIORI based on other literature,  
4 based on a history of information that chicken was  
5 causal and when we set out to do the risk assessment,  
6 we were trying to quantify to what extent; and so, the  
7 causality was not established by the calculation of  
8 population, attributable fraction. That was a fraction  
9 that we used as a quantification but we did not say,  
10 uh, huh, because it's a certain percent, that's  
11 causation. We knew that from a body of information  
12 that was collected beforehand.

13 A Just so that we are on the same page, we could  
14 both agree with that and still agree that the number of  
15 cases that results from this multiplication may be an  
16 overstatement?

17 JUDGE DAVIDSON: Asked and answered. We did  
18 that already.

19 BY MR. BATES:

20 Q An etiological fraction that you derived from  
21 the 1980's; is that correct?

22 A That's correct.

1 Q And do you recall in the model expressing some  
2 reservations about those studies?

3 MR. SPILLER: I apologize, Mr. Bates, for the  
4 interruption. You said from some 1980 study. Did you  
5 mean studies within the 1980's or did you mean  
6 literally 1980, one year?

7 MR. BATES: 1980's, plural.

8 MR. SPILLER: I apologize for the  
9 interruption.

10 THE WITNESS: Would you go back to the  
11 question, please?

12 MR. BATES: Yes.

13 BY MR. BATES:

14 Q You and I just agreed, I think, that the  
15 etiological fraction that we're talking about is based  
16 on some studies from the 1980's?

17 A Yes.

18 Q And I was just asking whether in the risk  
19 assessment you expressed some reservations about those  
20 studies.

21 A Yes, we did.

22 Q And we talked before about the recognition in

1 this document that the CDC case control studies was  
2 underway?

3 A Yes.

4 Q And I take it it was the view expressed here  
5 and your view that when those data came in, one could  
6 use those to calculate the etiological fractions?

7 A That was expressed in the document. Yes.

8 Q And the model that was used -- the 1980's  
9 studies resulted in a 57 percent fraction --

10 MR. SPILLER: Objection to form. Eighty  
11 versus '80's.

12 JUDGE DAVIDSON: Eighties.

13 MR. BATES: I'm sorry.

14 BY MR. BATES:

15 Q The 1980's studies resulted in a 57 percent  
16 reduction; is that correct?

17 A Well, to be precise, there were two studies.  
18 One had a population attributable fraction of 48.5 and  
19 the other had a fraction which was 66.7 percent; and we  
20 recognized that those studies were based on samples.  
21 We incorporated uncertainty about them; and because we  
22 didn't know which one was the better estimate, we

1 modeled between the two of them so that the mean  
2 estimate from the model was 57 percent. But you have to  
3 understand that that is a distribution. That's the  
4 central value but there was a whole range of population  
5 attributable fractions considered there.

6 Q I understand. So we talked a moment before  
7 about Exhibit G-1452 which was the CDC draft study we  
8 talked about. Do you have that handy?

9 A I think you must have taken that back.

10 MR. BATES: Your Honor, may I approach?

11 JUDGE DAVIDSON: Certainly.

12 BY MR. BATES:

13 Q This is Exhibit G-1452 that we were discussing  
14 earlier.

15 MR. SPILLER: Excuse me. Mr. Bates, did you  
16 mean attachment three of G-1452?

17 MR. BATES: Thank you. Attachment three of G-  
18 1452.

19 BY MR. BATES:

20 Q Will you turn to page 23, please? It's  
21 actually page 101 in the exhibit.

22 A Yes.

1 Q This is the table we were discussing before  
2 about population attributable fraction?

3 A Yes.

4 Q And this said that the "A" chicken prepared in  
5 the restaurant has a population attributable fraction  
6 of 44 percent?

7 A Yes.

8 Q And if you go down to I guess the fifth entry  
9 from the bottom of that table it says, "'A' chicken  
10 prepared at home."

11 A Yes.

12 Q And there is no population attributable  
13 fraction for that; is that correct?

14 A That's what it says in this table. Well, let  
15 me take that back. I don't know. I don't see what the  
16 code is for "N/A." Is that not available or not  
17 applicable? I'm not sure what that is; but I do see  
18 there's not a number in that column.

19 Q And if you go to the column that says "AOR" it  
20 says .7 for the chicken prepared at home?

21 A Yes.

22 Q And specifically, what does that suggest when

1 you have an AOR that's less than one, I guess?

2 A That suggests that in the study, if you ask  
3 cases if they had eaten chicken at home and you ask  
4 controls if they had eaten chicken at home then the  
5 proportion of cases who would respond, yes, I ate  
6 chicken at home would be more than the proportion of  
7 the -- I'm sorry. Did I say cases? The controls would  
8 have a higher proportion of people who said yes, I ate  
9 chicken at home than the cases would have.

10 Q So am I right that we have sort of competing  
11 risk factors here? We have one set of risk factors for  
12 chicken at a restaurant that says there's a risk, that  
13 cases for disease more frequently from exposure to  
14 controls. You have the reverse of that at home.

15 A If that is what the data indicate.

16 Q So if we were just working with these data,  
17 the 24 percent number, fraction, couldn't be projected  
18 across all chicken because when you ate it at home the  
19 relationship switches. Is that correct?

20 A I think what it's saying is that cases were  
21 more likely to have eaten chicken at a restaurant and  
22 controls were more likely to have eaten chicken at

1 home.

2 Q So if we are trying to get overall chicken  
3 numbers, we have to find some way to reconcile those  
4 things, things going in different directions? Is that  
5 right?

6 A I think your statement is correct, and I think  
7 there's an awfully lot of other things that need to  
8 happen, too. A case control study can only answer  
9 questions that have been asked.

10 So if you notice that those population  
11 attributable fractions -- there will be some things  
12 that are not addressed but they don't -- I'm trying to  
13 add up in my head -- that there will be some things for  
14 which you will not have the answers.

15 Q I understand.

16 So in order to get at that, what if one tended  
17 to do a correlation between chicken consumed and cases  
18 in the FoodNet database to see what that relationship  
19 might be and if it turned out that the number of cases  
20 had decreased as the amount of chicken consumed  
21 increased, would that suggest that the relationship  
22 observed at home might be more accurate than the

1 relationship observed in a restaurant?

2 MR. SPILLER: I object. It's beyond the scope  
3 of direct. I don't believe this is in the written  
4 direct testimony. It seems to be an extrapolation of  
5 what someone might wish were there, but I believe it  
6 wasn't.

7 MR. BATES: If I may, Your Honor. The model  
8 says if we had these data we would use them. I'm not  
9 trying to figure out how we would use them because we  
10 do have them; and in fact, I believe we had them before  
11 the January data.

12 JUDGE DAVIDSON: You say, you believe we have?  
13 Are they in the record?

14 BY MR. BATES:

15 Q Dr. Bartholomew --

16 JUDGE DAVIDSON: I asked you a question.

17 MR. BATES: These data were available July of  
18 2000.

19 JUDGE DAVIDSON: Which document?

20 MR. BATES: This is attachment three to G-  
21 1452.

22 JUDGE DAVIDSON: So it's already in the

1 record?

2 MR. BATES: Yes.

3 MR. SPILLER: As a draft, if I may, Your  
4 Honor. It doesn't mean that the data is in the record.

5 JUDGE DAVIDSON: All right. Overruled. I  
6 will let you go a little bit further with this; but if  
7 the witness is not comfortable with this because it's a  
8 draft or because she didn't review it, then you have to  
9 stop.

10 MR. BATES: All right. I understand.

11 JUDGE DAVIDSON: All right. Go ahead.

12 BY MR. BATES:

13 Q Dr. Bartholomew, I was asking you about a  
14 potential way of trying to understand whether the risk  
15 factor associated with eating in restaurants would be  
16 more powerful than the risk factors associated with  
17 eating at home because they point in different  
18 directions.

19 I'm going to ask you now, did you review Dr.  
20 Cox's testimony in this case?

21 A I have read Dr. Cox's testimony; yes.

22 Q That's fine. I'm going to show you page 29

1 from that testimony.

2 JUDGE DAVIDSON: The exhibit number?

3 MR. BATES: The exhibit number, B-1901. It's  
4 attachment one and it's page 37 to attachment 29 in the  
5 document.

6 BY MR. BATES:

7 Q Would you take a look at that page? Is there  
8 a graph on that page?

9 A There is a graph.

10 Q And does that graph purport to show the  
11 relationship between the consumption of chicken overall  
12 and cases of illnesses negatively related? The more  
13 chicken you eat the less illness you had?

14 MR. SPILLER: Objection. Beyond the scope.  
15 I, too, eagerly await the cross examination of Dr.  
16 Cox's written direct testimony but this witness is  
17 being asked about the contents of Dr. Cox's testimony  
18 and that's not her testimony; so, it's beyond the  
19 scope.

20 JUDGE DAVIDSON: I assume it's preliminary to  
21 something.

22 MR. BATES: Yes, it is, Your Honor. I'll get

1 right to the point.

2 JUDGE DAVIDSON: Why are you asking the  
3 question when it's in there? It states it.

4 Let her look at it. You don't have to read it  
5 into the record. Ask your questions.

6 BY MR. BATES:

7 Q So does that graph -- strike that. I'll just  
8 -- if we were to find that there was a negative  
9 relationship between consumption of chicken overall in  
10 cases, that would suggest that the risk factor for  
11 eating at home here which is less than one would be  
12 more representative on the whole than the risk factors  
13 of eating at restaurants which points in the other  
14 direction?

15 A I'm not sure whether I agree or not. I have  
16 not thought this over.

17 One thing that should be clear is that what is  
18 associated with developing campylobacteriosis is the  
19 contact and exposure to campylobacter, and there may be  
20 some aspects of cooking at home that would permit  
21 people to kill campylobacter more so than other -- it  
22 depends how people cook it.

1 Q Well, then this will be quite quick. There  
2 are studies, aren't there, including the one that you  
3 deleted from the record that showed that the overall  
4 risk of consuming chicken is in fact what I might call  
5 negative? That is to say, the cases ate less chicken  
6 than the controls?

7 MR. SPILLER: Objection. The question calls  
8 for speculation about of what was in a study that is  
9 not in the record.

10 MR. BATES: Well, I believe it is, Your Honor.  
11 It's B-35. We just talked about it earlier, the one  
12 they deleted from their model.

13 JUDGE DAVIDSON: Well, is it or isn't it? I  
14 mean, I don't have a repository here.

15 MR. SPILLER: I will yield to the description  
16 of it as a document. The question said, that was  
17 deleted from your record.

18 MR. BATES: Risk assessment. Risk assessment.

19 MR. SPILLER: It was not in the risk  
20 assessment documents but it is a --

21 MR. BATES: Your Honor, B-35.

22 JUDGE DAVIDSON: As long as I know it is of

1 record, you can answer the question, if you know.

2 THE WITNESS: As I recall, the Hopkins study  
3 could be interpreted as having a population  
4 attributable -- you know, I don't remember whether it  
5 was specifically chicken or undercooked chicken that  
6 was very similar to the Harris study so that we would  
7 have reported it as being -- and we did in the draft  
8 risk assessment document as being confirmatory of the  
9 same value that the Harris study had.

10 The reason we dropped it had nothing to do  
11 with what it told us. It had to do with: We went back  
12 and tried to recalculate population attributable risks  
13 and we found discrepancies in the numbers presented in  
14 the table. We could not rectify the numbers; and so,  
15 therefore, we thought that the results might be  
16 unreliable.

17 MR. BATES: Well, Your Honor, I'm not going to  
18 ask her to read something that's in the record.

19 JUDGE DAVIDSON: All right. Thank you.

20 BY MR. BATES:

21 Q There was a study in 1987, in Dubuque, is that  
22 right, G-564, by Schmidt, et al.? Do you remember that

1 study? It's G-564.

2 A Excuse me. Say that again.

3 Q Are you familiar with the Schmidt, et al in  
4 Dubuque, Iowa, 1987? It's Exhibit G-564.

5 A I can't say that I recall it.

6 Q So you don't know whether that found risks one  
7 way or the other?

8 A No.

9 Q Are you familiar with the Ikram study in  
10 Christchurch, New Zealand from 1992, G-370?

11 A Yes.

12 Q Am I right that that said there was no -- they  
13 found no positive correlation between eating chicken  
14 and --

15 JUDGE DAVIDSON: Excuse me. What is that  
16 exhibit number?

17 MR. BATES: It's G-370. I'm sorry. G-307.

18 JUDGE DAVIDSON: I don't have a 370.

19 MR. BATES: It's 307, I believe.

20 JUDGE DAVIDSON: Thank you.

21 THE WITNESS: Do you have a copy of that  
22 paper?

1           MR. BATES: Your Honor, I can do this, but I'm  
2 afraid it will waste time, to show her things and ask  
3 her to read. I'll be glad to do it if --

4           JUDGE DAVIDSON: Well, that's where it belongs  
5 if you're just showing her things and asking her to  
6 read them. If you have a question concerning what's in  
7 there and whether or not it affects her testimony, show  
8 it to her, have her read it, ask her if it changes her  
9 testimony or what you want to ask her about it.

10          MR. BATES: All right. Let's do that. We  
11 will just try to do this as quickly as possible.

12          BY MR. BATES:

13          Q     Let's start with the Ikram study from  
14 Christchurch, New Zealand.

15          JUDGE DAVIDSON: G-307; correct?

16          MR. BATES: That's right.

17          May I approach, Your Honor?

18          JUDGE DAVIDSON: Yes, sir.

19          BY MR. BATES:

20          Q     Here's a copy of the study. And would you  
21 look at the table on -- I guess it's page two of the  
22 exhibit. Do you see that? Table one.

1 A Oh, table one? Okay.

2 Q Right. And it says that the risk factors for  
3 Campylobacteriosis infection associated with poultry.  
4 Do you see that? And then it says, "chicken." And it  
5 shows that the odds ratio is less than one?

6 A Yes.

7 Q So we do have the Ikram study and odds ratio  
8 for all chicken is less than one; is that correct?

9 A And I see that we have, when eaten at a  
10 friend's house it has an odds ratio of 3.1.

11 Q I understand. What we're trying to focus on  
12 here is whether we can get -- the question is whether  
13 all chicken is positive or negative risk when we have  
14 the CDC study pointing in two different directions.  
15 I'm trying to see if there are other studies that would  
16 help us shed some light on this. So I'm looking for  
17 all chicken.

18 We talked quickly a moment ago about the  
19 Hopkins study that was deleted. That's Exhibit B-35.

20 JUDGE DAVIDSON: Why do you keep saying it was  
21 deleted?

22 MR. BATES: I'm sorry.

1 JUDGE DAVIDSON: We had an objection based on  
2 that that it was only deleted in the risk assessment  
3 and not from the record.

4 MR. BATES: There were two Hopkins studies.  
5 I'm trying to focus on that.

6 JUDGE DAVIDSON: I know; but when you say  
7 "deleted," you confuse me.

8 MR. BATES: Okay.

9 JUDGE DAVIDSON: Give me the number and I'll  
10 tell you whether I like it or not.

11 MR. BATES: B-35.

12 JUDGE DAVIDSON: B-35?

13 MR. BATES: "B" as in Bear, 35.

14 JUDGE DAVIDSON: You'll have to give me a copy  
15 of that. I only have one disk here and --

16 MR. BATES: Very well, Your Honor.  
17 I'm handing it to the witness, Your Honor.

18 BY MR. BATES:

19 Q And would you turn to page two of the exhibit,  
20 please, and the beginning of the second full paragraph?  
21 It says, "Ill persons were less likely than either set  
22 of controls to have eaten chicken." Then we also

1 worried about undercooked. Overall, ill less likely  
2 than either set of controls to have eaten chicken.

3 MR. SPILLER: I'm sorry. I'm having trouble  
4 finding the word "overall" there. Are you quoting  
5 that?

6 MR. BATES: I'm sorry. What I read was: "Ill  
7 persons were less likely than either set of controls."

8 MR. SPILLER: And for completeness, would you  
9 offer the witness the next --

10 MR. BATES: I already did that. I said, more  
11 likely to have eaten chicken that was undercooked.

12 What I'm trying to drive at is what we are  
13 looking at when we look at all of the controls and  
14 cases in the study, not just bits and pieces because we  
15 have a bits and pieces problem with the cases and  
16 the --

17 JUDGE DAVIDSON: What is the question?

18 BY MR. BATES:

19 Q What we have seen in these two studies, then,  
20 when you look at all the cases, when you look at all  
21 the cases put together as opposed to subgroups, overall  
22 chicken is more like eating at home than it is eating

1 in a restaurant?

2 A Would you please repeat the question? When  
3 you look at?

4 Q When we try to understand whether there is a  
5 risk factor associated with eating all chicken, not  
6 just eating it in a certain place -- and we have the  
7 CDC study that says if you eat at home it's less than  
8 one and if you eat at a restaurant it's more than one.  
9 Am I right that these studies shed some light on  
10 whether overall, regardless of where you eat the  
11 chicken, the odds ratio is negative?

12 (The witness examined the document.)

13 THE WITNESS: I think that the studies  
14 demonstrate that some ways of eating chicken are risky  
15 and others are less risky.

16 BY MR. BATES:

17 Q Now, let's look then at Exhibit G-564, which  
18 is the -- I believe, the Schmitz study in Debuque that  
19 I was referring to a moment ago.

20 Your Honor, do you have that on your --

21 JUDGE DAVIDSON: Yes, I have it. Thank you.

22

1 BY MR. BATES:

2 Q I'm handing it to the witness.

3 So if we look at this study, which was in  
4 Debuque, I believe, in 1987 -- would you turn to page  
5 3? I'm sorry, page 4. And in the discussion section  
6 near the bottom in the right-hand column, the next to  
7 the last full paragraph, it says, "We found no  
8 epidemiological association with consumption of  
9 chicken," correct?

10 MR. SPILLER: Did you say right-hand column  
11 near the bottom?

12 MR. BATES: I did.

13 JUDGE DAVIDSON: "Although we found"?  
14 That's -- although -- I see.

15 MR. BATES: That's correct.

16 JUDGE DAVIDSON: Okay.

17 BY MR. BATES:

18 Q And -- just to move along -- are you familiar  
19 with the recent case control study in England by  
20 Rodriguez --

21 MR. SPILLER: I'm sorry, Your Honor, I  
22 apologize for interrupting. I think the witness has

1 already testified that she was not familiar with this  
2 study and that it was not cited in the risk assessment.  
3 Counsel may recall that. If she isn't and if it's not,  
4 then I think we're beyond the scope.

5 MR. BATES: Well, it's an exhibit in evidence,  
6 Your Honor. I -- want to ask her one question --

7 JUDGE DAVIDSON: Well, I don't have any -- you  
8 can ask the question, but I don't understand the last  
9 question. You said -- I know what you're trying to do,  
10 but you're leaving my records in shambles here. You're  
11 point out -- and you start reading, and you ask the  
12 witness to read it, and then you move on to something  
13 else. You don't have any question about that, then why  
14 does she have to look at it?

15 MR. BATES: So when we -- I'll -- let me ask  
16 about the Rodriguez study, then I'll ask the question.

17 JUDGE DAVIDSON: All right.

18 BY MR. BATES:

19 Q So the Rodriguez study, would you look at  
20 the --

21 A I don't have it.

22 Q This is Exhibit G-17 --

1 JUDGE DAVIDSON: She didn't; there's no  
2 question. That was the problem. That's what I just  
3 said. There was no question asked.

4 BY MR. BATES:

5 Q When one looks at the Rodriguez study, and  
6 these other studies that we just talked about --

7 JUDGE DAVIDSON: Do you have the number?

8 MR. BATES: G-1711.

9 JUDGE DAVIDSON: 1711?

10 MR. BATES: Correct.

11 JUDGE DAVIDSON: I need a copy. Hate to tell  
12 you, but, you know, the people that prepared this --  
13 CDs for me -- gave me five of them, and this one  
14 doesn't go up to G-1711.

15 Thank you. Now let's -- the question is?

16 BY MR. BATES:

17 Q The question is when we look at the Rodriguez  
18 study, which in the abstract says, "No statistically  
19 significant risk associated with consumption of  
20 chicken," other than -- nor with reported domestic  
21 kitchen practices. We look at this study, we look at  
22 the other studies we just talked about -- we get, do we

1 not, a picture that says, "Consumption of chicken per  
2 se isn't a risk"?

3 A And I think that we've stated that consumption  
4 of chicken, if it had no campylobacter on it, is not  
5 a -- is not a risk.

6 Q Well, these chickens had campylobacter on  
7 them, didn't they?

8 A We don't know that, do we?

9 Q We do. I direct your attention to Exhibit G-  
10 564, this -- study on page 4.

11 A What is this --

12 MR. SPILLER: Object to the form of the  
13 question. We're talking about these chickens in the  
14 context of Exhibit G-1711, and the witness has been  
15 questioned about their campylobacter status. Counsel  
16 testified, "We do;" and now we're off to another study.

17 MR. BATES: No, the same study. This is the  
18 Schmitz study we just talked about --

19 JUDGE DAVIDSON: Well, now you were in the  
20 Rodriguez study.

21 MR. BATES: I'm sorry. I was talking about  
22 all the studies that we just mentioned. You asked what

1 my question was, Your Honor -- if you put them all  
2 together, don't we get that picture?

3 JUDGE DAVIDSON: All right. And her answer  
4 was, I think, that we do if you're just talking about  
5 certain chickens, but not if you consider all the  
6 chickens -- chicken -- I'm sorry. I won't even try.

7 What was your answer?

8 THE WITNESS: My answer was that if chicken  
9 has campylobacter, it's a risk factor.

10 JUDGE DAVIDSON: And then you said, "Well, it  
11 does, doesn't it?"

12 MR. BATES: Well, look at page 4 --

13 JUDGE DAVIDSON: Is this all the studies?  
14 They all -- all these studies that you referred to that  
15 you put on the record, portions of, referred to  
16 portions of, deal with chickens that have  
17 campylobacter? That's the import of your statement,  
18 which is not testimony in this case.

19 MR. BATES: Let's then -- take your point --  
20 let's talk about the studies, what they say about  
21 whether there is campylobacter on the chicken.

22 JUDGE DAVIDSON: All right.

1 BY MR. BATES:

2 Q Exhibit G-564 has the one-year study of  
3 epidemial campylobacteriosis in mid-western cities?

4 A And this is an article that I'm less familiar  
5 with than some of the others.

6 Q Well, just look at the -- doesn't it say --  
7 MR. SPILLER: Object -- form of the  
8 question --

9 JUDGE DAVIDSON: Page 4, right-hand  
10 paragraph --

11 BY MR. BATES:

12 Q Page 4, right-hand column, where we were  
13 reading before --

14 JUDGE DAVIDSON: The paragraph that starts  
15 with "Although we found" -- did you find it --

16 BY MR. BATES:

17 Q Did you find it, doctor?

18 A Yes.

19 JUDGE DAVIDSON: Okay.

20 BY MR. BATES:

21 Q That statement says, "Large numbers of chicken  
22 carcasses at retail stores were contamination" --

1           A     Yes.  And I need to say that we're still  
2 finding that today, but the problem -- or the question  
3 is "What is the campylobacter status at the point of  
4 ingestion," so that if you find, as you do cooking at  
5 home is not coming out as a strong risk factor, it's  
6 because probably people at home are taking better care  
7 to cook their chicken so that the campylobacter are  
8 killed by the time they eat them.

9           Q     So you're suggesting there's something going  
10 on in a restaurant that's different than going on at  
11 home?

12          A     I'm suggesting that people at home take better  
13 care.

14          Q     Restaurant cooking practices are less good  
15 than home cooking practices and that would explain the  
16 difference of --

17          A     Well, I don't want to point my finger at all  
18 restaurants.  I think some restaurants take care also.

19          Q     In either event, what you're -- am I right  
20 that what you're suggesting is that we're trying to  
21 understand cause here.  You've got what's known to  
22 statisticians as a feedback problem, is that right?

1 Do you know what a feedback problem is?

2 A No.

3 Q Well, let me put it in my own words. You've  
4 got eating chicken in a restaurant, resulting in an  
5 increased risk factor of disease. It might be that the  
6 problem is the chicken, or it might be the problem is  
7 the restaurant doing something to the chicken.

8 Is that correct?

9 A I -- that's a difficult one to answer. It's  
10 hard to imagine the restaurant doing something to put  
11 campylobacter on the chicken.

12 Q It is? Well, what about ill food handlers at  
13 restaurants? Big problems.

14 A No. And when I say no, I mean compared to the  
15 amount of campylobacter that are coming in day after  
16 day on chicken.

17 Q Just stay with me. Ill food handlers in  
18 restaurants is a problem, regardless of the big or  
19 small.

20 MR. SPILLER: Beyond the scope of direct.

21 MR. BATES: Excuse me --

22 JUDGE DAVIDSON: It's fairly obvious. The

1 witness has already agreed to that. I don't know why  
2 you're pushing it.

3 BY MR. BATES:

4 Q So we know -- let's go back to the CVC draft  
5 1452. It's attachment 3. And if we look at Table 4 on  
6 page 101, and we also see that eating non-poultry meat  
7 in a restaurant has a risk factor of 21 percent. Do  
8 you see that?

9 A Yes.

10 Q That's similar to the etiological fraction for  
11 chickens in restaurants, right?

12 A That's correct.

13 Q Well, doesn't that cause you to wonder whether  
14 there's something going on in a restaurant that's  
15 independent of whether it's chicken or meat -- because  
16 they both have similar risk factors?

17 MR. SPILLER: Object to the form of the  
18 question as it presumes independence when the  
19 restaurants incorporate both chicken and other meat.

20 JUDGE DAVIDSON: All right. I'm going to  
21 sustain the objection. I think you've beaten this  
22 horse enough. The record speaks for itself. You have

1 the data. You have an opportunity, in brief, to make  
2 whatever argument you please. Move on to something  
3 else.

4 BY MR. BATES:

5 Q So when we do the -- we were just talking  
6 about the etiologic fraction of the total number of  
7 campylobacter cases. And when you do your calculation,  
8 is your next step to try to estimate the number of  
9 those campylobacter cases which are resistant?  
10 So if I were to draw another circle inside my second  
11 circle -- we're trying to do next. Is that correct?

12 A That's correct.

13 Q And the quantification that you're doing  
14 here -- you are going from all cases, to chicken cases,  
15 to resistant cases.

16 A May I make a suggestion --

17 Q Yes.

18 A -- that that circle should --

19 JUDGE DAVIDSON: Excuse me. The circle is not  
20 in the records, so don't believe that.

21 THE WITNESS: Okay.

22 JUDGE DAVIDSON: He just -- what he said was

1 fairly clear --

2 THE WITNESS: Supposition --

3 JUDGE DAVIDSON: -- he stepped from total  
4 population to the chicken to resistant.

5 THE WITNESS: Okay.

6 MR. BATES: Did I get something wrong? Do you  
7 want to clarify that?

8 JUDGE DAVIDSON: No, she was just worried the,  
9 I think, the circles; but they're not in the record.

10 THE WITNESS: Where are they placed? Where  
11 it's placed.

12 BY MR. BATES:

13 Q So what happens to the formula that you use,  
14 the multiplication? When you've got a situation like  
15 eating chicken at home, which -- where the fraction is,  
16 well, reversed or negative? How do you factor that  
17 into this multiplication?

18 A Well, as you know, we didn't do it that way.  
19 We had an overall factor attributed to chicken which we  
20 were not separating out. This is eaten pink, this is  
21 eaten at a restaurant, this is -- we had a global  
22 value.

1 Q I understand, but when you -- I'm just trying  
2 to -- in the risk assessment, you said if one had these  
3 data, one could use them to do the calculation. I'm  
4 now trying to understand how one would do that.

5 A Well, just as I said, we would have used all  
6 the various attributable fractions and come up with a  
7 global attributable fraction that we would apply.

8 Q Got it. At if that fraction turned out to be  
9 less than one, or negative, then what would you end up  
10 doing?

11 A It would not turn out to be -- you cannot have  
12 an attributable fraction that's negative. You can have  
13 an odds ratio that's less than one, but you cannot have  
14 negative risk.

15 Q If the odds ratio were less than one, then  
16 what would you do?

17 A Well, this is supposition and I think that, as  
18 we've seen, it -- the global estimate would not be.

19 Q Well, we're going to argue that in the brief,  
20 so I'm just trying to understand what you would do if  
21 an odds ratio were less than one.

22 MR. SPILLER: Objection --

1 BY MR. BATES:

2 Q How would you make this -- how would you make  
3 it work?

4 MR. SPILLER: Objection. I'm educated by my  
5 witness. I now recognize the question invites  
6 speculation.

7 JUDGE DAVIDSON: Yes, but I think she can  
8 answer it. If you did come up with that kind of less  
9 than one, what would it mean? It's just hypothetical;  
10 it doesn't mean that you're saying that that is the  
11 result.

12 THE WITNESS: If an odds ratio were less than  
13 one? That -- an odds ratio less than one still does  
14 not imply a zero risk. It means that a certain -- that  
15 the cases are less at risk, perhaps, than -- or I  
16 should say that the controls were less at risk, but it  
17 still does not imply zero risk. So I'm struggling to,  
18 right now, to think about what it would be. It would  
19 be a non-zero value, but not very large.

20 BY MR. BATES:

21 Q So if you had -- if you had an odds ratio less  
22 than one, and you took -- you then tried to multiply --

1 resistance times something less than one, how do you  
2 get a value from that? That's what I don't understand.

3 MR. SPILLER: Again, objection. Not merely  
4 speculation, but speculation multiplied now.

5 MR. BATES: I'm not pursuing it, I'm  
6 just trying to get sense.

7 JUDGE DAVIDSON: All right. With that double  
8 slip of the chart, is this a convenient place? The  
9 witness has been on the stand almost three hours --  
10 almost two hours.

11 All right, we'll take a 10-minute recess.

12 (A brief recess was taken.)

13 MR. BATES: Dr. Bartholomew, ready to resume?

14 THE WITNESS: Yes.

15 BY MR. BATES:

16 Q Now just to try to pick up about where we left  
17 off, when we were -- we were going from the total  
18 indication fraction issues, which was dependent on the  
19 year you picked, which was roughly 1.7 million and 1.4  
20 million, and we're going to the percentage of those  
21 that were campylobacter cases attributable to chicken.

22 A Yes.

1 Q Yes.

2 A Yes.

3 Q Thank you.

4 A I'm sorry.

5 Q No, no, that's -- we're trying to get this  
6 right. And in your model you use 57 percent.

7 A That's the mean value.

8 Q Would you agree with me that if, as you  
9 suggested in the model, we use the new CVC data, that  
10 number might be 24 percent or it might be even lower?

11 A I would not agree that we would have  
12 disregarded totally other information so that 24  
13 percent was restaurant dining. I think we would have  
14 looked around for what else, because, as you know, our  
15 consumptions -- the way we use consumption is not  
16 individuals sitting around injecting chicken. We were  
17 talking about the exposure of the population to the  
18 chicken, with a lot of implication of secondary  
19 transmission and that sort of thing.

20 So I'm saying that we would -- if we would use  
21 the CVC data, we would not just pick up that 24 percent  
22 and run with it. There would be other modeling that

1 would need to transpire also.

2 Q Including the fact that when eating at home,  
3 the number goes the other way.

4 A Yes.

5 Q So then the next step in the process is to try  
6 to estimate the number of those chicken cases which are  
7 resistant. Am I right, or have I got that wrong?

8 A Yes.

9 Q I got it right. To try to estimate the number  
10 of those chicken cases which are resistant, is that  
11 correct?

12 A The number of cases that are from chicken and  
13 are Fluoroquinolone resistant are --

14 Q So you needed -- you have 57 percent here. It  
15 might be less than that based on the new study. Yes?

16 A Yes.

17 Q And now you've got to get a percentage for  
18 this next fraction?

19 A Right.

20 Q Am I right that the way you do that -- I'm  
21 going to draw another circle, so -- if you just said,  
22 well, we're going to look at the -- all the resistant

1 cases -- this -- is that right?

2 A Right.

3 Q And then did you say and we're going to pull  
4 out of there the cases that -- I'm drawing a small  
5 circle inside the big circle -- you pull out of that  
6 the number of cases that were attributable to foreign  
7 travel.

8 A Yes, conceptually, that's what went on, mm-  
9 hmm.

10 Q Then you said, am I right, that you said we're  
11 also going to pull out of that the number of cases --  
12 and I'm drawing another circle that's smaller -- that  
13 were related to prior treatment --

14 A Yes.

15 Q Then am I right that you said everything else  
16 is chicken?

17 A Yes, we did.

18 Q Well, we now have the Predence study. That  
19 what we've been talking about, the Predence study. The  
20 CVC study that we've been talking about -- Exhibit G-  
21 1452 -- an attachment to Exhibit 1452.

22 And am I right that that is a risk factor in

1 Table 4, that we've been talking about, at page 101,  
2 for drinking water?

3 MR. SPILLER: Objection to form. Misstates  
4 the record. If counsel is referring to the seventh  
5 line down, it has a different title.

6 MR. BATES: Let me be real precise.

7 BY MR. BATES:

8 Q Drank untreated water from a lake, river, or  
9 stream. Do you see that?

10 A Yes, I do.

11 Q And do you recall in the risk assessment,  
12 making the statement that there is resistance to  
13 campylobacter in water?

14 A I don't recall that. Could you point it out  
15 for me?

16 A Well, why don't you look at page 49 to 50, and  
17 in particular -- it's G-953, pages 49 to 50.

18 A Yes, I see that.

19 Q Yes. So we do find Floraquinolone-resistant  
20 campylobacter in water, do we not?

21 A It appears that in the effluent from abattoir  
22 and sewage purification plants, they do find it.

1 Q And that water often goes into lakes and  
2 streams and so on, is that correct?

3 A I hope not too much of it.

4 Q We'll let another agency worry about that.

5 My only point is should we have another circle  
6 of some size -- I don't know how big it is -- for  
7 resistant cases from water?

8 A Well, I think that we concluded that poultry  
9 farm runoff would also be attributable to use in  
10 chickens.

11 Q Based on what, do you remember?

12 A We discussed with our microbiologist -- and  
13 that our conclusion was that without selection  
14 pressure, use of fluoroquinolones, you very rarely find  
15 resistant campylobacter.

16 At the time that we did the risk assessment,  
17 the fluoroquinolone use in poultry was the only  
18 agricultural fluoroquinolone approved; so that that  
19 would be the selection pressure, considered to be the  
20 largest one for creating the resistance in water. So  
21 we attributed that to chicken also.

22 Q But your own report says, does it not, that

1 there was 11 percent resistance rate in -- I'm reading  
2 from page 50 -- 11 percent resistance rate coming from  
3 a sewer treatment plant that did not receive meat  
4 processing solution. That's not run-off from chicken,  
5 is it?

6 A I can't say. And as I said, it was an  
7 assumption that we made that most of it was --

8 Q I agree with that. I'm just trying to  
9 understand whether there might not be other things that  
10 one would want to subtract in order to get a picture of  
11 what that fraction might be.

12 A Well, the water is not treated with  
13 fluoroquinolones, so that it would ostensibly come from  
14 either the use of the fluoroquinolone in the chicken,  
15 or fluoroquinolone -- the use in people. And we had a  
16 little blurb for taking care of fluoroquinolone use in  
17 people also, which --

18 Q But that was part of treatment, yes? That's  
19 getting a prescription. That's not coming out of a  
20 waste water treatment?

21 MR. SPILLER: Objection to the form of the  
22 question, which presumes that effluent from humans that

1 had been treated would not survive sewage treatment.  
2 Counsel describes them as separate, not established.

3 JUDGE DAVIDSON: I'll sustain the objection.

4 BY MR. BATES:

5 Q When you said that you pulled out prior  
6 treatment, tell me what you meant by that?

7 A We estimated, from the 1998-1999 campylobacter  
8 case control study, that proportion of the resistant  
9 isolates that was due to either travel or prior  
10 fluoroquinolone use; and we applied that proportion to  
11 Norm's data so that we could have an annual update.

12 And in doing so in a risk model, you use  
13 distributions, so that you have variability -- you  
14 incorporate the possibility that the number that you're  
15 using is that number, or some other number. So you  
16 have uncertainty about it.

17 Q Just to be clear, though, what you were trying  
18 to do was to identify the number of resistant isolates  
19 that resulted from someone taking a prescription.  
20 That's what this circle I drew was all about, is that  
21 correct?

22 A That's correct.

1 Q You weren't trying to identify resistant  
2 campylobacter that came out of a waste -- treatment?

3 A Not specifically, no.

4 Q So wouldn't we want to, if we could, try to  
5 account for some portion of resistant campylobacter  
6 that wound up in the environment, got in the water, and  
7 people were exposed to it?

8 A I don't know. I suppose if your focus was  
9 that, campylobacter in water, that you might want to do  
10 that, yes.

11 Q And returning to page 101 of attachment 3 to  
12 Exhibit G-1452, which is the Table 4 that we've been  
13 discussing, I think you pointed out to me that there's  
14 something -- some portion of the proposition trivial  
15 risk which is not attributed to anything?

16 A Would you repeat the citation, please?

17 Q Yes, certainly. It's Exhibit G-1452,  
18 attachment 3.

19 JUDGE DAVIDSON: Page 101?

20 MR. BATES: Page 101, Table 4.

21 BY MR. BATES:

22 Q And my question was do you recall testifying

1 that there's a portion of the etiologic fraction that's  
2 not attributed to anything?

3 A Yes.

4 Q And would I be right that that's more or less  
5 25 percent, if I had those numbers on there, that's  
6 unattributed to anything?

7 A I haven't done that addition, but I'd say it's  
8 about that, okay.

9 Q So this picture that I drew over trying to  
10 understand what sources other than chicken we should  
11 subtract in order to get the chicken number -- are you  
12 saying that, with regard to the unattributed 25 or less  
13 percent, there are no resistant cases in that portion?

14 A I would say that in 1998-99, that we had  
15 attributed all of the domestically acquired resistance  
16 to chicken; so if it was not chicken-associated, then  
17 ostensibly it would not have been resistant.

18 Q So when -- with that -- I guess I asked a  
19 different question. You answered -- with regard to  
20 that 20 percent, the assumption you made says there  
21 were no resistant campylobacter provided by the 25  
22 percent?

1           A     Well, as I -- one thing that you said was that  
2 the source was not know for that 25 percent.

3           Q     Right.

4           A     And to the extent that something in that 25  
5 percent was not chicken-associated, then there would --  
6 then it would not have included resistant. But there  
7 is -- there's uncertainty here. We don't know what  
8 that 25 percent --

9           Q     There may or my not be other things that have  
10 to come out of this -- is that --

11          A     You are looking at the pool of resistant  
12 bacteria there, right?

13          Q     Correct. I tried to go from -- I thought the  
14 way that you tried to come up with a fraction for  
15 multiplying times the number of chicken cases was to  
16 say, well, what are all of the resistant cases, and  
17 let's pull out foreign travel, pull out prior  
18 treatment. We talked maybe we should pull out a  
19 little -- of the water.

20          A     Yes.

21          Q     And so there might be some things in this  
22 other attributed portion that we might want to pull out

1 too.

2 A Well, you're looking at a table that's  
3 developing a population-attributable fraction for  
4 campylobacter cases, not for resistant cases.

5 Q I understand that. I'm just trying to say one  
6 has to assume, therefore, in this 25 percent, there's  
7 no percentage of resistance; because if there is, one  
8 would want to pull it out in order to make sure you  
9 have the right number.

10 A I guess I'll go back to what I said earlier.  
11 To the extent that the unknown portion is -- was a  
12 source other than chicken, that there would be no  
13 other -- I'm having trouble making these two things  
14 match because here we're talking about attribution of  
15 campylobacter, and there you're talking about  
16 attribution of the resistance. And so I'm having  
17 trouble making your two statements match.

18 Q All right, let's try this. We have this 25  
19 percent unknown.

20 A Unknown with respect to where they got their  
21 campylobacter, yes.

22 Q Right. And we have -- in addition, we have

1 population-attributable fractions for non-poultry meat  
2 and -- other things, on Table 4. Is that correct?

3 A Yes.

4 Q And so we know that campylobacter comes not  
5 just from chickens?

6 A That's true.

7 Q And we know, at least in the case of water  
8 that there sometimes resistant campylobacters in water;  
9 and water is one place where people get campylobacter.  
10 Correct?

11 A Yes.

12 Q And that's why we may not be sure how big it  
13 is, but there's a fraction here that we would know if  
14 we pulled it out?

15 A Twice I've said I'm not sure that it belongs  
16 to other than chicken or human use --

17 Q We'll go over that. But if it turned out that  
18 some of these other sources that we just talked about,  
19 the unattributed ones, the non-poultry meat and  
20 restaurant, and so on -- had some resistant  
21 campylobacter -- in that case, it wouldn't be from  
22 prior treatment, then one would want to pull those

1 things out as well. Yes?

2 A If you had sources that you could justify, I  
3 think you would want to pull them out. Now, our risk  
4 assessment was very clear about what it was assuming.  
5 It was assuming that the -- what the selection  
6 pressures were. And so I -- I mean, I could answer  
7 your question in the hypothetical that if you knew of  
8 something else as a selection pressure, you would want  
9 to account for it.

10 Q And if one -- that would mean that the  
11 percentage that you got would go down some, yes?

12 A If I were subtracting out, yes, it would have  
13 to mean that.

14 Q In your work on the EPA water panel, have you  
15 become familiar with a study that the U.S. Geological  
16 Survey is doing on pharmaceuticals and streams in the  
17 United States?

18 A Not through that. I'm aware of that study to  
19 the extent that I know it's out there. I haven't  
20 studied it.

21 Q And are you aware that the results of that  
22 study have been recently published?

1 MR. SPILLER: Objection. Beyond the scope of  
2 direct. Way beyond.

3 MR. BATES: Your Honor, I would -- I have  
4 marked Exhibit B-1945, which is a --

5 JUDGE DAVIDSON: You have an objection  
6 pending. Care to respond to it?

7 MR. BATES: I'm sorry.

8 JUDGE DAVIDSON: You have an objection  
9 pending. Now you're going to start marking papers?  
10 That doesn't -- that doesn't -- that's not the way I  
11 operate.

12 BY MR. BATES:

13 Q You've testified --

14 JUDGE DAVIDSON: Now --

15 MR. BATES: All right.

16 JUDGE DAVIDSON: I want you to respond to the  
17 objection.

18 BY MR. BATES:

19 Q A moment ago you just testified that the  
20 resistance in water came from --

21 JUDGE DAVIDSON: You're still back on that, is  
22 that it? I'm ruling -- I'm sustaining the objection.

1 I don't want to see any more business with respect to  
2 what we're going to take out, what we're not going to  
3 take out. The record speaks for itself. If you have  
4 those things in the record, you can put it in the  
5 brief.

6           You've gone through with this witness 15 times  
7 or more the fact that certain things had to come of her  
8 calculation. She stands by her calculation. She  
9 hasn't changed that. We understand it has limits, and  
10 she has put in the assumptions, and you can take it  
11 from there.

12           I don't understand why we're wasting hours on  
13 this particular aspect of it.

14           Now if you move on to something else, I'll be  
15 happy to listen to you. If you want to stay with this,  
16 you've finished your cross-examination.

17           MR. BATES: No, one or two more --

18           JUDGE DAVIDSON: Okay, thank you.

19           BY MR. BATES:

20           Q     So we go through our calculations -- we start  
21 with a -- we go to the campylobacter, we go to --

22           JUDGE DAVIDSON: Just --

1 BY MR. BATES:

2 Q -- and then we go to --

3 JUDGE DAVIDSON: -- excuse me. I thought I  
4 just said I don't want to hear any more about that. I  
5 mean, if you want to explain to me what you're doing,  
6 I'll be glad to listen; but to go back through this  
7 over and over again -- and you've asked the same  
8 questions more than once -- because I realize the  
9 witness is not giving you the answers you'd like to  
10 hear; and she may not be totally responsive. But we're  
11 in an area where I don't think we're getting much for  
12 the record. And that's my problem.

13 MR. BATES: I'm just trying to get to --

14 BY MR. BATES:

15 Q We talked before about the final step in the  
16 calculation.

17 JUDGE DAVIDSON: No, you're talking to me now,  
18 not the witness. What are we doing?

19 MR. BATES: I'm -- I'm simply trying to recall  
20 the process by which we get to the final step of the  
21 calculation -- focus on the final step.

22 JUDGE DAVIDSON: It's not in her testimony?

1 MR. BATES: Excuse me?

2 JUDGE DAVIDSON: It's not in her testimony?

3 MR. BATES: The final step --

4 JUDGE DAVIDSON: The process by which she got  
5 to her calculation?

6 MR. BATES: It is in her testimony.

7 JUDGE DAVIDSON: Then why do you have to  
8 recall it?

9 MR. BATES: I'm not going to go through the  
10 detail; I'm just trying to get to the end -- I'll be  
11 happy to start with the end point.

12 JUDGE DAVIDSON: Well, if you have something  
13 that you're going to ask her about that, that's fine.  
14 You can start at the end point, ask her the question,  
15 and move on.

16 BY MR. BATES:

17 Q So the end point of the calculation was, as I  
18 think we discussed, that you estimated the number of  
19 cases that were fluoroquinolone-resistant of chicken  
20 that were prescribed fluoroquinolone?

21 A Yes.

22 Q And I think, recalling what we talked about

1 before, that you did attempt to estimate a number of  
2 those cases where there was a treatment -- is that  
3 correct?

4 A That's correct.

5 Q And did you attempt to estimate the number of  
6 cases where a bacterium was susceptible, where there  
7 was a treatment failure?

8 A No.

9 Q Now hypothetically, if it turned out that the  
10 rate of success or failure was the same for resistant  
11 cases as in susceptible cases, then what would happen  
12 to the health impact --

13 MR. SPILLER: Object. I understand you can  
14 ask a hypothetical, but the hypothetical needs a basis.  
15 I've not heard the basis laid for that particular  
16 hypothetical.

17 BY MR. BATES:

18 Q Now I have Exhibits G-354 --

19 JUDGE DAVIDSON: Is this the basis for the  
20 hypothetical?

21 MR. BATES: Yes.

22 JUDGE DAVIDSON: Thank you. Witness got a

1 copy of it?

2 MR. BATES: Excuse me, Your Honor?

3 JUDGE DAVIDSON: Does the witness have a copy  
4 of Exhibit 354? G-354? Are we referring to a page and  
5 line?

6 MR. BATES: Yes, I'm just trying to find  
7 the -- this is going to require a couple of steps here.

8 BY MR. BATES:

9 Q Will you look, please, at page 3, the section  
10 entitled, "Clinical Outcome." And if you look at the  
11 top of the second column on that page, this indicates  
12 that there were two patients with campylobacter who  
13 were prescribed Ciprofloxacin and failed treatment. Is  
14 that correct?

15 A I will need to take a time to read this  
16 because I have not read it from -- if I read it at all,  
17 I haven't read it for a long time.

18 Is this a set of patients, all of whom had  
19 resistant campylobacter? I didn't see that in that  
20 passage.

21 Q We look at -- let me direct your attention to  
22 the section in the first column on that page. It says,

1 "Bacteriological outcome."

2 And as you go up to Table 2, it says number of  
3 patients in the treatment group that indicated -- of  
4 Ciprofloxacin -- 27; and it says campylobacter  
5 species -- 21. Is that the first -- the number of  
6 isolates?

7 A Number of people with campylobacter.

8 Q Then if you look at page 3, right-hand column,  
9 it says that we had -- one of the patients who had only  
10 campylobacter; seven were susceptible -- seven were  
11 resistant isolates. Do you see that?

12 A You say the top of the right-hand column?

13 Q Right-hand column about midway down, page 3.

14 A Okay.

15 Q So we've got seven patients with susceptible,  
16 seven with resistant.

17 JUDGE DAVIDSON: Two resistant.

18 MR. BATES: Seven patients with susceptible,  
19 and seven with resistant, okay?

20 JUDGE DAVIDSON: Where are you reading this?

21 MR. BATES: The sentence begins: "Of the  
22 patients affected with campylobacter species

1 isolate" --

2 JUDGE DAVIDSON: Yes.

3 MR. BATES: -- "and were treated with  
4 Ciprofloxacin" --

5 JUDGE DAVIDSON: Go ahead.

6 MR. BATES: -- "four of seven were  
7 susceptible, and two of seven were resistant."

8 JUDGE DAVIDSON: That's what I thought, but  
9 you kept saying seven resistant, seven --

10 MR. BATES: Seven patients with --

11 JUDGE DAVIDSON: I understand what it says,  
12 but your question, I believe, left out the two of seven  
13 when you got to the second part.

14 MR. BATES: I want to go back to the -- of  
15 this paragraph where it says that there were two  
16 people -- there were two clinical failures: one was  
17 susceptible, one was resistant.

18 JUDGE DAVIDSON: Okay.

19 THE WITNESS: I don't see any -- you're  
20 pointing me to something that talked about duration of  
21 illness.

22

1 BY MR. BATES:

2 Q Well, go up to the top of page 3. The  
3 first -- they are talking about cases of clinical  
4 failure. They say there were two with the  
5 Ciprofloxacin, one resistant and one susceptible. Is  
6 that correct?

7 A Let's see. One of these patients, the  
8 sentence -- for 7 days, having -- on admission that was  
9 resistant. The same isolate was subsequently isolated  
10 2 days after Ciprofloxacin therapy was initiated. And  
11 Ciprofloxacin-susceptible species was isolated from the  
12 other patient at admission. That patient's illness  
13 lasted four days.

14 I'm not sure -- is this -- that was a  
15 susceptible, it lasted four days.

16 JUDGE DAVIDSON: All right. Excuse me.

17 THE WITNESS: Okay.

18 JUDGE DAVIDSON: We'll go off the record.

19 Read that over carefully and --

20 (A brief recess was taken.)

21 JUDGE DAVIDSON: We're back on the record.

22 MR. BATES: Your Honor, maybe it would assist

1 if I -- we wrote some numbers on the chart --

2 JUDGE DAVIDSON: Well, if you're just refer --  
3 she's -- it's not the numbers that are the problem,  
4 it's the fact that you're referring -- you say the top  
5 of page 3. I look at the top of page 3 and I see -- on  
6 the right-hand column -- they recovered within 48  
7 hours. And you say it says two and one. I don't -- I  
8 can't follow you.

9 MR. BATES: At the top of page 3 there were no  
10 cases of clinical failure with Aithromycin and only two  
11 with Ciprofloxacin.

12 JUDGE DAVIDSON: Oh, and you're looking at --  
13 I'm looking at a different exhibit than you have.  
14 That's --

15 MR. BATES: It's G-354, page 3. The top of  
16 the right column.

17 JUDGE DAVIDSON: Okay, I have a different  
18 exhibit then. So if that's the problem -- it says G-  
19 354, page 3. The top of the right-hand column starts  
20 with "Recovery within 48 hours."

21 MR. BATES: That's correct. And the -- if I  
22 may, the second sentence -- the next sentence following

1 that, it says there were no cases of Azithromycin  
2 failure in the Azithromycin group, and only two  
3 failures -- in the Ciprofloxacin group.

4 JUDGE DAVIDSON: Go ahead. If the witness can  
5 follow you, it's okay with me. I'm having -- talk  
6 about that when you're ready.

7 THE WITNESS: Okay. So -- are you going to be  
8 talking about -- there's two failures. There's one  
9 susceptible, one resistant, among the failures. Is  
10 that correct?

11 BY MR. BATES:

12 Q Correct.

13 A Okay. Now what do I have to -- what -- is it  
14 about the four out of seven and the two out of seven --

15 Q We will get to that in a moment.

16 A Okay.

17 Q If you look at page 2, left hand column, just  
18 about where it says, "Laboratory studies." Do you see  
19 the definition of treatment failure?

20 A Yes. "Treatment was considered a failure if  
21 diarrhea or any symptom persisted for more than 72  
22 hours after treatment was initiated."

1 Q So would you agree with me, using that  
2 definition, that we have seven susceptible cases, seven  
3 resistant cases? Yes?

4 Yes, we're on page 3, right-hand column.

5 MR. SPILLER: Objection. We're in a chase  
6 for "doesn't it say," and I'm willing to stipulate it  
7 says what it says. But I think it's painful and  
8 unproductive, so I object to asking the witness doesn't  
9 the exhibit say something.

10 MR. BATES: I think the purpose of the  
11 question is to clarify how we understand this paper.  
12 There's obviously some confusion about what this paper  
13 says. I'm simply trying to see if I can get an  
14 understanding between the witness and myself about an  
15 inference to be drawn from what's said in this paper.

16 MR. SPILLER: Then the objection is beyond the  
17 scope of direct, because I don't think what this paper  
18 says is in the direct testimony that we're about cross-  
19 examining here.

20 JUDGE DAVIDSON: I'm going to sustain the  
21 objection. Move on.

22 Do you need some additional time, Mr. Bates?

1 MR. BATES: I just have one more -- one more,  
2 Your Honor. It should be short.

3 JUDGE DAVIDSON: I just asked if you needed  
4 time before you ask your next question. You can have  
5 it if you want it.

6 MR. BATES: No, no --

7 JUDGE DAVIDSON: Okay, go ahead.

8 BY MR. BATES:

9 Q Now when you worked with the EPA microbial  
10 risk assessment, did you become aware of what the  
11 population risk threshold was that EPA used for  
12 microbial -- in water?

13 MR. SPILLER: Object to the question as it's  
14 beyond the scope of written direct. The witness  
15 mentioned that work as a part of her qualifications.  
16 She did not include in her written direct testimony  
17 content, conclusions, or compilations of that research.

18 JUDGE DAVIDSON: Well, I'll listen to what you  
19 have to say in response to the objection. If it's  
20 preliminary to something else, I'll allow it. I'll  
21 have to see what we're talking about.

22 MR. BATES: Your Honor, there is a population

1 risk for campylobacter infections, based on this  
2 calculation we just went through. I'm trying to  
3 understand the relationship between that population  
4 risk and the risk that is used to judge what is safe in  
5 other contexts.

6 JUDGE DAVIDSON: I'm sorry, I didn't hear what  
7 you just said. It's safe in what?

8 MR. BATES: Safe in other contexts.

9 JUDGE DAVIDSON: Other contexts?

10 MR. BATES: In water. That's with a  
11 population risk --

12 JUDGE DAVIDSON: Well, how does that pertain  
13 to her testimony, that's what I want to know.

14 MR. BATES: We're trying to understand what is  
15 the significance of whatever number falls out --  
16 because of this -- whether it's -- whether it can be  
17 calculated --

18 JUDGE DAVIDSON: You've been doing that for  
19 quite some time, trying to understand that, haven't  
20 you?

21 MR. BATES: This time I'm trying to put it in  
22 a context of having --

1 JUDGE DAVIDSON: Oh, well, one or two  
2 questions; but if you can't get succinct answers from  
3 the witness, you're just going to have to stop.

4 BY MR. BATES:

5 Q Ms. Bartholomew, do you recall roughly the  
6 population risk that you calculated for the U.S.  
7 population? The risk assessment was about 1 in 33,000  
8 or 34,000?

9 MR. SPILLER: The form of the question -- and  
10 the population risk you are describing is water, or  
11 mice, or Ciprofloxacin?

12 MR. BATES: Like I said, in their risk  
13 assessment, so we're talking the population risk  
14 resulting from risk calculation and --

15 JUDGE DAVIDSON: Exhibit numbers. That's --  
16 pointing to that chart, it's just confusing in the  
17 record.

18 MR. BATES: It is Exhibit 9433.

19 JUDGE DAVIDSON: Thank you.

20 BY MR. BATES:

21 Q Do you have a Table 1.2?

22 A Yes. And did you frame the question in terms

1 of the population?

2 Q Yes.

3 A Okay. So that's the Table 5.2 --

4 Q I think it's 1.2, is that right? On page 14.

5 A On page 14. I'm sorry, I was looking --

6 Q What page are you looking at?

7 A I'm looking at page 79.

8 Q That's the same page.

9 A Okay. For the general U.S. population, the  
10 mean in 1998 was 31 in 34,945; and in 1999, it was 1 in  
11 32,912.

12 Q Is that about 3 in 100,000?

13 A I would say yes.

14 Q Do you know if the population risk that EPA  
15 uses for say drinking water is 1 in 10,000?

16 MR. SPILLER: Object. Relevance and beyond  
17 the scope.

18 JUDGE DAVIDSON: I'll let her answer, if she  
19 knows.

20 THE WITNESS: I have heard the number 1 in 10  
21 to the fourth for some things. I can't say  
22 specifically whether it was for that.

1 MR. BATES: Well, I think -- just one moment.

2 JUDGE DAVIDSON: Certainly.

3 MR. BATES: I think that's all I have.

4 JUDGE DAVIDSON: All right. We'll take a  
5 short recess and we'll change places for redirect --  
6 unless you don't have any.

7 MR. SPILLER: Your Honor, I believe it's  
8 possible we don't have any, but I need to consult  
9 with --

10 (A brief recess was taken.)

11 JUDGE DAVIDSON: Say it again.

12 MR. SPILLER: Thank you, Your Honor. No  
13 questions on redirect.

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

16 I think this would be a good time to break for  
17 lunch, and we will return back and allow you to cross-  
18 examine Dr. Cox, who I see is here today, even though  
19 he's scheduled for tomorrow. Thank you for coming.

20 MR. SPILLER: I would just like to add that  
21 Dr. Cox arrived at 1:30 this morning, so could we have  
22 a short session?

1 JUDGE DAVIDSON: Oh, okay, gee, I don't expect  
2 to finish it this afternoon. We might wait till 10:00  
3 tomorrow, now. He's tired. In fact, I'll state for  
4 the record at this time, and if you ask me, I'll repeat  
5 it again, if Dr. Cox feels that his cross-examination  
6 is too tiring, we can adjourn whenever he's tired, if  
7 it's a convenient place for counsel. And we can  
8 reconvene tomorrow morning.

9 Right now, is an hour sufficient for lunch, or  
10 do you need more? Okay, we'll adjourn until 12:35.

11 (Whereupon, at 11:35 a.m., a luncheon recess  
12 was taken.)  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22

## A F T E R N O O N   S E S S I O N

(12:34 p.m.)

JUDGE DAVIDSON: We're on the record.

MR. NICHOLAS: Just momentarily, Your Honor?

JUDGE DAVIDSON: Mr. Spiller, are you handling  
this one?

MR. SPILLER: Yes, Your Honor.

JUDGE DAVIDSON: Are we ready?

MR. SPILLER: After we get a witness, yes,  
Your Honor.JUDGE DAVIDSON: Okay, let's put Dr. Cox on  
the stand.MR. NICHOLAS: Bayer calls Louis Anthony Cox  
to the stand, please.

Whereupon,

LOUIE COX, JR.

was called as a witness and, having been first duly  
sworn, was examined and testified as follows:JUDGE DAVIDSON: All right, please be seated.  
Give your full name and address to your counsel and  
then see what happens.

THE WITNESS: I am Louie Anthony Cox, Jr., of

1 Cox Associates, 503 Franklin Street, Denver, Colorado  
2 80218.

3 MR. NICHOLAS: Thank you, Dr. Cox.

4 May I approach the witness, Your Honor?

5 JUDGE DAVIDSON: Certainly.

6 MR. NICHOLAS: Your Honor, I'm about to hand  
7 Dr. Cox a document which I'm going to ask him to  
8 identify. It's B-1901. It is Mr. Cox's personal copy  
9 and has several mostly page notations on there. I'd  
10 like to use this copy, if I might, and we'd be happy to  
11 show it to counsel.

12 DIRECT EXAMINATION

13 BY MR. NICHOLAS:

14 Q Dr. Cox, could you identify this document,  
15 please?

16 A Yes, this is my written direct testimony.

17 Q And would you read the exhibit number, please,  
18 the bottom right-hand corner?

19 A It's Exhibit B-1901.

20 Q And would you turn to page 8, please, page 8  
21 of your testimony?

22 A Page 8, um-hmm. Yes.

1 Q And can you identify the signature there?

2 A That is my signature.

3 Q Thank you, Dr. Cox.

4 MR. NICHOLAS: I have no further questions,  
5 and we're ready for cross-examination.

6 JUDGE DAVIDSON: All right, do you understand  
7 what he was saying about the penciled notations on  
8 that?

9 MR. SPILLER: Not yet, but I hope to ask some  
10 questions about it, Your Honor.

11 JUDGE DAVIDSON: Well, would you like to look  
12 at it first, or have you seen it?

13 MR. SPILLER: That was going to be my first  
14 question.

15 CROSS-EXAMINATION

16 BY MR. SPILLER:

17 Q Dr. Cox, may I see the copy of your testimony  
18 and the annotations?

19 A Certainly, you may.

20 Q Thank you.

21 MR. SPILLER: May I have a moment, Your Honor?

22 JUDGE DAVIDSON: Certainly.

1 MR. SPILLER: Thank you, Your Honor.

2 JUDGE DAVIDSON: All right. Before we  
3 proceed, to avoid any confusion, because I certainly  
4 have a little bit here, my copy of Dr. Cox's testimony,  
5 page 1 is page 2, or maybe it's page 2 that's page 1.  
6 So I'll put the burden on you, Mr. Spiller, to make  
7 sure that we're talking about the same page. Use the  
8 numbers in the lower right-hand corner of the exhibit,  
9 so that everybody -- so that I can be on the same page  
10 that you're on, if you ask questions about the exhibit.

11 MR. SPILLER: Yes, Your Honor. And to clarify  
12 for me, I didn't observe that problem until later on in  
13 the attachment. You aren't literally speaking of pages  
14 1 and 2, but of subsequent pages that have discrepant  
15 numbers?

16 JUDGE DAVIDSON: No, the first page of the  
17 exhibit in mine is blank. And what shows as page 2 on  
18 my computer is page 1 on the exhibit.

19 MR. SPILLER: Then we do, indeed, have a  
20 discrepancy, Your Honor, and perhaps some questions  
21 from Dr. Cox -- we now have two problems to address.

22 JUDGE DAVIDSON: All right.

1 BY MR. SPILLER:

2 Q Dr. Cox, on the copy of your testimony that  
3 you have, am I correct that in addition to the page  
4 cross-references that your counsel mentioned, there are  
5 a number of interlineations, insertions of words,  
6 letters, I assume cross-references, that you've  
7 inserted in there?

8 A Yes, this is a -- a copy I marked up on the  
9 plane. It has two main kinds of insertions. One is  
10 where the PFOF responses from CVM raised questions or  
11 showed need for clarifications. The other is, since  
12 there are no hyperlinks in this document as there were  
13 in the original, I put page numbers next to several  
14 places so that I can quickly find the supporting  
15 analysis.

16 Q Thank you, Dr. Cox.

17 MR. SPILLER: Your Honor, to make sure that  
18 we're all playing from the same deck, so to speak, I  
19 request that during the cross-examination, we let the  
20 witness work from a copy more similar to ours without  
21 those notations. His counsel can hold your copy and  
22 when the circumstances are appropriate, we can discuss

1 on the record what information we need to get from it?

2 JUDGE DAVIDSON: Okay.

3 MR. SPILLER: Is counsel going to provide a  
4 copy to Dr. Cox?

5 MR. NICHOLAS: If you have a clean copy of his  
6 testimony, I think that would probably be the best  
7 one --

8 MR. SPILLER: I don't.

9 I apologize, Your Honor, for the delay. If  
10 you want to look at this, you don't have any notes in  
11 it that you know of, right?

12 BY MR. SPILLER:

13 Q Now, to attend to the problem that the Court  
14 pointed out, Dr. Cox, referring to the lower right-hand  
15 corner of Exhibit B-1901 that you have, is there a  
16 small word "page" followed by the numeral "1" on the  
17 very top page?

18 A Yes, there is.

19 Q And on the second through fifth pages --

20 A 2 through 5.

21 Q And is there only one page number on each of  
22 those pages?

1           A     Yes, that's correct. In fact, that's also  
2 true for 6, 7 and 8.

3           Q     And just for comparison, let's figure where  
4 the pagination separates. If you look at B-1901  
5 attachment 1, that has page 9 on the exhibit stamp and  
6 no number on the page, am I correct?

7           A     Yes, starting on page 9 of the exhibit stamp,  
8 that's correct.

9           Q     And then on page 10 of the exhibit stamp,  
10 there is a typed number 2 beneath that?

11          A     Or the Microsoft Word 2, yes.

12          Q     In my questions to you, I will refer to the  
13 exhibit stamped number, the small number that follows  
14 right after the term Exhibit B-1901.

15          A     All right, so I can just add eight to  
16 Microsoft Word. That will work.

17          Q     Or you can just rely on the exhibit, which is  
18 what I will do.

19          A     Okay.

20          Q     And now I need to straighten myself out with  
21 the Court's record, because it may be that the scanning  
22 has somehow introduced different pagination.

1 MR. SPILLER: Your Honor, did I hear you  
2 correctly that your electronic version has a numeral 2  
3 on the very first page of his testimony.

4 JUDGE DAVIDSON: Yes. But it says it's a  
5 docket stamp number. So the --

6 MR. SPILLER: Let me check.

7 JUDGE DAVIDSON: The docket stamp number is  
8 number 1. So if we use the docket stamp number, we'll  
9 be on the same page. It's just that for some reason  
10 they've got a cover sheet on her that they've labeled  
11 as number 1.

12 MR. SPILLER: I'm afraid you will notice that  
13 with several of the exhibits that are in the electronic  
14 versions, Your Honor. And if it's acceptable, I will  
15 continue to refer to the docket stamp number.

16 JUDGE DAVIDSON: I think we will all be on the  
17 same page with that.

18 MR. NICHOLAS: I agree, Your Honor. These are  
19 all sequentially numbered.

20 JUDGE DAVIDSON: Okay, thank you.

21 MR. SPILLER: We are all on the same page now,  
22 so to speak.

1 BY MR. SPILLER:

2 Q Good afternoon, Dr. Cox. I am Robert Spiller  
3 with the Center for Veterinary Medicine. If any of my  
4 questions are not clear, I'll trust you to stop me to  
5 make sure that we have a good understanding about the  
6 question being answered.

7 In your testimony, I noticed that your  
8 signature occurs at page 8 of 95, and that limits your  
9 declaration that it is true and correct to the  
10 foregoing material. Do you now adopt pages 9 through  
11 95 of Exhibit 1901 as also your testimony, subject to  
12 the same declaration of truthfulness and correctness  
13 and subject to the same perjury penalty?

14 MR. NICHOLAS: Object to the form of the  
15 question, Your Honor. I believe Dr. Cox's signed  
16 statement incorporates by reference his attachment  
17 there.

18 JUDGE DAVIDSON: Looking at docket stamp page  
19 number 9 or number 10?

20 MR. SPILLER: Docket stamp number -- page 8,  
21 page number 8, Your Honor. At the top line.

22 JUDGE DAVIDSON: Okay. If there's going to be

1 a disagreement, I've got to look at it.

2 MR. SPILLER: Your Honor, if I could direct  
3 your attention to page 6, line 21?

4 JUDGE DAVIDSON: Let me get to the other one  
5 first, all right?

6 MR. SPILLER: Sorry, Your Honor.

7 JUDGE DAVIDSON: Sorry. It's just -- okay, I  
8 have it. Page 8, I have the one that Mr. Spiller  
9 referred to. Now, there's another declaration?

10 MR. NICHOLAS: No, Your Honor. What I'm  
11 merely pointing out is that on page 6, line 21, it  
12 explains that the attachment is incorporated by  
13 reference, and therefore is subject to the declaration.

14 JUDGE DAVIDSON: Well, I'll still allow his  
15 question, because it's not necessarily that clear.

16 MR. NICHOLAS: Thank you, Your Honor.

17 MR. SPILLER: Now, Dr. Cox --

18 THE WITNESS: Yes.

19 MR. SPILLER: Thank you. Now, in order that  
20 my co-counsel might have a copy to replace that, could  
21 we borrow one of the copies that you now have a  
22 duplicate of Dr. Cox's testimony for Ms. Stenberg to

1 refer to?

2 MR. NICHOLAS: Certainly.

3 BY MR. SPILLER:

4 Q Dr. Cox, if I understand your qualifications  
5 correctly, you are an expert in risk analysis; is that  
6 correct?

7 A Yes, I am.

8 Q Does risk analysis include a number of  
9 subdisciplines, risk communication, the ethics of risk,  
10 risk measurement and risk -- did I say communication?

11 A You did.

12 Q Are those subsets of risk analysis?

13 A Risk analysis has notoriously vague  
14 boundaries. Its traditional definition consists of  
15 three major parts: Risk assessment, which seeks to  
16 rate actions for their probable consequences; risk  
17 management, which seeks to decide what to do once the  
18 risks have been assessed; and risk communication, which  
19 tries to decide what to say about the risks.

20 There are also associated fields that include  
21 risk measurement.

22 Q Thank you. You agree in general that for

1 matters in science, experts in a given field are, in  
2 general, to be accorded more weight than those outside  
3 that field?

4 MR. NICHOLAS: Objection, Your Honor. Calls  
5 for a legal conclusion of the witness.

6 JUDGE DAVIDSON: He can answer.

7 THE WITNESS: I think -- in what context?

8 BY MR. SPILLER:

9 Q For instance, in the context of understanding  
10 scientific testimony, if the scientific testimony were  
11 in the field of risk analysis, would you value it  
12 higher if it comes from a risk analyst than you would  
13 from, say, a lawyer?

14 A I think that's very content dependent.

15 Q So for instance, in your testimony at page 31,  
16 in the two bottom paragraphs on that page, do you have  
17 that page?

18 A Yes, I do.

19 Q When you criticize Dr. Smith and Dr. Angulo  
20 for their epidemiological conclusions, you do that on  
21 the basis of your epidemiological expertise?

22 A I do it on the basis of the content of their

1 statements. So I'm -- I'm not following your boundary,  
2 I guess, between different flavors of relevant  
3 expertise. I'm just looking at the statements and  
4 saying, are they correct according to principles that  
5 are used in statistics, in epidemiology, in risk  
6 assessment, and so forth.

7 Q Do you have a degree in epidemiology?

8 A No, I don't.

9 Q Microbiology?

10 A Although I do teach courses in epidemiology,  
11 I do not have a degree in microbiology.

12 Q Poultry science?

13 A No.

14 Q On page 35 of your testimony, where you  
15 testify that CVM, CDC and various groups opposed to the  
16 use of animal microbials have long asserted in academic  
17 publications and so on, could you identify the various  
18 groups that you're referring to there?

19 A I can certainly identify some of them.  
20 They're listed as sponsors of an upcoming conference on  
21 anti-microbial risk assessment, and some of those  
22 sponsors, including APUA, are I think well identified

1 as opponents to continued use of animal antibiotics.  
2 Others are less well identified.

3 Q And for the record, would you translate APUA?  
4 That sounds like it might be an acronym.

5 A It is. That's APUA. And let's see, it's the  
6 Alliance for Prudent Use of Antibiotics, I believe.

7 Q So you mentioned "groups," plural. I assume  
8 that there's another that you had in mind in this, as  
9 you describe it, campaign.

10 A Yes. Can you -- I'm not quickly finding the  
11 line. I know there are no line numbers. Can you just  
12 point it out to me?

13 Q I'll give you one. On page 35 of your  
14 testimony, the last five lines.

15 A Thank you. And wouldn't you know it. I was  
16 looking at the other page, 37. Yes, here, I see it.  
17 And various groups opposed to the use of anti-  
18 microbials -- certainly.

19 In addition to APUA, there would be the Keep  
20 Antibiotics Working group. There are some  
21 environmental activist groups that I know are very  
22 interested in this issue. And I can think of names if

1 you'd like. There are some European groups.

2 Q Yes, please. It's good to know who are  
3 members of the campaign, so when you can think of those  
4 let us know.

5 A Okay.

6 Q If no more come to mind now, I'll move along.  
7 Do you recall any more now?

8 A I'm not -- I do recall a few other groups,  
9 yes. But as I say, a good source might be the upcoming  
10 conference where there are a lot of stakeholders on  
11 both sides.

12 Q You mentioned some environmental groups. By  
13 name, do you recall those?

14 A I think Environmental Defense is one. If  
15 you're asking for a comprehensive list of those who'd  
16 go on record as being opposed to the continued use of  
17 animal drugs, I can't give you a comprehensive list.

18 Q Only those that you recall now.

19 A Okay.

20 Q And in the next sentence, you mention that  
21 this campaign has established as conventional wisdom  
22 the belief that chickens are the main source or

1 certainly one of the most important sources of human  
2 CP. I assume you mean campylobacteriosis?

3 A Yes.

4 Q And am I correct that your testimony is to the  
5 effect that your wisdom is different than that  
6 conventional wisdom and yours is the correct one?

7 A I wouldn't put it that way.

8 Q Perhaps I misunderstood. Do you share then  
9 this conventional wisdom?

10 A That chickens are one of the main source or  
11 certainly one of the most important sources of human  
12 campylobacteriosis?

13 Q Yes.

14 A I do not.

15 Q And between your view and the conventional  
16 wisdom today, what is your testimony is the correct  
17 wisdom?

18 A I think they address slightly different  
19 issues. I think the conventional wisdom that you refer  
20 to is based almost entirely on the analysis of  
21 associations, statistical associations, between  
22 checking consumption and campylobacteriosis. I believe

1 that my view and the view of an increasing number of  
2 researchers -- but still a small minority -- is that  
3 that statistical association does not correspond to  
4 causation.

5 As an expert in risk assessment, my primary  
6 interest is in probable consequences of actions; hence,  
7 I focus on the causal question.

8 Q And may I summarize that as you're right and  
9 they're wrong?

10 A No, you may not. You may summarize it as they  
11 have spread a very widely shared perception about  
12 sources, meaning statistical associations, and I  
13 represent a small but growing minority who look beyond  
14 the associations to say, what are the causes of the  
15 associations. There's a distinction.

16 Q And you have, I read in your Exhibit B-1573 on  
17 page 3 --

18 A I don't know the numbers.

19 Q All right. I'll have to get that to you.

20 I'm handing you now Exhibit B-1573. Tell me  
21 if you recognize that.

22 A Oh, yes. It is a bio --

1 MR. SPILLER: I'm sorry. Your Honor, may I  
2 hand you one?

3 JUDGE DAVIDSON: Yeah, because I don't seem to  
4 have it, either.

5 MR. SPILLER: I apologize. I believe it is in  
6 the record.

7 THE WITNESS: I recognize it as being a bio of  
8 mine, apparently from about a year ago.

9 BY MR. SPILLER:

10 Q Well, it's referred to in your testimony of  
11 December the 13th of 2002; am I correct?

12 A As I say, this appears to be a bio from about  
13 a year ago. It appears to be the one referred to.

14 Q And in that bio, on page 3 of Exhibit B-1573,  
15 you mention the degree that you just referred to. You  
16 have a Ph.D. in risk analysis from MIT.

17 A Yes, I do.

18 Q But MIT doesn't list you as really having a  
19 Ph.D. degree in risk analysis, does it?

20 A I believe that they do. I have a diploma that  
21 says "risk analysis" on it.

22 MR. SPILLER: Your Honor, I believe our next

1 number to use for marking an exhibit is G-1806. I mark  
2 this as G-1806.

3 (Government Exhibit 1806 was  
4 marked for identification.)

5 MR. SPILLER: On counsel's copy, it will just  
6 be written in ink.

7 BY MR. SPILLER:

8 Q Take a look at this. I'll ask you about it in  
9 a moment.

10 A Um-hmm.

11 Q Dr. Cox, the document that I just handed you  
12 that's labeled G-1806, do you recognize the logo and  
13 the letterhead?

14 A Well, this is MIT.

15 Q Is that the institution you attended?

16 A Yes, indeed, it is.

17 Q And are the dates of attendance reflected  
18 there the dates that you attended MIT?

19 A That looks right.

20 Q And does it bear the signature of a person  
21 saying that it's the facsimile signature of the  
22 registrar in the lower right-hand corner?

1           A     It has a Mary R. Callahan, it looks like a  
2 stamp to me, yes.

3           Q     And for your masters of science in operations  
4 research, it identifies that degree by specific name,  
5 doesn't it?

6           A     Yes.

7           Q     And for your Ph.D., it says electrical  
8 engineering and computer science as the department,  
9 right?

10          A     As the department, yes, core six.

11          Q     And does not indicate risk analysis, is that  
12 right?

13          A     Not on here, that's correct.

14          Q     Likewise, your bachelor of arts from Harvard  
15 that you mention in your description as being -- and  
16 I'm looking at B-1573, page 3, it says AB in  
17 "mathematical economics," right?

18          A     Specializing in mathematical economics. It's  
19 a general studies degree.

20          Q     I'm sorry. I don't see the words  
21 "specializing in." Am I correct that in your CV you  
22 said that your degree was in mathematical economics?

1 MR. NICHOLAS: Your Honor, the document speaks  
2 for itself.

3 JUDGE DAVIDSON: Yes.

4 BY MR. SPILLER:

5 Q And Dr. Cox?

6 A Well, actually, I'd like to slow you down a  
7 little bit. The word "likewise" suggests that you're  
8 perceiving a pattern of discrepancies where I believe  
9 that none exist. If you check with MIT a little more  
10 thoroughly, you will find out that I do have a Ph.D.  
11 from the department of electrical engineering, but in  
12 risk analysis.

13 If you check a little more deeply with Harvard  
14 University, you'll find out that I do have an A.B. in  
15 general studies, but that economics was my specialty  
16 and mathematical economics within that field.

17 Q And your degree at Harvard was actually in  
18 economics, wasn't it?

19 A Well, it was from the department of economics,  
20 but it would have been an A.B.

21 Q And if we consulted at Harvard with their  
22 registrar's office, and if we had been referred to the

1 Harvard general counsel's office, do you agree that  
2 they would have said that your degree --

3 MR. NICHOLAS: Objection, Your Honor. Counsel  
4 assuming facts not in evidence.

5 JUDGE DAVIDSON: Let him finish the question,  
6 then you can object.

7 MR. SPILLER: I will withdraw the question,  
8 Your Honor, and borrow an exhibit sticker.

9 I apologize, Your Honor. May I have a moment?

10 JUDGE DAVIDSON: Certainly.

11 (Government Exhibit 1807 was  
12 marked for identification.)

13 MR. SPILLER: I'm passing the witness what's  
14 been marked and not yet in evidence, Exhibit G-1807.

15 BY MR. SPILLER:

16 Q Dr. Cox, do you recognize the letterhead there  
17 as the Harvard University that you attended?

18 A Indeed, I do.

19 Q And am I correct that the representative of  
20 the university's office of the general counsel  
21 indicates that you received your undergraduate degree,  
22 an A.B. in economics, in 1979?

1           A     Yes, although --

2           MR. NICHOLAS: Your Honor, I'm going to object  
3 to this. We don't know who -- whether this has been  
4 signed. This has not been apparently signed by  
5 anybody.

6           JUDGE DAVIDSON: Unfortunately, your witness  
7 has already answered yes. Let him explain, and I'll  
8 listen to the explanation.

9           THE WITNESS: Thank you. Yes, but I believe  
10 there are at least two errors on this. One is, I'm  
11 pretty sure that I was class of 1978.

12           What happened is I went through in three years  
13 instead of four, and I wasn't originally expecting to  
14 do that. I believe the class was '78, and I believe  
15 that my degree is in general studies, although my  
16 concentration was certainly in economics and  
17 specifically mathematic economics. So what you're  
18 showing me, I rush to say, is news to me, although not  
19 necessarily bad news. But I was working full time in  
20 1979.

21           So anyway, you're showing me news and if you  
22 have some question about it, do ask. But especially my

1 Ph.D. degree, I'm rather proud of it and it is --

2 BY MR. SPILLER:

3 Q You mention, Dr. Cox, in Exhibit B-1573, on  
4 page 11 -- let me know when you have the page.

5 A I'm there.

6 Q Under awards and honors, you have five awards  
7 there or honors. Two of them are elected full member  
8 of the Operations Research Society of America.

9 A That's right.

10 Q And the other, elected full member of the  
11 American Statistical Association. And you have  
12 translated a part of what that means up above, under  
13 professional societies for each of them.

14 A Um-hmm.

15 Q You transcribe -- translate full membership.

16 A Yes.

17 Q But you weren't actually elected full member  
18 of ASA, were you?

19 A I certainly was.

20 JUDGE DAVIDSON: Need some more time,

21 Mr. Spiller?

22 MR. SPILLER: Yes, I apologize, Your Honor.

1 BY MR. SPILLER:

2 Q Dr. Cox, isn't it a fact that one becomes a  
3 full member of the ASA by sending in a completed  
4 application form and \$85?

5 A It is certainly not; that's for general  
6 membership. Unless they've changed the rules. I was  
7 invited, in 1992, as a recognition of my contributions  
8 to the field.

9 Q And so if the ASA membership application form  
10 lists "full member" and includes one year's  
11 subscription and shows \$85, you'd say that's wrong?

12 MR. NICHOLAS: I'm going to object, Your  
13 Honor. This assumes facts not in evidence. The  
14 question assumes facts not in evidence.

15 JUDGE DAVIDSON: I don't know. It's  
16 preliminary to something.

17 THE WITNESS: Would you like me to explain how  
18 the ASA works?

19 MR. SPILLER: I've found the document I need  
20 to label now.

21 (Government Exhibit 1808 was  
22 marked for identification.)

1 MR. SPILLER: I'm handing the witness what has  
2 been marked and is not yet in evidence as G-1808.

3 MR. NICHOLAS: Your Honor, I request the  
4 opportunity to look at this before the witness is asked  
5 that question.

6 MR. SPILLER: I'm now handing a copy to  
7 counsel.

8 JUDGE DAVIDSON: Are you giving copies of  
9 these to the reporter, Mr. Spiller?

10 MR. SPILLER: Yes, Your Honor.

11 JUDGE DAVIDSON: Okay, thank you.

12 Have you had a chance to look at it yet, Mr.  
13 Nicholas?

14 MR. NICHOLAS: I have, Your Honor.

15 JUDGE DAVIDSON: You may ask the next  
16 question.

17 BY MR. SPILLER:

18 Q Dr. Cox, looking at what's been marked G-1808,  
19 from whom does that purport to be?

20 A From Bill Smith.

21 Q And how is his name described at the bottom  
22 and what is the title?

1           A     William B. Smith, Executive Director, American  
2     Statistical Association. Dated May 2003.

3           Q     And does he indicate any membership category  
4     such as full elected member or elected full member?

5           A     Not in 2003, no.

6           Q     And does he use the term such as "only" to  
7     describe a complete list of the categories of  
8     membership in that organization?

9           A     Not in 2003.

10          Q     Without another document, Dr. Cox, would you  
11     agree that in forms, the Institute for Operations  
12     Research and Management Sciences would similarly say  
13     that your class of membership there is regular?

14          A     I may have -- I may have let my dues lapse.  
15     It may not be down to regular. For the statistical  
16     association, I was sponsored by Hunter, who is an  
17     eminent statistician. I remember getting the  
18     invitation. So although I see what you're talking  
19     about here, I can tell you back in 1992, it was a bit  
20     different.

21          Q     And is it your testimony here today that you  
22     were elected in 1992 to full membership in the American

1 Statistical Association?

2 A That is my understanding. I was invited based  
3 upon nomination and election, according to the letter  
4 that I received, yes. And as I say, Professor Hunter  
5 was my sponsor, as I recall, if you wish to verify.

6 Q Thank you, Dr. Cox.

7 You did work in causal inference some years  
8 ago, at least as far back as 1995, am I correct?

9 A Oh, yes.

10 Q So you would have been aware of the  
11 appropriate use of causal inference well before 1999,  
12 am I correct?

13 A Certainly.

14 Q Is it fair to say that your testimony, taken  
15 as a whole, expresses disagreement and disapproval of  
16 the FDA risk assessment in this record, that's  
17 Government Exhibit G-953? Are you familiar with the  
18 FDA risk assessment for campylobacter in chicken?

19 A Yes, I am.

20 Q And is it fair to take your testimony as  
21 expressing disagreement, disapproval with that?

22 A Do you mean disagreement with its conclusion?

1 Or disapproval with its conclusions or its approach?

2 Q Let's take those in turn. Do you disagree  
3 with its conclusion?

4 MR. NICHOLAS: Your Honor, if the witness  
5 could be provided with a copy of the document counsel  
6 is referencing?

7 JUDGE DAVIDSON: Of course.

8 And feel free to ask for that if other  
9 questions come up referring to documents you don't have  
10 in front of you.

11 THE WITNESS: Thank you.

12 JUDGE DAVIDSON: We don't want you to have to  
13 do everything from memory.

14 THE WITNESS: I appreciate that. Thank you.

15 BY MR. SPILLER:

16 Q Dr. Cox, I'm handing you now what is in  
17 evidence as Exhibit G-953.

18 A Thank you.

19 Q And if I may, I'll remove these items of  
20 correspondence. I don't plan to ask you further  
21 questions about these.

22 A Okay.

1 Q While you're looking at that --

2 MR. SPILLER: Your Honor, I did not move and I  
3 do now move Exhibits G-1806 from MIT, G-1807 from  
4 Harvard, and G-1808 from the American Statistical  
5 Association, in evidence.

6 JUDGE DAVIDSON: No, I'm not going to receive  
7 them at this point. I will allow receipt -- Dr. Cox  
8 has given an explanation for most of your questions and  
9 apparent discrepancies that you allegedly found. I  
10 will allow, however, if you remind me -- both sides --  
11 at the conclusion, a short opportunity for filing  
12 documents to support one way or another, if you think  
13 it's important. It will be very short and will be  
14 limited to alleged discrepancies in witnesses'  
15 testimony or cross-examination. It won't involve -- I  
16 don't want to see any more exhibits or new things. All  
17 right?

18 So I'm not going to receive that in evidence  
19 as of now. I may subsequently receive it in evidence,  
20 if the material you provide me shows that there was, in  
21 fact, material discrepancy.

22 All right?

1 BY MR. SPILLER:

2 Q Dr. Cox, I think the question we were working  
3 on was whether or not it's fair to interpret your  
4 written direct testimony, that's Exhibit B-1901, as  
5 expressing your disagreement with the FDA risk  
6 assessment in this matter, which is Exhibit G-953.

7 A I think it will be most useful to talk  
8 specifics. There are things in that that I disagree  
9 with. There are important things in it that I disagree  
10 with. But I don't disagree with every sentence in it.

11 Q Let's begin that discussion with an answer to  
12 my question. In general --

13 A Is it fair? I don't think so.

14 Q Do you agree with its conclusions?

15 A Which ones?

16 Q The conclusion of the number of persons  
17 estimated to have suffered from campylobacteriosis  
18 attributable to chicken consumption in the United  
19 States for the years 1998 to 1999, who were treated  
20 with a fluoroquinolone?

21 MR. NICHOLAS: Your Honor, if counsel could  
22 point to the exhibit and show the witness what he's

1 referring to, it might --

2 BY MR. SPILLER:

3 Q Dr. Cox, was my question not clear to you?

4 A I wouldn't -- I don't think it addressed  
5 suffering. But if you mean the 10,000 to 15,000  
6 conclusion, roughly speaking, I do believe that that's  
7 inaccurate as interpreted by CVM.

8 Q And do you disagree with its methods, as well?

9 A Yes, I do. And models.

10 Q But in May of 1999, you agreed with CVM's risk  
11 assessment, didn't you?

12 A Agreed about what?

13 Q You agreed that its statistical and risk  
14 assessment methodology was appropriate?

15 A I think we have to be careful here. I was  
16 asked, first by David and then by CVM, to review the  
17 methodology. In April of '99, I sent a many-paged  
18 letter to David before understanding the problem very  
19 well.

20 Q Would you identify David for the record,  
21 please?

22 A My colleague, David Vose. Sorry.

1 Q Thank you.

2 A I sent him a fairly detailed letter suggesting  
3 how one might tackle the approach. I believe that what  
4 I said on the CVM website and at CVM is that the  
5 approach seemed to me, a priori, to be sensible. The  
6 assumptions seemed to me to be well-documented. That  
7 generally I liked the approach, but I felt it was very  
8 important to validate it before using it for any  
9 purpose and before accepting it.

10 MR. SPILLER: I'm just marking, Your Honor, an  
11 exhibit not yet in evidence.

12 (Government Exhibit 1809 was  
13 marked for identification.)

14 BY MR. SPILLER:

15 Q Dr. Cox, you mentioned that you had engaged in  
16 correspondence in April of 1999. I hand you now what's  
17 been marked G-1809 and ask you if that reflects the  
18 correspondence to which you referred.

19 A I was thinking of something a little earlier,  
20 but this is from the same era. Are we still talking  
21 about a Product Y here?

22 Q In your consulting work, does it sometimes

1 happen that as you design risk analyses, you discuss  
2 products in the abstract or by code name to avoid  
3 identifying products and manufacturers.

4 A It sounds plausible to me. I don't know that  
5 I've seen that before, but yes.

6 Q Do some of your clients like to be held  
7 confidential?

8 A Surely. And this does contain -- this does  
9 contain the thought keys that I was thinking of. Let  
10 me just clarify, this was before I knew what the  
11 problem was that we were looking at.

12 Q And when you evaluated this approach of David  
13 Vose's, am I correct that the data analysis elements  
14 that are described in your summary on page 1 of 10 are  
15 data elements that -- sometimes not bearing the same  
16 variable name, are nonetheless incorporated in FDA's  
17 risk assessment?

18 A I'm sorry. Would you please ask the same  
19 question again?

20 Q Aren't those same data analysis elements also  
21 in FDA's risk assessment, Exhibit G-953?

22 A No. If you look at number 3, the potency

1 parameter and also the number of episodes are not  
2 reflected. There certainly is a big K. But -- those  
3 parameters are not reflected in the risk assessment.  
4 The joint frequency distribution of type K cases per  
5 episode -- the joint frequency distribution is  
6 certainly not reflected.

7           Were you limiting your question to just the  
8 data analysis elements on page 1 here?

9           Q     No, and I think we can also ask about the  
10 conclusions you have on that page. Beneath the text  
11 box on page 1 of 10 of what's been marked G-1809, you  
12 have a two-sentence conclusion. Am I correct, you  
13 concluded: This seems to me to be a very practical and  
14 technically sound approach; I have no remaining  
15 concerns.

16           A     With emphasis on "seems" and in the context of  
17 April, this seemed like a good approach to the problem  
18 David had described. Which I would distinguish from  
19 the problem that CVM was undertaking to solve.

20                    Completing my answer to your former question  
21 about data elements, and bearing in mind that you said  
22 you were not referring or limiting your question only

1 to page 1, I would refer you also to page 3 of 10,  
2 paragraph marked paragraph 2. Moreover, probability --  
3 my response, Q2, yet the probability that exactly one  
4 person will become ill may be less than the probably  
5 that two or more will become ill, right? That data  
6 element, and in fact information related to dose  
7 response information for individuals or for small  
8 groups or for families or for clusters as highlighted  
9 in bold, close to the bottom of the page -- those  
10 parameters have not been captured in the current model  
11 and numerous other parameters have not been captured in  
12 the current model.

13           Completing my answer to your question two,  
14 yes, I did say this seems to me to be a very practical,  
15 sound approach. I have no remaining concern. I want  
16 to clarify again the context for that was the problem  
17 as described to me by my colleague, David Vose, not the  
18 problem that I have referred to in the context of the  
19 CVM risk assessment.

20           Q     And from your knowledge of epidemiology,  
21 referring to page 3 of 10 as you just did, the fourth  
22 line from the bottom of the page, the bolded term,

1 clusters of cases, in epidemiology, a cluster of cases  
2 is called an outbreak, isn't it?

3 A Not necessarily. They can be spacial  
4 clusters. An outbreak is more likely to be a temporal  
5 cluster. Let me just say, not necessarily.

6 Q And so in your note Q2, the probability of  
7 more people becoming ill would describe the mechanism  
8 of an outbreak, would it not?

9 A Yes. If a chicken is contaminated, it could  
10 be for an outbreak. Or, in the current context, it  
11 could be that, I mean, often only the first person in  
12 the family who gets campylobacteriosis is recorded, and  
13 it's not recorded as an outbreak; it's recorded as a  
14 sporadic case. So I think we need to be a little bit  
15 careful with that term "outbreak."

16 Q And from your knowledge of the epidemiology of  
17 campylobacteriosis outbreaks, you know that they are  
18 the minority of the cases of human campylobacteriosis  
19 in developed countries, don't you?

20 A Yes, based on reported data. Again, but the  
21 caution on the exact meaning of "outbreak." For  
22 example, if several people in the same family get sick,

1 it's an outbreak.

2 Q You conditioned that based on reported data.  
3 You're not suggesting that we should base things on  
4 other than reported data, are you?

5 A Oh, sure, there's lots of data I'd like to  
6 have, including data on multiple incidents within one  
7 family or multiple people in the same restaurant.

8 Q So that was your professional opinion to Dr.  
9 Vose in April of 1999. And for your professional  
10 opinion, you billed him and he paid, right?

11 A Yes. Well, I think he didn't really pay me  
12 for the opinion so much as for the analysis, the  
13 reasoning.

14 As you can see from the tone, this is  
15 colleagues chatting about an interesting hypothetical  
16 problem.

17 Q And one of those colleagues took home over  
18 \$1000 for it, right?

19 A Probably.

20 Q And in December of 1999, did you attend at  
21 FDA's invitation and expense a public meeting to  
22 evaluate the FDA risk assessment?

1           A     That sounds right, yes.

2           Q     And that's when you did the PowerPoint slide  
3 presentation that you mentioned earlier?

4           A     On FDA's website. I would have done it  
5 shortly before then but, yes.

6           Q     And at that time, you said, am I correct, it's  
7 a pretty good approach, pretty sensible study, it hangs  
8 together?

9           MR. NICHOLAS: Your Honor, if counsel would  
10 provide the witness with copies of the documents?

11          THE WITNESS: Thanks. But I do recognize  
12 those remarks as being my opinion at the time. It was,  
13 a priori, a pretty reasonable approach.

14          BY MR. SPILLER:

15          Q     Thank you. I think, if I can express them  
16 fairly, that will save us time and a document. I think  
17 you will recognize these. "All in all, I think it's a  
18 job well done"?

19          MR. NICHOLAS: Your Honor, the document speaks  
20 for itself.

21          JUDGE DAVIDSON: If he doesn't want to answer  
22 it, if he doesn't remember, he can say so.

1 THE WITNESS: Would you read the quote back  
2 again, please?

3 BY MR. SPILLER:

4 Q Yes. "All in all, I think it is a job well  
5 done."

6 A And your question?

7 Q Do you remember saying words to that effect to  
8 the conference to evaluate CVM's risk assessment on  
9 December 9, 1999?

10 A Yes. But let me clarify. I said that about  
11 the job that David had done responding to their  
12 request. So I thought he had done a good job of  
13 documenting assumptions. I thought that the model was  
14 fairly explicit. I had not at that time acquainted  
15 myself with the data or validity of the model.

16 Q Dr. Cox, I hand you now what's been marked  
17 Government Exhibit 1810, not yet in evidence. Here's a  
18 copy for the Court. A copy for Madam Reporter. A copy  
19 for counsel.

20 (Government Exhibit 1810 was  
21 marked for identification.)

22 MR. SPILLER: I will not ask questions about

1 it until counsel signals his readiness.

2 I would like to note for the record that this  
3 is the first day of the transcript that -- the second  
4 day has already been admitted in this docket, at the  
5 behest of AHI, as Exhibit A, like alpha, 121.

6 THE WITNESS: Okay.

7 MR. SPILLER: I'm sorry, Dr. Cox. There's no  
8 question. We're waiting until your counsel is ready.

9 THE WITNESS: While we're waiting, would it be  
10 okay --

11 JUDGE DAVIDSON: There's nothing pending. The  
12 record will reflect everything that you say, so let's  
13 not assume. If you want to explain an answer, feel  
14 free to do so.

15 THE WITNESS: That's just it, Your Honor.

16 JUDGE DAVIDSON: -- previous question?

17 THE WITNESS: Previous question.

18 JUDGE DAVIDSON: Your explanations are quite  
19 long to start with.

20 THE WITNESS: I felt that there was a quote  
21 out of context. And I happened to turn to the exact  
22 context, and I wondered whether it would be useful to

1 read.

2 JUDGE DAVIDSON: Well, if it's here, we will  
3 get to that. If it doesn't --

4 THE WITNESS: Okay, thank you.

5 MR. NICHOLAS: Your Honor, if I could take one  
6 more minute to look at this?

7 JUDGE DAVIDSON: Certainly.

8 MR. NICHOLAS: Thank you.

9 I'm ready, Your Honor. Thank you.

10 BY MR. SPILLER:

11 Q Dr. Cox, I know you wanted to complete an  
12 earlier answer of a question. And whenever I ask you  
13 to look at a quote, I intend for you to look at  
14 context. So fill us in on the context that you just  
15 described, please.

16 A Thank you. It's on page 141.

17 JUDGE DAVIDSON: Of this exhibit?

18 THE WITNESS: Of this exhibit, G-1810, that I  
19 was just handed. The page number is in the upper  
20 right-hand corner. It's the page on which the first  
21 complete sentence is, I mean -- like 10, it -- the  
22 study, the model -- it has to make a few baroque

1 assumptions, K being the big one, to get across big  
2 data gaps, but it is very explicit about that. So all  
3 in all, I think that is a job well done. I want to  
4 invite you to critically examine a few assumptions if  
5 you share that conclusion.

6 So it is contingent on the validity of that  
7 big K.

8 MR. SPILLER: Thank you, Dr. Cox.

9 THE WITNESS: You're welcome.

10 MR. SPILLER: Your Honor, I can avoid a number  
11 of other questions with a motion to admit in evidence  
12 G-1810. So then Dr. Cox, I can avoid asking you did  
13 you say or didn't you say.

14 JUDGE DAVIDSON: Mr. Nicholas?

15 MR. NICHOLAS: Your Honor, given the fact that  
16 Mr. Spiller was interested in the context in which  
17 these statements were made, I would prefer to have him  
18 address the questions explicitly to the witness and  
19 have that opportunity.

20 JUDGE DAVIDSON: I know what you prefer, but  
21 are you objecting to the admission of this document  
22 into evidence?

1 MR. NICHOLAS: No, I am not, Your Honor.

2 JUDGE DAVIDSON: Okay, it's in evidence.

3 (Government Exhibit 1810 was  
4 received in evidence.)

5 MR. SPILLER: Thank you, Your Honor.

6 BY MR. SPILLER:

7 Q Dr. Cox, one summarizing comment, and I think  
8 I can move on. On page 140 of Exhibit G-1810, lines 18  
9 to 24?

10 A Yes.

11 Q I've mis-cited you. Sorry.

12 MR. SPILLER: Your Honor, may I have a moment?

13 JUDGE DAVIDSON: Certainly.

14 BY MR. SPILLER:

15 Q On page 143, Dr. Cox, lines 15 through 21, am  
16 I correct that you are agreeing there explicitly with  
17 the model's incorporation of the aggregation of end  
18 sequences into one large probability? Is that what you  
19 called a "big K"?

20 A Yeah. Big K in this model -- the model says  
21 risk is equal to big K exposure. That was my simple  
22 statement of the model. And big K, also called K RES,

1 K sub RES when we're talking about resistant  
2 campylobacteriosis, K with no subscripts when we're  
3 talking about ordinary campylobacteriosis, that is the  
4 big K that I'm talking about.

5 Q And so without reading you the text, on 144,  
6 lines 3 through 8 --

7 A Wait a minute, I'm sorry. Were we finished?  
8 Did I answer your question about 143?

9 JUDGE DAVIDSON: I thought you did.

10 BY MR. SPILLER:

11 Q Yes, in general. Never mind. I'll ask a  
12 question.

13 And so that's consistent with what you say on  
14 144, lines 3 through 8, about modeling the product to  
15 put the number of things together, right?

16 A Yes, again, in the context of given David's  
17 assumptions and what he was trying to do. I talk about  
18 big or wholesale validation, where you try to say is  
19 this model correct and useful. And then I talk about  
20 little validation, saying do its consequences follow  
21 from its premises, so is it logically valid, even if  
22 it's not necessarily empirically valid. So these

1 comments are directed at a logical matter, if you would  
2 make the big K model work, a lot of little factors,  
3 that would be a terrific thing to do.

4 Q And the risk assessment itself, referring to  
5 what is now G-953, didn't change much between then and  
6 now, did it, Dr. Cox?

7 A On that, a somewhat imponderable question.  
8 The big K principle has been carried through ever  
9 since. I now see it as a real disaster.

10 Q That's the summary I was looking for earlier.

11 A You got it.

12 Q In the risk assessment, am I correct that the  
13 changes are collected and are summarized and they  
14 reflect -- excuse me, let me give you the cite. If you  
15 would look in Exhibit G-953?

16 A Yes. I have it here.

17 Q At page 25. Those are the changes that were  
18 made between the December draft to which you addressed  
19 the comments that we just described and the final  
20 version which is now this exhibit, right?

21 A I will assume so. There are things like the  
22 days in calculation and an appendix that I'm not sure

1 are captured here. But let's go with that. It looks  
2 pretty plausible.

3 Q One of your key criticisms, your first  
4 criticism in your detailed testimony -- I'm now  
5 referring to your testimony B-1901 at page 9 --

6 A Yes.

7 Q -- was that the CVM model follows a  
8 nontraditional risk assessment methodology that yields  
9 invalid conclusions about human health risks, right?

10 A Yes.

11 Q At the time of your 1999 review that we just  
12 discussed with CVM, you were aware of how human health  
13 risks assessments should be carried out? Question.

14 A Pause. Yes, I was aware of how to do human  
15 health risk assessment generally. I had not yet  
16 studied this field, as I have now.

17 Q In fact, this is the first microbial or  
18 antimicrobial risk analysis you've ever done, right?

19 A Well, there was one with Virginia Misen that  
20 I've also done. But this was certainly one of the  
21 first.

22 Q If it's not the first, it's the second?

1           A     Well, it's less than tenth, I'm sure. I've  
2 also looked at a couple of other -- oh, you said anti-  
3 microbial risk assessment, and here I was thinking of  
4 microbial risk assessment.

5           A     So yes, I think this is the first time I  
6 looked at anti-microbial risk assessment.

7           Q     So you were aware of how human health risk  
8 assessments were done then. And yet you didn't raise  
9 that allegation that they didn't follow traditional  
10 risk assessments at the time, did you?

11          A     It didn't seem relevant. Back then, it was an  
12 exciting and innovative method.

13          Q     Well, as to how it's become relevant, Dr. Cox,  
14 when did you first work for AHI on --

15          A     I resist the implication.

16          Q     And would you answer the question, anyway,  
17 please?

18          A     John Keeling at AHI first approached me soon  
19 after that public meeting. And I don't remember the  
20 chronology of when exactly I started work for them in  
21 terms of billable work, but it would have been soon  
22 after this public meeting.

1 Q I forgot to ask you, at the public meeting,  
2 FDA paid for your travel and per diem to that meeting,  
3 right?

4 MR. NICHOLAS: Asked and answered, Your Honor.

5 JUDGE DAVIDSON: It was a previous -- the  
6 question dealing with his payment from FDA was for Dr.  
7 Gross, for the original. But if I'm wrong, we will let  
8 him answer it again.

9 MR. NICHOLAS: Thank you, Your Honor.

10 BY MR. SPILLER:

11 Q Do you recall the question?

12 A Yes. And it was if the FDA paid me a per diem  
13 and expenses. Yes, they did.

14 JUDGE DAVIDSON: That's for the meeting, the  
15 transcript in 1810?

16 THE WITNESS: Yes, Your Honor. Yes.

17 BY MR. SPILLER:

18 Q And that covered your consultancy time that  
19 you necessarily expended to assemble the PowerPoint  
20 presentation that you described?

21 A It covered partly, yes.

22 Q And you gave us the discounted rate.

1 A Right.

2 Q Did you give AHI a discounted rate?

3 A Initially, I did, yes.

4 Q And so your work for AHI continued for some  
5 time, past the discounted rate into the full rate  
6 period?

7 A Yes, it did.

8 Q And that continues to this day?

9 A To this hour.

10 Q And have you independently or separately also  
11 worked for Bayer during any of that time?

12 A I don't believe so.

13 Q Without getting into any unseemly details, is  
14 it fair to say that AHI has required more of your time  
15 and therefore has paid for more of your time than the  
16 government ever did on this project?

17 A Yes. Well, "required" may be too strong. AHI  
18 asked me for a bid on what I thought it would take to  
19 develop a sound approach to risk modeling, and I gave  
20 them that bid. And that refers to the number of  
21 contracts. So it was a negotiated and repetitious  
22 arrangement, rather than a requirement of time.

1 Q And you did work up an assessment for AHI, am  
2 I correct?

3 A Several, yes.

4 Q One of which you mentioned, I think in your  
5 testimony, had been submitted for publication in the  
6 International Journal of Infectious Diseases?

7 A Yes, that's correct.

8 Q And was there anything unusual about that  
9 particular issue of the International Journal of  
10 Infectious diseases?

11 A Yes, there was.

12 Q And among the things that were unusual was  
13 that issue devoted to the therapeutic use of  
14 Fluoroquinolone in poultry, the effect on  
15 campylobacter, and the potential to human health  
16 consequences? That was the topic of that supplement?

17 A Yes.

18 MR. NICHOLAS: Your Honor, if the witness  
19 could be provided the document as well, and so obtain  
20 his answers to the questions?

21 JUDGE DAVIDSON: He can ask for it, and you  
22 should provide it if you're going to ask any detailed

1 questions about the document.

2 (Government Exhibit 1811 was  
3 marked for identification.)

4 MR. SPILLER: Your Honor, I'm handing the  
5 witness what has been marked and is not yet in evidence  
6 as Exhibit G-1811. One for the Court, one for the  
7 reporter, one for counsel.

8 I won't ask you any questions about it until  
9 counsel signals that they've had a chance to look at  
10 it.

11 BY MR. SPILLER:

12 Q Dr. Cox, is this a publication of a paper that  
13 you developed while working for AHI?

14 A In part, yes.

15 Q And how was the work funded that resulted in  
16 this paper?

17 A I believe that the costs of distributing the  
18 special issue -- actually, this is outside my area of  
19 expertise. I think I know the answer, but it's  
20 something that I'm not an expert on.

21 Q The question that I meant to ask, and I  
22 apologize if I didn't ask it is, how did you get paid

1 for the work you did to write the paper that eventually  
2 went to this journal?

3 A I'm not sure that I did get paid. That paper  
4 was a lot of work. But there was a workshop in  
5 Boston -- I can't remember exactly where it was held,  
6 but there was a workshop in Boston where a bunch of  
7 folks got together to talk about, is there a better way  
8 of doing this. And I participated in that. And then  
9 this was the paper that came out of that workshop.

10 Q And were most of those folks that attended  
11 that conference government folks, or were they folks  
12 working with Bayer and AHI?

13 A I think they were mainly -- I think it was  
14 academic, and --

15 Q You're an academic, aren't you, Dr. Cox?

16 A In part, yes. I know there were some  
17 academics. And there were some industry folks. There  
18 were people like Diane Newell, who I had not previously  
19 met, who I know works for Bayer and is a witness in  
20 this case. And there were not government folks,  
21 although my impression was they wanted to have them  
22 there. But again, I didn't organize the meeting. It's

1 really outside my expertise.

2 Q And that workshop actually was by invitation  
3 only, wasn't it?

4 A Perhaps. I certainly got an invitation.

5 Q And the fellow authors, referring to the  
6 exhibit before you on its third page, which is numbered  
7 only in the upper right-hand corner with a fax  
8 transmittal number, 004, five of those seven  
9 contributing authors are witnesses either for AHI and  
10 Bayer in this matter, aren't they?

11 A Is that right?

12 Q And there was a statement by Ginivan, who's  
13 not a witness here, that was attached to Dr. Carnival's  
14 testimony here, wasn't it?

15 A I believe so, yes.

16 Q And the last two lines on the page indicate  
17 that the publication of the supplement is aided by an  
18 unrestricted grant from Bayer Healthcare. What's your  
19 understanding of how that grant was applied and  
20 distributed?

21 MR. NICHOLAS: Object, Your Honor. The  
22 witness --

1 THE WITNESS: It's outside my area of  
2 expertise. I think --

3 JUDGE DAVIDSON: He'll answer if he knows. He  
4 doesn't.

5 BY MR. SPILLER:

6 Q Do you know what a vanity journal is, Dr. Cox?

7 A Yes, I do.

8 Q Is that what this was?

9 A I've -- I don't know. It's not in deadline, I  
10 can tell you that. I don't think it was. And again, I  
11 tend to have some area of expertise. I think Bayer  
12 helped to -- Bayer, with some of the production costs.

13 MR. NICHOLAS: I object. The witness already  
14 testified. It's outside --

15 JUDGE DAVIDSON: You're interrupting your own  
16 witness. You can move to have it stricken if you don't  
17 want his answer on the record, but let him finish.

18 THE WITNESS: Well, the point is we wrote the  
19 stuff independently and sent it in for legitimate  
20 review. And I don't know what happened from there.

21 BY MR. SPILLER:

22 Q Was it reviewed by the regular review panel of

1 the International Journal of Infectious Diseases? Or  
2 was it reviewed by the guest editors that are  
3 identified there?

4 A I am not clear on what the review process was.

5 Q Do you know if they turned down any papers  
6 submitted by Bayer or AHI witnesses?

7 A I don't know. I know that we did get some  
8 reviewer comments back.

9 Q Turning back to your testimony, Dr. Cox, and  
10 within that page 30, three-zero --

11 A Yes.

12 Q You mentioned -- excuse me, let me find it --  
13 the second bullet begins with the words "by contrast."  
14 Do you see on page 30 the second bullet?

15 A I am looking at it, yes.

16 Q And without clouding the transcript with more  
17 words, I will just let you read that quietly. And then  
18 signal me when you're through, and I'll have a  
19 question.

20 A Okay, ready.

21 Q So the references you mentioned there, your  
22 thorough studying of those references led you to

1 conclude that they all support your notion that it's  
2 restaurant dining that's the major cause of  
3 campylobacteriosis, rather than chicken consumption; is  
4 that right?

5 A No, that -- there are several refinements  
6 necessary. First, I wouldn't pretend to a thorough  
7 study of these references. And secondly, I think  
8 Eberhart Phillips contains information on both sides of  
9 the question. Also, the -- what I rely on, if I can,  
10 is the data, not the citation.

11 See, if this is consistent with the data of  
12 Effler, et al., 2001, but not necessarily with what  
13 Effler himself concluded from the data using logistic  
14 progression models and not doing a very thorough job.

15 Q I want to make sure I understand you. When  
16 you say it's consistent with the data, you mean it's  
17 consistent with your interpretation of the data, even  
18 though that may be, in the instant you mentioned,  
19 inconsistent with the author's evaluation of that same  
20 data?

21 A To the extent possible, I would like to remove  
22 "interpretation" and "evaluation" from there, and just

1 address the question is the hypothesis consistent with  
2 the data itself, not with somebody's interpretation of  
3 the data.

4 Q So in the Adak citation -- am I pronouncing  
5 that right?

6 A I don't know. Sounds good to me.

7 Q There's a citation that the author's name is  
8 Adak. It's identified in your testimony as B-122.  
9 Without me tossing you an exhibit --

10 A Oh, please do.

11 Q -- do you recall if restaurant dining is  
12 actually evaluated in that paper?

13 MR. SPILLER: I'm now handing the witness  
14 Exhibit B-122.

15 THE WITNESS: Thank you.

16 MR. SPILLER: I believe it's in the record,  
17 but I have a copy for the Court.

18 BY MR. SPILLER:

19 Q Dr. Cox, would you take the time necessary to  
20 refer me to the part of that article that considers  
21 restaurant dining, apart from chicken, as a risk  
22 factor, please?

1           A     This is a reference for the rather-than-  
2 chicken assumption, per se, portion, not for the  
3 restaurant dining portion. So I cannot refer you to  
4 the restaurant dining. This reference doesn't support  
5 that point.

6           Q     So when you put that cite after the italicized  
7 for emphasis text, "thus restaurant dining rather than  
8 chicken consumption, per se," we should not take that  
9 to mean that your reference actually supports your most  
10 recent previous emphasized sentence?

11          A     To the contrary. This is a compound sentence  
12 that entails at least two propositions. One  
13 proposition is that restaurant dining is a risk factor.  
14 The other is that chicken consumption, per se, does not  
15 appear to be such a factor. This reference supports  
16 the second of those two points.

17          Q     Dr. Cox, on page 4 of that reference --

18          A     Um-hmm. Yes, okay.

19          Q     There are a number of references to  
20 consumption of chicken, including one that has an  
21 adjusted odds ratio of 4.65, am I correct?

22          A     Which -- can you point it out to me?

1 Q I'm on page 4, table 2.

2 A Got it.

3 Q The sixth factor down. It's titled,  
4 "Consumption of hot chicken away from home,  
5 undercooked."

6 A Well cooked. Undercooked, cases 9, controls  
7 4. Yes. I'm looking at it. So you're looking at the  
8 odds ratio of 4.65, confidence interval, .95 to 22.8.  
9 Is that what you're referring to?

10 Q I am.

11 A Okay, I see it.

12 Q Does that not support a relationship of  
13 consumption of chicken?

14 A On the face of it, it does not. If I'm  
15 reading it correctly, the confidence interval is from  
16 below 1 to above 1. Also, these are crude odds ratios.  
17 And thirdly, the relation that you're referring to is  
18 not a statistical association, but a causal relation,  
19 then, a fortiori, does not. But even on the face of  
20 it, it doesn't. It isn't a statistical association.

21 Q So following your lead, the consumption of  
22 barbecued chicken, undercooked, showing an odds ratio

1 of 16, and the confidence intervals, as you pointed  
2 out, are not inclusive of one, and the T value is less  
3 than .01, would be in this listing significant  
4 association between consumption of chicken --

5 A Ah, good question. And had the T values been  
6 calculated to adjust for multiple testing, it would be  
7 evidence of association. But as you will see, as  
8 within so many studies, we have, I think, over a dozen  
9 factors here each being tested and a few of them  
10 showing up as being significant -- don't be impressed  
11 by big odds ratio because of the logarithm scale that  
12 goes as low as zero but as high as 70.

13 Q And your second reference for that sentence,  
14 Friedman G-228?

15 MR. NICHOLAS: Your Honor, I believe that  
16 sentence has more than two references --

17 JUDGE DAVIDSON: He just said the second  
18 one --

19 THE WITNESS: Okay, Friedman, et al.

20 BY MR. SPILLER:

21 Q You reference that about 13 times in your  
22 testimony, didn't you?

1           A     I love that data step.

2                   MR. SPILLER:  I'm sorry, Your Honor.  This is  
3 in the record.

4                   BY MR. SPILLER:

5           Q     And again, there is no restaurant dining  
6 factor used in this study, is there?

7                   MR. NICHOLAS:  Your Honor, I would object.  
8 This whole study is in draft form attached to Dr.  
9 Angelo's testimony.  And if the witness is going to be  
10 asked about it, I would request that he be provided a  
11 copy of I think it's Attachment 3 to Dr. Angelo's  
12 testimony, which I think is G-228.  This is an abstract  
13 from the CDC website --

14                   JUDGE DAVIDSON:  Let's hear what the question  
15 is first.  If you've got a problem and he needs to look  
16 at the entire study, then we'll let him look at it.

17                   MR. NICHOLAS:  Thank you, Your Honor.

18                   BY MR. SPILLER:

19           Q     Dr. Cox, does your reference tell anybody  
20 anything other than the author's name and the year  
21 here?  Can you distinguish from that whether it's this  
22 Friedman, or the Friedman that --

1           A     Oh, this -- I'll just stipulate, it is this  
2 Friedman.

3           Q     Thank you.

4           A     But then your question about restaurant  
5 dining?

6           Q     Am I correct, since you've indicated that this  
7 is the study you're referring to --

8           MR. NICHOLAS: Your Honor, I believe the  
9 witness indicated this is the person, not the study.

10          THE WITNESS: Correct.

11          MR. NICHOLAS: He is not referring to this  
12 particular abstract --

13          JUDGE DAVIDSON: Let's get it straight.

14          THE WITNESS: It's really the data that  
15 matters.

16          BY MR. SPILLER:

17          Q     I want to accommodate your counsel's concern,  
18 and I want to play through some of the difficulties we  
19 have with citations. In the list of references for  
20 your paper, in your written direct testimony at page  
21 89?

22          A     Yes.

1 Q You have two Friedmans, am I right, two  
2 Friedman cites?

3 A Two Friedman cites, yes, I do.

4 Q And both of them are 2000. And one of them  
5 has, according to your cite, a web citation of -- and I  
6 won't recite it all.

7 A Yes.

8 Q And that is the same web citation on G-228,  
9 isn't it?

10 A I believe that it is.

11 Q So this is the one you were citing?

12 A Yes, this is the study and I've analyzed these  
13 data.

14 Q Where in the data reflected in this exhibit is  
15 any consideration of restaurant dining as a risk  
16 factor?

17 A That's really two questions. In the data,  
18 restaurant dining appears for over a dozen variables  
19 that are marked with D, perhaps for dining, at the end  
20 of them. Compared to A, for at home.

21 Where it's reflected in this exhibit, to the  
22 extent that it is, is -- when you say eating chicken or

1 turkey in the home was a protective factor, eating  
2 chicken or turkey that was cooked outside the home on  
3 the previous page and eating a non-poultry meat that  
4 was cooked outside the home. "Outside the home"  
5 includes restaurant dining. So that would be right  
6 around the middle of this paragraph.

7 Q And in your testimony, you refer to the  
8 findings of these, and you refer to this as an  
9 international study?

10 A Correct.

11 Q So where in the findings do we see restaurant  
12 dining?

13 A The same -- this is very much like your  
14 previous question. This finding supports not the  
15 restaurant dining, but the not chicken per se point.  
16 In other words, chicken at home, the risk is lower.  
17 Chicken outside the home, the risk is higher. My point  
18 is, why.

19 Q I think I'm learning. Let's fast forward.  
20 Which of these cites provide support for the italics  
21 emphasized part of that quote on page 30 of your  
22 testimony, that restaurant dining rather than chicken

1 consumption per se appears to be the major human health  
2 threat?

3 Correct me if I'm wrong, but I think we've  
4 established that it's not Adak and it's not Friedman.  
5 I think you said it wasn't Eberhardt-Phillips, right?

6 A Well, hold on. If I -- if you mean the  
7 italicized portion in its entirety --

8 Q I do.

9 A Then I don't believe that we have established  
10 that it's not Adak. I think Adak supports or provides  
11 some evidence in favor of its not being chicken per se.  
12 And I think that Friedman, et al., as we've just seen,  
13 indicates that chicken at home -- I admit -- we haven't  
14 gotten down to business yet, but in preliminary  
15 analysis, it suggests that chicken at home is not a  
16 risk factor and chicken outside the home is.

17 So I don't really agree that these references  
18 aren't supporting the italicized debate.

19 Q Am I correct that neither Adak, Friedman,  
20 Eberhart-Phillips, or Kassenborg specifically refer to  
21 restaurant dining as a risk factor?

22 A Did you mention Friedman just then in that

1 list?

2 Q If I did not, I intended to.

3 A Friedman refers to eating outside the home  
4 rather than to restaurant dining. So if you're looking  
5 for the phrase "restaurant dining," I agree with you.

6 Q To you, as a scientist, does "outside the  
7 home" mean "restaurant"?

8 A To me, as a normal human being, "outside the  
9 home," means a superset of restaurant. It means  
10 outside the home. Restaurants are usually outside the  
11 home. But I don't equate the two.

12 MR. SPILLER: May I have a moment, Your Honor?

13 JUDGE DAVIDSON: Is this a convenient time for  
14 a break?

15 MR. SPILLER: Yes, Your Honor.

16 JUDGE DAVIDSON: We'll take a 10-minute  
17 recess.

18 MR. NICHOLAS: If I may, I request that we  
19 would adjourn this afternoon. As I mentioned,  
20 earlier --

21 JUDGE DAVIDSON: We will adjourn early. But  
22 right now, let's take a break.

1 (A brief recess was taken.)

2 MR. NICHOLAS: Your Honor, I'd like to make a  
3 request. I think that Dr. Cox is obviously eager to  
4 testify. I think if we can limit this afternoon to a  
5 half-hour, would that be a convenient break point, 30  
6 to 40 minutes from now, 3 o'clock.

7 JUDGE DAVIDSON: I was going to suggest  
8 something along those lines.

9 MR. SPILLER: That would be fine, Your Honor.  
10 And I would ask my colleagues to check me, and I take  
11 it as the understanding, the common understanding that  
12 however we restrict it today, we finish tomorrow.

13 MR. NICHOLAS: As long as we have an  
14 opportunity to redirect, we have no objection.

15 JUDGE DAVIDSON: Proceed.

16 MR. NICHOLAS: Proceed.

17 BY MR. SPILLER:

18 Q In our consideration of these papers, Dr. Cox,  
19 I don't believe I've given you yet Eberhart-Phillips,  
20 B-295, am I correct, you don't have that yet, do you?

21 A I don't believe I do.

22 MR. SPILLER: It's in the record already.

1 BY MR. SPILLER:

2 Q And just for context, Dr. Cox, this is another  
3 of the papers that you cited in support of that  
4 compound piece of your testimony. As you point out,  
5 it's compound on page 30 of your testimony, right?

6 A Correct.

7 Q Actually Eberhart-Phillips at B-295, page 5,  
8 concludes that campylobacteriosis -- and I'm on page 5,  
9 right-hand column -- is a common disease with a number  
10 of common causes, the most important being consumption  
11 of undercooked chicken. Right? That's the first  
12 sentence of their conclusion? And without me reading  
13 the record, Dr. Cox, would you agree that Dr.  
14 Kassenborg's testimony also included that she found  
15 that eating chicken or turkey at commercial  
16 establishments was the only risk factor that remained  
17 independently associated --

18 MR. NICHOLAS: Your Honor, if the witness  
19 could be provided with a copy of Dr. Kassenborg's  
20 testimony?

21 JUDGE DAVIDSON: He's absolutely entitled to  
22 see it.

1 MR. SPILLER: I'm handing the witness G-1460  
2 which is in evidence.

3 THE WITNESS: And you said she also concluded?

4 MR. SPILLER: I did.

5 THE WITNESS: Come again, please.

6 BY MR. SPILLER:

7 Q Would you refer in her testimony to page 8,  
8 lines 16 through 18? I won't read it.

9 A Yes. I'm looking at it now.

10 Q And isn't that one of her conclusions?

11 A Well, I think this is a different conclusion.  
12 You'll notice this one refers to risk factors and is  
13 specifically talking about statistical association.  
14 The Eberhart-Phillips conclusion that you just  
15 mentioned uses common causes. Campylobacteriosis is a  
16 common disease with a number of common causes, the most  
17 important being, at least for campylobacteriosis in New  
18 Zealand, the most important being the consumption of  
19 undercooked chicken. I guess it doesn't say whether  
20 it's in restaurants.

21 Now, Dr. Kassenborg -- it is not clear to me  
22 that these are the same conclusions. She is drawing a

1 conclusion about causes. She is drawing a conclusion  
2 about risk factors.

3 Q And both of them are drawing a conclusion  
4 about the chicken, aren't they?

5 A That's an interesting question. She may be  
6 drawing a conclusion about things correlated from  
7 chicken. In other words, saying that chicken is a risk  
8 factor. Well, being male is a risk factor. Being male  
9 is correlated with eating chicken.

10 The conclusion about a risk factor really  
11 doesn't specify the cause.

12 Q Do you think when a male eats something that  
13 contains campylobacteriosis, it's his hormones or the  
14 campylobacter that gives him campylobacteriosis?

15 A I won't speculate. I think there is probably  
16 a host of these interactions. But I don't know --

17 Q And the Rodriguez paper, which is G-1886 -- I  
18 don't think you have that yet.

19 A Not yet.

20 Q And by the way, whenever these piles of paper  
21 start to overwhelm you, wave at me and I will place  
22 them here and I will fetch the ones you need --

1           A     Thank you.

2           Q     And without my reading it, Dr. Cox, in  
3     Rodriguez's summary of the study, don't they identify  
4     consumption of chicken in a restaurant as statistically  
5     significantly associated with being a case that's being  
6     a case suffering from campylobacteriosis?

7           A     Let's see. There was no statistically  
8     significant risk associated with consumption of chicken  
9     other than in restaurants, nor with reported domestic  
10    kitchen hygiene factor. Is that the sentence you're  
11    referring to?

12          Q     I think the sentence that I was reading from  
13    beings at the end of the fourth line of the summary.  
14    Travel abroad and consumption of chicken in a  
15    restaurant were statistically significantly associated  
16    with being a case --

17          A     Ah.

18          Q     So the last paper in that series that you  
19    cited was the Eppler paper.

20          A     I don't follow you. You mean not last in  
21    order but last in our getting to them.

22          Q     Yes, the one that we have not yet attended to.

1 And that's Exhibit G-185.

2 A Thank you.

3 Q And in the abstract, you see a sentence  
4 without my reading it that begins, "In matched logistic  
5 regression." In that exhibit on page 1, in the double  
6 indented abstract.

7 A Yes, I've found it.

8 Q The signal there that they comment on includes  
9 eating chicken prepared by a commercial food  
10 establishment in the seven days before the case illness  
11 onset as significant independent predictors of illness.  
12 Right?

13 A In their logistic progression model, yes.

14 Q And without me reading it, in the last line  
15 don't they signal that even after further study, if  
16 associated with commercially prepared chicken?

17 A Commercially prepared chicken -- I'm sorry,  
18 did you say significantly associated?

19 Q I don't believe I did in the last question. I  
20 believe I asked, didn't they say that further -- even  
21 after further study if associated --

22 A No --

1 MR. NICHOLAS: Your Honor, I'm going to  
2 object. The way this has been characterized, I believe  
3 it says further study is needed. It says, further  
4 study of the associated is needed.

5 MR. SPILLER: I stand corrected. Counsel is  
6 correct. I'll withdraw the last question.

7 THE WITNESS: I --

8 JUDGE DAVIDSON: There's no question pending.

9 BY MR. SPILLER:

10 Q So in summary, Dr. Cox, isn't it so that all  
11 of the cites that you cited for that sentence in your  
12 testimony actually support the contention that chicken  
13 consumption is associated with campylobacteriosis?

14 A Absolutely not. If you'll look at table 1 of  
15 Effler, you'll see on that on that page 3 of this  
16 exhibit you just handed me, from a restaurant there's  
17 an association in this model. For chicken eaten at  
18 home, there's a statistically significant protective  
19 effect. For cooking raw chicken at home, there's a  
20 statistically significant protective effect; the risks  
21 are down by 50 percent. For touching any raw chicken  
22 at home, there's a statistically significant reduction.

1 Your risks are only .6 of what they otherwise would  
2 have been.

3 For turkey, well, turkey looks marginally  
4 different. And then we have ham and beef and so forth.  
5 The italicized statement was that restaurant dining  
6 rather than chicken consumption, per se, appears to be  
7 the major human health threat for CP,  
8 campylobacteriosis. And I believe that each of the  
9 sources drawn from provides substantial evidence to  
10 support that.

11 Q Did I understand you correctly just now, Dr.  
12 Cox, to say it was protective for eating chicken  
13 outside the home?

14 A I don't remember my words, but I did mean that  
15 the math odds ratio is statistically significantly  
16 smaller for those who've eaten chicken at home, cooked  
17 chicken at home, touched raw chicken at home and so  
18 forth, than for people who have not.

19 Q You can help me understand this then. We're  
20 looking at Effler, page 3, table 1, under dietary or  
21 environmental exposure, top line, chicken eaten outside  
22 the home.

1 A Yes.

2 Q Fifty-four percent of the patients and 38  
3 percent of the controls there, with an odds ratio of 2.  
4 Am I right that more patients than controls were --

5 A Ate chicken outside the home, yes. And solely  
6 from a restaurant.

7 Q And so both of those do associate the  
8 consumption of chicken in those circumstances with  
9 campylobacteriosis?

10 A They associate consumption of something  
11 outside the home, and that something can be chicken.  
12 That something, if you look down at ham, can be ham.  
13 If you look down to steak or to -- actually not steak.  
14 Steak is protective. So ham is a better example.

15 But to get at what chicken, per se, chicken by  
16 itself causes, I think you have to go beyond these  
17 associations and look at the data, which I've been able  
18 to do for Effler, which I've been able to do for  
19 Friedman. That's where you find out what's really  
20 going on.

21 Q And without my pestering you with it, Effler's  
22 conclusions are recorded in this table 1?

1           A     Some of his I think most important  
2 quantitative conclusions are in table 1. Not in his  
3 abstract, which is in his summary, but yes, in table 1.

4           Q     So where you and he disagree, you would  
5 suggest that we go with Cox on the Effler study, or go  
6 with Effler on the Effler on the Effler study?

7           A     I would recommend starting with the Effler  
8 data and using generally accepted and commercial  
9 programs and seeing what they say.

10          Q     And do you suggest that he did not?

11          A     I suggest -- I state that he used a particular  
12 model conditional logistic progression without  
13 reporting the standard model diagnostics and tests that  
14 would roughly correspond to what I just said. He  
15 didn't quantify model uncertainty, he didn't specify  
16 how variable testing was done. So I think there are a  
17 number of statistical limitations to this analysis.  
18 However -- well, and I'll stop there.

19          Q     Let's turn to another of the recurring cites  
20 in your testimony, the Rosenquist paper. It's G-1788.  
21 That one, I believe you cite 11 times in your  
22 testimony. Does that sound approximately correct?

1 A Yes. Yes. Thank you.

2 Q In your discussion of the Effler paper, Dr.  
3 Cox, do I understand that you think it's important to  
4 explicitly treat the issue of uncertainty?

5 A I think it's important to account for the  
6 issue of uncertainty, yes.

7 Q Thank you. Referring to your testimony, page  
8 15, in the last paragraph, the last sentence, you're  
9 teaching me to be careful about these citations. I  
10 think you seem to say that Rosenquist supports that  
11 sentence. Am I understanding that correctly?

12 A Yes. It's my belief, which I have a feeling  
13 we're about to test, that Rosenquist has stated,  
14 without completing hazard identification, that we're  
15 going to assume there's a risk. Yes.

16 Q And that connection is simply assumed and is  
17 not present in the data. That's what you said.

18 A Yes.

19 Q So let's look at Rosenquist page 3 -- sorry,  
20 I'll let you finish your answer.

21 A I was going to say, yes, but there's some  
22 ambiguity in my mind on exactly how to parse this

1 sentence, which I hope won't be relevant. The question  
2 is, it is not present in the data. Did Rosenquist say  
3 that? Or did Rosenquist simply support the assumption?  
4 Rosenquist just said, hey, we're going to assume  
5 there's risk in the analysis, or did he go further and  
6 say I looked at the data -- but I'm not sure, as I sit  
7 here, whether he looked at the data or whether he said,  
8 we're just going to assume that it's there.

9 Q Well, let's check. Let's look at Rosenquist,  
10 G-1788, page 3, the right-hand column. And this one  
11 long paragraph that begins with the number of the  
12 human -- and would you read to yourself the next  
13 sentence that begins, "the high prevalence," that ends  
14 with, and I'd like you to count these, 12 references.

15 A Okay.

16 Q They have 12 references for the support that  
17 chickens play an important role in the transfer of  
18 campylobacter in humans?

19 A No, it's seem to support.

20 Q And did Rosenquist, et al., distinguish that  
21 seeming support from real support in their paper?

22 A Are you asking what they meant by seeming to

1 support?

2 Q No. I'm asking did they distinguish, as I  
3 understood your last answer, between seem to support  
4 and actually support? Do they say anywhere in this  
5 paper that those 12 references only seemed to support?

6 A They say that right there. I'm sorry, am I  
7 being unresponsive?

8 Q No, I'm not being precise enough. Did you  
9 read those papers?

10 A I have read through some -- I have read  
11 through some of them lightly, some of them more  
12 carefully, most of them. The only ones I have really  
13 studied are the ones where I can put my hands on the  
14 data.

15 Q While we're on the Rosenquist study, Dr. Cox,  
16 I'd like to show you one of the citations of that.

17 MR. SPILLER: Your Honor, this will take me a  
18 moment to set up, if I can do it efficiently.

19 JUDGE DAVIDSON: The witness is starting to  
20 fade. Do you want to break here?

21 MR. SPILLER: That's fine with me, Your Honor.

22 JUDGE DAVIDSON: Okay, I accede to your

1 request.

2 THE WITNESS: Thank you.

3 JUDGE DAVIDSON: You are excused today. You  
4 will be back tomorrow.

5 THE WITNESS: Thank you.

6 (The witness was excused.)

7 JUDGE DAVIDSON: And we have a little bit of  
8 housekeeping to take care of.

9 Have you had a chance to confer about the FOI  
10 requests and responses, et cetera, and whether you want  
11 them in or out?

12 MR. NICHOLAS: No, we haven't, Your Honor. We  
13 wanted to speak to you first thing in the morning.

14 JUDGE DAVIDSON: That's my deal. All or  
15 nothing. Now, we've got response to -- were you  
16 supposed to give me a response to something else, or is  
17 that the same area?

18 MS. STEINBERG: We do have two other matters I  
19 have a response, if I may approach to hand you a copy.  
20 I'll be filing this with dockets this afternoon. It is  
21 CVM's opposition to the entry into the evidentiary  
22 records of two documents of six that were moved by

1 Bayer --

2 JUDGE DAVIDSON: Okay, so you don't have to --  
3 sorry, you do it your way. That's fine.

4 The record of this proceeding is every bit as  
5 good as the written order from me. So I won't repeat  
6 the order insofar as it pertains to the 1924, 1925,  
7 1926, and 1927. I'm allowing them in. You don't have  
8 an objection, so they will be in the record as  
9 received.

10 (Respondent Exhibits 1924  
11 through 1927 were marked for  
12 identification and received in  
13 evidence.)

14 JUDGE DAVIDSON: All right, you want to file  
15 this, your objection, and I'll rule on it.

16 MS. STEINBERG: Thank you, Your Honor.

17 JUDGE DAVIDSON: Is there a B-1935?

18 MR. KRAUSS: Your Honor, may I clear that up  
19 tomorrow? B-1935 may have been something that we  
20 marked yesterday.

21 JUDGE DAVIDSON: Doesn't matter; I just wanted  
22 to make sure I didn't miss it, that's all.

1 MR. KRAUSS: I will clear it up tomorrow, Your  
2 Honor.

3 JUDGE DAVIDSON: Now, is there a G-1805?

4 MR. SPILLER: I don't believe there is, Your  
5 Honor, but I'm not positive. I will try to --

6 JUDGE DAVIDSON: They're just gaps in the  
7 numbers. I don't mind if you miss a number; I've just  
8 got to make sure I didn't miss an exhibit somewhere.

9 MR. SPILLER: I think it's a missing number,  
10 Your Honor. We skipped to make sure that we didn't --

11 JUDGE DAVIDSON: That's okay. That's all  
12 right. And tomorrow morning, you're going to let me  
13 know what you think about the 1804? What about 1801?  
14 What did we do with that? Were we supposed to respond  
15 to that today? Did you already respond?

16 MR. NICHOLAS: Your Honor, if I may, 1801 is  
17 the one that we responded to yesterday afternoon with a  
18 reply --

19 JUDGE DAVIDSON: That's in the FOI business?

20 MR. NICHOLAS: That's correct, Your Honor.

21 JUDGE DAVIDSON: So is 1804, though. Because  
22 I ruled it out, but it seems to me that was a response

1 of somebody in the Agency. That was a FOI one too.

2 All right, 1801 is also, right?

3 MR. NICHOLAS: I believe so, Your Honor.

4 JUDGE DAVIDSON: It's still all or nothing.

5 So we'll wait until what you decide tomorrow. They'll

6 be in or out, but they'll certainly stay in the

7 administrative record.

8 MS. ZUCKERMAN: Your Honor, may I just make

9 one comment about --

10 JUDGE DAVIDSON: My behavior? Sure. Go

11 ahead.

12 MS. ZUCKERMAN: No, Your Honor. As I

13 understood your direction this morning, the in or out

14 ruling is based on the fact that Bayer's motion

15 yesterday dealt with FOIA-related documents. However,

16 the motion and all the attachments, which I think are

17 over a thousand pages, actually include four

18 declarations, several of which attempt to change

19 testimony that's been filed in this proceeding. So to

20 attempt to address those --

21 JUDGE DAVIDSON: Which exhibit are we talking

22 about?

1 MS. ZUCKERMAN: These are Exhibits B-1938, B-  
2 1939, those are declarations from two Bayer witnesses  
3 changing their testimony. And B-1940 and 1941 are from  
4 Bayer employees, Bayer counsel.

5 I have drafted a two-page opposition under the  
6 belief that we had to submit something today.

7 JUDGE DAVIDSON: Well, you did. You said you  
8 were going to, to those. But I was concerned -- maybe  
9 I misread it, but I thought we were talking about the  
10 FOI request. Now --

11 MS. ZUCKERMAN: We were. Except, attached to  
12 that, Bayer's opposition, was a motion to introduce  
13 these --

14 JUDGE DAVIDSON: New exhibits? They were  
15 declarations?

16 MS. ZUCKERMAN: Yes. And -- four  
17 declarations, four or five into the evidentiary record.

18 JUDGE DAVIDSON: I'll have to look at them  
19 again. I don't recall them being anything more than  
20 with respect to the FOI stuff. If I'm wrong, I will  
21 change that.

22 MR. NICHOLAS: Your Honor, if I may, they are

1 all related to the FOI stuff. When we received the  
2 files from CDC in the what's called SAS format, we  
3 compared those files with the files we had previously  
4 received from CDC and when we compared those files, we  
5 noticed there were some discrepancies between  
6 particular files that some witnesses had based  
7 testimony on. And so we moved to withdraw in those  
8 declarations those portions of the testimony that were  
9 deemed inaccurate as a result of being provided  
10 inaccurate files by CDC.

11 MS. ZUCKERMAN: If I may, Your Honor,  
12 actually, that's true up to a point. There is one  
13 declaration that purports not only to withdraw certain  
14 portions of testimony, but to actually change the  
15 testimony that's been submitted and resubmitted in  
16 paragraph. May I file these now?

17 JUDGE DAVIDSON: Certainly. You can file  
18 whatever you want to file. You're just leading me more  
19 into the conclusion that everything should be out  
20 rather than in. Because it stays in the administrative  
21 file.

22 And as I said, I think you'll recall when we

1 had that informal conference on the telephone, that  
2 your request, Mr. Nicholas, after you found out that  
3 it's provided in different formats, I'm pretty sure I  
4 said to you at that time, if you find specific areas  
5 that have caused you a problem because the information  
6 provided was either not available or was misleading or  
7 not subject to interpretation, that I wanted to know  
8 about the specifics of what was involved. And I didn't  
9 hear anything.

10 MR. NICHOLAS: Your Honor, we got those files.  
11 It took us some time --

12 JUDGE DAVIDSON: I know. I understand. But  
13 I'm saying, the same -- even though that was off the  
14 record and it was procedural only, the same thing  
15 applies.

16 If there is a specific reason to change  
17 something based on the fact that you didn't get the  
18 information in the proper format or for whatever other  
19 reason, then I want to know specifically about that  
20 now.

21 In your request, taking representations of  
22 counsel, that there was one of the requests more than

1 just deleting things, it was adding something.

2 MR. NICHOLAS: Your Honor, I believe what's  
3 contained in the motion that we filed yesterday are the  
4 declarations to trace the chain of custody, if you  
5 will.

6 When we received the CDC files initially in  
7 this Excel format, when we received the SAS files from  
8 CDC, how we went about trying to match them up together  
9 and, as a result of that, what testimony we believed  
10 was incorrect as a result of that.

11 And I do believe in one instance that  
12 testimony has addressed what the discrepancy was and  
13 how it would change the testimony. I don't believe it  
14 represents the testimony here.

15 JUDGE DAVIDSON: That's what I'm going to have  
16 to decide, I guess.

17 Do you think you covered it sufficiently in  
18 your motion?

19 MR. NICHOLAS: Yes, I do, Your Honor.

20 JUDGE DAVIDSON: Okay, and I've got a  
21 response. I'll work on it.

22 MS. ZUCKERMAN: Thank you, Your Honor.

1  
2  
3  
4  
5  
6  
7

MR. NICHOLAS: Thank you, Your Honor.

JUDGE DAVIDSON: Okay, we're adjourned until  
9:00 a.m. tomorrow morning.

(Whereupon, at 2:50 p.m., the hearing was  
adjourned, to reconvene Wednesday, May 7, 2003 at 9:00  
a.m.)

\* \* \* \* \*