

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-1571  
New Animal Drug Application (NADA) :  
140-828 (Baytril) :  
:  
----- X

Food and Drug Administration  
5600 Fishers Lane  
Rockville, Maryland

Wednesday, May 7, 2003

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

BEFORE:

DANIEL J. DAVIDSON, Administrative Law Judge

**Diversified Reporting Services, Inc.**  
1101 Sixteenth Street, NW Second Floor  
Washington, DC 20036  
(202) 407-9200

2000N-1571

TR 16

## APPEARANCES:

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On behalf of Respondent Bayer Corporation:

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Also present:

Dennis D. Copeland, D.V.M., Director  
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C O N T E N T S

WITNESSES:	DIRECT	CROSS	REDIRECT	RECROSS
<del>Louis</del> Louie Cox, Jr.			942 1081	942 1109

RESPONDENT EXHIBITS:	IDENTIFIED	RECEIVED	WITHDRAWN
273 - 280 - Motion	935	935	
1573 - Cox's biographical sketch	937	937	
1935 - Pages from Modern Epidemiology	927	927	
1936 - Hollander abstract	1122	1122	
1946 - Document from MIT Registrar's Office	928	941	1122
1947 - Certified copy of Cox's MIT transcript	929	941	1122

GOVERNMENT EXHIBITS:

1809 - 4/99 Cox letter to Voxe		1126	
1816 - Robinson study	1125	1125	
1817 - Portion of Rosner textbook	1125	1125	

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

1  
2 JUDGE DAVIDSON: Good morning. Come to order.  
3 We'll go off the record for a moment while I get set up  
4 here.

5 (Off the record.)

6 JUDGE DAVIDSON: Preliminary matters?

7 MR. KRAUSS: Good morning, your Honor.  
8 Gregory Krauss on behalf of Bayer. I have one  
9 preliminary matter.

10 You had asked about whether there was an  
11 Exhibit B-1935, and I went back and checked and then  
12 recalled that after Dr. Angulo's testimony regarding  
13 incidence and confounding, I had copied some pages out  
14 of Modern Epidemiology on those topics.

15 He had said Modern Epidemiology, by Rothman  
16 and Greenland, is the book that they use at CDC and  
17 that he was most familiar with, so I had copied those  
18 pages and forgot to do anything with them until you  
19 reminded me about 1935.

20 At this time, I would like to move into  
21 evidence B-1935, which is the cover, certain title  
22 pages, and related subject index entries from that book

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1 that relate to incidence and confounding.

2 JUDGE DAVIDSON: Have you got copies for  
3 everybody?

4 MR. KRAUSS: Excuse me, your Honor?

5 JUDGE DAVIDSON: Copies for everybody.

6 MR. KRAUSS: Yes, your Honor.

7 JUDGE DAVIDSON: Including the reporter?

8 MR. KRAUSS: Yes, your Honor.

9 MR. SPILLER: The Center does not object, your  
10 Honor.

11 JUDGE DAVIDSON: No objection, then it's moved  
12 in. But I want to see it and have it and have the  
13 reporter have a copy.

14 MR. KRAUSS: Yes, your Honor. Thank you, your  
15 Honor.

16 (Respondent Exhibit 1935 was  
17 marked for identification and  
18 received in evidence.)

19 JUDGE DAVIDSON: Okay. Mr. Nicholas?

20 MR. NICHOLAS: Your Honor, I have one  
21 preliminary matter as well. Yesterday, Mr. Spiller  
22 questioned Dr. Cox about his degrees and background,

1 and, as a result of that, your Honor, in about 10  
2 minutes we spoke to the Registrar's office at MIT and  
3 what I'd like to present to the Court are two things,  
4 your Honor.

5 One is marked B-1946 and it's from the  
6 Registrar's office at MIT and it clearly shows that  
7 when you get the raw data and you ask the right  
8 questions you will get the correct answer. It will  
9 show, your Honor --

10 JUDGE DAVIDSON: Well, that says what it says.  
11 Let's move on. Come on.

12 MR. NICHOLAS: So this is one exhibit. This  
13 is 19 --

14 JUDGE DAVIDSON: 46?

15 (Respondent Exhibit 1946 was  
16 marked for identification.)

17 MR. NICHOLAS: -- 46, your Honor. And the  
18 other exhibit, your HONOR, is the transcript from MIT  
19 that clearly shows that Dr. Cox got his B.A. from  
20 Harvard -- A.B. from Harvard in 1978 and it's a  
21 certified copy of his transcript and I'd like to mark  
22 that as 1947.

1 JUDGE DAVIDSON: Okay. Copies?

2 MR. NICHOLAS: I might add it also shows that  
3 Mr. Cox -- Dr. Cox got primarily A's at MIT.

4 JUDGE DAVIDSON: Wow. I'm not surprised.

5 (Respondent Exhibit 1947 was  
6 marked for identification.)

7 JUDGE DAVIDSON: Okay.

8 MS. STEINBERG: Your Honor, would you like us  
9 to respond now to your question on the documents that  
10 have been moved into evidence or have been ruled on?

11 JUDGE DAVIDSON: I'm ready to rule on that  
12 part. I was waiting to hear about the -- what I  
13 consider the underlying documentation with respect to  
14 the FOI which you were supposed to have decided on, but  
15 I don't know if I even want to let you at this point.  
16 As far as I'm concerned, it's out. All of it.

17 So if you give me the numbers, I'll mark them  
18 out. This is the letters and correspondence dealing  
19 with your FOIA request. It stays in the 1285, it  
20 becomes a particular issue in the case, you can still  
21 refer to it but I don't consider it the quality that I  
22 like to have as evidence in my case.

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1 MS. STEINBERG: Your Honor, that would be G-  
2 1801, B-1937, and there's a question about the next  
3 four, B-1938 through B-1941. These are declarations by  
4 two Bayer witnesses and one Bayer employee and one  
5 Bayer counsel, and I would like verification of --

6 JUDGE DAVIDSON: I mean, those, too, if they  
7 deal with the FOIA request.

8 MS. STEINBERG: Yes. B-1940 and B-1941, a  
9 declaration by Michael <sup>Vaughn</sup> ~~Bond~~ do deal with the FOIA  
10 request. B-1938 and B-1939, the declarations from two  
11 witnesses go a little bit further and admit to errors  
12 in testimony, and we'd like to address that as well,  
13 your Honor.

14 JUDGE DAVIDSON: Address it?

15 MS. STEINBERG: Well, CVM would like to join,  
16 if Bayer is willing to move to withdraw those portions  
17 which are admittedly in error, or alternatively, CVM  
18 would like to move to strike those portions of the  
19 testimony which are admitted in error.

20 JUDGE DAVIDSON: Well, they're not admitted.  
21 Are we talking about previous exhibits?

22 MS. STEINBERG: In the declarations of Dr.

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1 Burkhardt and Dr. <sup>DeGroot</sup>~~DeGroot~~.

2 JUDGE DAVIDSON: I thought you were supposed  
3 to confer on these before this morning?

4 MS. STEINBERG: We did, your Honor.

5 JUDGE DAVIDSON: And what did you decide? You  
6 couldn't decide?

7 MS. STEINBERG: Well, we could not reach  
8 agreement on this.

9 MR. NICHOLAS: Your Honor, if I may, with  
10 respect to those two declarations, I think it's  
11 important for the Court to understand the circumstances  
12 under which that testimony was presented, based upon  
13 data that was supplied by CDC.

14 JUDGE DAVIDSON: I got it. I'm sorry. It's  
15 not your fault. It's mine. I don't understand when  
16 you say testimony. You're talking about other exhibits  
17 testimony as opposed to these declarations.

18 MR. NICHOLAS: The declarations by Dr.  
19 Burkhardt and Dr. <sup>DeGroot</sup>~~DeGroot~~ are in part withdrawing part  
20 of their written direct testimony which was submitted  
21 in December. What was contained in their written  
22 direct testimony in December was in part based upon

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1 inaccurate information that was provided to Bayer by  
2 the Centers for Disease Control.

3 So upon review of the two data sets, we  
4 determined, or the witnesses determined, that certain  
5 minor portions of their testimony were inaccurate and  
6 therefore should be withdrawn, and we put those in the  
7 declarations as a way of explaining the circumstances  
8 rather than dealing with withdrawing their testimony.  
9 And one of the witnesses, I believe, although perhaps  
10 both, has stated that these changes do not affect  
11 generally the conclusions they reached in the  
12 testimony.

13 MS. STEINBERG: Your Honor, one additional  
14 thing, if I may. Dr. <sup>DeGroot</sup>~~DeGrowth~~ seems to change part of  
15 his testimony in that declaration, and I just want to  
16 be on record saying CVM would oppose any change to  
17 written direct testimony at this late date --

18 JUDGE DAVIDSON: When you say change, you mean  
19 an addition?

20 MS. STEINBERG: A substitution, withdrawing  
21 part of it and substituting --

22 JUDGE DAVIDSON: And adding something else.

1 MS. STEINBERG: Yes.

2 JUDGE DAVIDSON: Well, it's not -- none of the  
3 exhibits are received, but I do require that for the  
4 record, probably you, Mr. Nicholas, submit something to  
5 the record indicating what portions of the testimony  
6 are being withdrawn, solely what's being withdrawn.

7 MR. NICHOLAS: Yes, your Honor.

8 JUDGE DAVIDSON: Okay?

9 MR. NICHOLAS: Thank you, your Honor.

10 JUDGE DAVIDSON: Because that has to be  
11 indicated on the record so we know what is in and what  
12 is out when we review the testimony of those witnesses.

13 MR. NICHOLAS: Certainly, your Honor. I would  
14 request that we are able to represent the circumstances  
15 under which it's withdrawn, your Honor.

16 JUDGE DAVIDSON: Well, I think you did that.  
17 Didn't you just do that?

18 MR. NICHOLAS: Well, I did, but as I  
19 understand it, none of these documents are in evidence,  
20 so --

21 JUDGE DAVIDSON: Doesn't matter. They're on  
22 the record as far as -- I mean, you can refer to them

1 all you want as long as you point out that I don't  
2 consider them evidence, but say that's your  
3 representation of what happened. So you want to  
4 represent it again?

5 MR. NICHOLAS: No, I'm fine, your Honor.  
6 Thank you.

7 JUDGE DAVIDSON: Okay. Let's see. Before I  
8 rule on your motion to add two exhibits and -- I think  
9 we've already let the others in -- I have some problems  
10 with our record.

11 First of all, apparently on December 20, 2002,  
12 a motion was filed which was unopposed, so it's not a  
13 problem, except that I never got a copy of it. Maybe  
14 that was one of those phantom faxes that you sent me.  
15 I think I know what happened. At one point your office  
16 was sending me faxes through my telephone number and I  
17 don't get them through my telephone number. I did call  
18 and straighten that out with one of your assistants.

19 But it's not important except for the fact  
20 that the record doesn't reflect these exhibits being  
21 moved -- being accepted in evidence. They were  
22 unopposed. So, for the record, Exhibits B-273 through

1 280, are now received in evidence, since that motion,  
2 which I know I have a copy of, says that it was  
3 unopposed.

4 MR. NICHOLAS: Thank you, your Honor.  
5 (Respondent Exhibits 273 through  
6 280 were marked for  
7 identification and received in  
8 evidence.)

9 JUDGE DAVIDSON: Now, yesterday during the  
10 cross-examination I was referred to Exhibit B-122,  
11 Exhibit B-295, and Exhibit B-1573 and Exhibit B-1886,  
12 with the representation that they were part of the  
13 record. They're not. They were never moved into  
14 evidence, as far as my records show. There may be  
15 others.

16 And at this point, while Mr. Spiller is  
17 looking to see what the problem is and straighten me  
18 out -- I'm sure he will -- if I said anything on the  
19 record that was in any way derogatory of our dockets  
20 management branch for not providing me with the right  
21 information, I have to apologize profusely and indicate  
22 that Mr. Lyle Jaffe has done a wonderful job of keeping

1 up with the record and what's going on and what's not  
2 going on, for the record.

3 He straightened me out with this one very  
4 quickly.

5 MR. SPILLER: Your Honor, I apologize for my  
6 misunderstanding which I presented to the record  
7 yesterday, that each of those Bayer exhibits was in the  
8 record.

9 The clearest of those I think is B-1573, which  
10 I believe is Dr. Cox's biographical sketch, which I  
11 believe both sides would probably want to be in the  
12 record, but I should ask explicitly of Mr. Nicholas if  
13 I have that right.

14 Did you intend for his biographical sketch to  
15 be presented to the record?

16 MR. NICHOLAS: We have no objection to it  
17 being in the record.

18 MR. SPILLER: And the Center concurs with that  
19 -- does not object to that, your Honor.

20 JUDGE DAVIDSON: All right. B-1573 is in the  
21 record.

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1 (Respondent Exhibit 1573 was  
2 marked for identification and  
3 received in evidence.)

4 MR. SPILLER: B-1886, I believe, is the  
5 ~~Rodriguez~~ <sup>Rodrigues</sup> article that is cited numerous times, and  
6 testimony yesterday includes the reference that it was  
7 cited numerous times in Dr. Cox's testimony. I had  
8 thought that Bayer had moved it in. I was evidently  
9 mistaken. The Center moves now for the admission of  
10 the ~~Rodriguez~~ <sup>Rodrigues</sup> paper, B-1886.

11 MR. NICHOLAS: If I may, your Honor, that  
12 document is in evidence. It's G-1711, I believe.

13 JUDGE DAVIDSON: Ah-ha. That's the problem.

14 MR. SPILLER: Thank you, Mr. Nicholas.

15 JUDGE DAVIDSON: So we don't have to do  
16 anything with that. That's G -- say that again.

17 MR. NICHOLAS: 1711, your Honor.

18 JUDGE DAVIDSON: Okay.

19 MR. SPILLER: And that may or may not be the  
20 case with Exhibits B-295 and B-122 which we referred to  
21 already, as your Honor pointed out, in yesterday's  
22 testimony. B-122 is the Adak paper, I believe, and B-

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1 295 is Eberhart-Phillips, which is also cited in Dr.  
2 Cox's testimony.

3 MR. NICHOLAS: Those are both in evidence,  
4 your Honor, with G numbers.

5 JUDGE DAVIDSON: Furnish them, please.

6 MR. SPILLER: Under the principle of  
7 countervailing blunders, I was accidentally right,  
8 because they were other exhibits.

9 JUDGE DAVIDSON: I thought you would  
10 straighten me out, as I said.

11 MR. SPILLER: Thank you, your Honor.

12 JUDGE DAVIDSON: Now, I've reviewed B-1924  
13 through 27; have been received in evidence. The only  
14 remaining ones I have to deal with are B-1923 and 1928.  
15 I'm having a big problem because, well, this agency  
16 doesn't provide, as many others do, for closing the  
17 record at a particular time. At some point in time  
18 it's got to close. And as far as I'm concerned, this  
19 is as good as any, because after this, there's no  
20 possibility of cross-examination, so I can't accept new  
21 stuff.

22 So I'm not going to accept those two exhibits

1 because they do include material which I find is  
2 additional and not the same as what was in before, when  
3 the Center had an opportunity to request cross-  
4 examination from those witnesses.

5 So 1923 and 1928 are not received in evidence,  
6 and I don't want to see any more evidence moved in  
7 unless it falls strictly under the very concise -- my  
8 own very concise guidelines for what constitutes "new"  
9 evidence.

10 In other words, if it's of such moment that I  
11 have to consider it before I can make a decision,  
12 because it affects the total outcome of the case and it  
13 has truly not been available prior to the time it's  
14 submitted, then I will consider it as new evidence and  
15 I will rule on whether I will accept it or not, even if  
16 it means delaying the proceeding, but it's got to be  
17 something really blockbuster size, otherwise I don't  
18 want any more exhibits that are trying to put evidence  
19 in the record or testimony, as of right this second.

20 Now, are there -- let's see. B-1946, and  
21 there was another one?

22 MR. NICHOLAS: 1947, your Honor, which was Dr.

1 Cox's --

2 JUDGE DAVIDSON: 1947. Was there an objection  
3 to that?

4 MR. SPILLER: No, your Honor. There is not an  
5 objection. I had thought that these documents would  
6 come in as a part of the redirect, but I'm happy to  
7 respond now.

8 I'd note that B-1946, although it's addressed  
9 to a different person, is the same information that we  
10 presented yesterday, and one of the reasons we would  
11 not object to its admission is that it also reflects  
12 that it's a Doctor of Philosophy and it does not  
13 specify risk analysis. Neither do the attached  
14 documents.

15 We do not object to B-1947. It also reflects  
16 an admirable great record and unless I have missed  
17 something here, also does not specify that the Ph.D.  
18 was awarded in risk analysis. It does -- one of them  
19 -- I think the commencement program does specify the  
20 thesis in the field of risk analysis and, as the  
21 witness' testimony yesterday indicated, the thesis was  
22 in risk measurement, which, as he testified, is a

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1 subset of risk analysis.

2 JUDGE DAVIDSON: Do you want to say something?

3 MR. NICHOLAS: No, your Honor. I think  
4 there's no reason to belabor the point. I think it's  
5 obvious that Dr. Cox is an expert in this field and --

6 JUDGE DAVIDSON: Okay. They are in evidence.  
7 I haven't yet heard a challenge to that.

8 (Respondent Exhibits 1946 and  
9 1947 were received in evidence.)

10 JUDGE DAVIDSON: That's it?

11 Okay. Dr. Cox, I think we're ready for you to  
12 resume your second favorite seat.

13 THE WITNESS: Thank you, sir.

14 JUDGE DAVIDSON: Let the record reflect that  
15 Dr. Cox is still under oath.

16 MR. NICHOLAS: Your Honor, I'd like to  
17 approach the witness and give him a copy of --

18 JUDGE DAVIDSON: Go ahead.

19 Whereupon,

20 *LOUIS*  
~~LOUIE~~ COX, JR.

21 was recalled as a witness and, having previously been  
22 duly sworn, was examined and testified further as follows:

## REDIRECT EXAMINATION

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BY MR. NICHOLAS:

Q And would you just identify that for the record, please, Dr. Cox, by the exhibit number?

A It's Exhibit number B-1901.

Q And that's a copy of your testimony. Is that correct?

A Yes. This appears to be a copy of my written direct testimony.

Q And the signature page, on page 8, I believe, is that your signature?

A Yes. It is.

Q Thank you.

A Thank you.

## RE CROSS EXAMINATION

BY MR. SPILLER:

Q Dr. Cox, in the document that Bayer's counsel just provided for you, B-1901, would you open that to page 16, please?

A Okay.

Q That's one of the many pages where you cited the Rosenquist, et al. article in the large paragraph

1 at the bottom of the page.

2 A Yes.

3 Q Based on Rosenquist at that point, your view  
4 that CVM model assumption of a linear relationship  
5 between exposure to contaminated chicken and the number  
6 of human campylobacteriosis cases is false. Is that  
7 right?

8 A Can you -- there are several things here. I  
9 don't see those exact words.

10 Q And exact words are important, aren't they?  
11 So I should get that right.

12 A Please.

13 Q In the sixth line of that large paragraph at  
14 the bottom, beginning with the word lacking --

15 A Yes.

16 Q -- I won't read it out loud, do you argue that  
17 the CVM model cannot correctly estimate the loads of  
18 people, and you cite Rosenquist?

19 A I do say that it cannot correctly estimate the  
20 risks from the microbial loads of campylobacter, yes.

21 Q And in the next sentence you say that the CVM  
22 model incorrectly assumes the risk is proportional to

1 the prevalence of contaminated chicken servings  
2 ingested.

3 A Yes, rather than recognizing it was  
4 disproportionately caused -- yes.

5 Q When you actually referred, though, to the CVM  
6 model, did you find that the CVM model was based on  
7 chicken servings or to the overall consumption of  
8 chicken?

9 A If I recall correctly, I think it's --

10 MR. NICHOLAS: Excuse me, your Honor. If the  
11 witness could be provided with a copy of the risk  
12 assessment, so he could have that document to review.

13 THE WITNESS: Oh, thank you. And perhaps the  
14 Rosenquist paper?

15 BY MR. SPILLER:

16 Q We'll get to the Rosenquist paper and I'll  
17 certainly provide you with a copy of the FDA's risk  
18 assessment. But I would like to ask your recollection  
19 of that.

20 Do you believe that the FDA risk assessment  
21 actually relied on servings?

22 A No, I don't think that it did.

1           Q     I'm giving you now a copy of the FDA risk  
2 assessment, G-953.

3           A     Thanks. I think you're -- perhaps you could  
4 restate your question. I'll try to give you a straight  
5 answer.

6           Q     Your quote beginning on the ninth line of the  
7 largest bottom paragraph on page 16, the sentence  
8 beginning, instead, it incorrectly assumes, continues  
9 that risk is proportional to prevalence of contaminated  
10 chicken servings ingested.

11                     And the question is whether or not you have  
12 accurately attributed the term servings to FDA or isn't  
13 that your insert instead.

14           A     Oh. Well, as you know, if several quantities  
15 are all proportional to each other, then something  
16 that's proportional to one is proportional to all,  
17 although with different constant in proportionality.

18                     I believe, although in 5 -- 6 or -- I don't  
19 remember where this is -- I have a hard time finding it  
20 -- I believe that CVM said that risk is proportional to  
21 exposure and in some places, I believe treated exposure  
22 in terms of pounds of contaminated chicken at the

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production

~~reduction~~ stage.

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And I believe that then consumption, servings, if there are four servings per unit, other things that are proportional to pounds of contaminated chicken would also be proportional to risk.

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Q I appreciate hearing your belief. Am I correct that you confirmed that the FDA risk estimate refers to pounds of chicken produced and not to servings ingested?

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A Without taking the time to re-read this document, I believe that it refers in some places, certainly to servings. I believe that it refers in defining exposure to pounds of contaminated chicken. I'm almost sure that that's at a point of production.

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So I think there are different exposure measures.

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Q At any rate, at several places in the paper, and we can go through them if we need to, but am I correct that you have complained of FDA's assertion of a linear relationship between the contaminated chicken and the illness in humans at a number of places in your testimony?

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1 A That is correct.

2 Q And among the support you cite for that is the  
3 Rosenquist 2000, and counsel has ~~provided~~<sup>requested</sup> that I  
4 provide you a copy of that. I'm happy to.

5 A Thank you.

6 Q Counsel still has the copy that I provided him  
7 yesterday. That Rosenquist article is Exhibit G-1788.

8 MR. SPILLER: And, your Honor, I believe I  
9 provided that yesterday.

10 BY MR. SPILLER:

11 Q And you quote that on the same page 16 of your  
12 testimony, don't you, Dr. Cox, about 7 lines up from  
13 the bottom of the page, the ~~lines~~<sup>line</sup> begins with the word  
14 invalidates. Do you see a sentence that begins as  
15 stated by Rosenquist, et al., ibid. You see that?

16 A I do.

17 Q And the ibid is in the same place, am I  
18 roughly right on the Latin, and so that is a back  
19 reference to the next previous cite to Rosenquist, et  
20 al., section 7.2.2. Am I right?

21 A That's correct.

22 Q And that's found, isn't it, on page 10 of

1 Exhibit G-1788?

2 A Yes, it is.

3 Q Well, go with me there and see if you can help  
4 me figure out how you got that quote.

5 A Uh-huh.

6 Q Your quote begins the minor effect. Am I  
7 right?

8 A Yes.

9 Q And that language occurs on the fourth line  
10 from the bottom of that page.

11 A Uh-huh.

12 Q And for convenience, and not to introduce an  
13 additional exhibit, I have a blowup of that page of the  
14 testimony. Unfortunately I don't have -- this is --

15 MR. NICHOLAS: Your Honor, I believe that's a  
16 blowup of the article. I believe counsel said it was a  
17 blowup of the testimony.

18 MR. SPILLER: I apologize. Counsel is  
19 correct. This is a blowup of one page of G-1788, page  
20 10.

21 BY MR. SPILLER:

22 Q And you can refer to whichever you want to,

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1 Dr. Cox. And what we're talking about is down at the  
2 bottom of the page where it says; <sup>"The minor..."</sup> ~~the minor~~. That's  
3 where your quote begins. And then as I try to read  
4 along, why don't you read your quote, and I want to  
5 follow along here.

6 A Okay. Do you want my interlineations or --

7 Q Yes, please, and I'll write them in here and  
8 we'll see how you constructed that.

9 A Okay. The minor effect, then my  
10 interpolation, less than 10 percent reduction --

11 Q All right. Pause there. Less than 10 percent  
12 reduction. And you fairly show that in the box  
13 brackets.

14 A Yes. And it's from six lines above.

15 Q Okay.

16 A It's in the same paragraph.

17 Q Right.

18 A On the number of, then my interpolation, CP  
19 standing for campylobacter --

20 Q And that's fair. You put that in box  
21 brackets, so we'll tuck that in.

22 A -- the number of positive carcasses at the end

1 of slaughter, even after introduction of a decrease of  
2 three log units -- and I said three log 10 units,  
3 although I see in this version of the article it just  
4 says three log units.

5 Q I'll write in 10.

6 A Okay. Demonstrate the need --

7 Q Do you have an S after the word "demonstrate"?

8 A Yes.

9 Q So we'll add that. That wasn't single, but  
10 that's a small thing, so we'll add that here.

11 Demonstrates.

12 A You're right. Of course, minor effect  
13 demonstrates.

14 Q All right. That's a grammatical correction  
15 that you made. Go ahead.

16 A Demonstrates the need for quantitative  
17 detection methods.

18 Q Okay.

19 A Comma, then there's my ellipsis -- shall I  
20 keep reading?

21 Q After methods, do you have a period?

22 A Yes, I have a period with an ellipsis.

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1 Q Okay. A period. So you ended the sentence  
2 there and then an ellipsis. Go ahead.

3 A Okay. Continuing to read from Rosenquist, as  
4 the effect of such a decrease --

5 Q Okay. I need you to pause here for just a  
6 minute. I'm off the end of my observed territory. We  
7 may have a discrepancy. There's a phrase in your  
8 testimony, Dr. Cox, that I don't think you mentioned  
9 here. Do you have a relatively large reduction in the  
10 number of campylobacter on the chickens, for example --  
11 that's in your testimony, right?

12 A Yes, I see that. Yes.

13 Q Yes. I see that. And that's not in the quote  
14 there, is it? In the original.

15 A Are you ask -- let me see.

16 Q Now I don't want to be unfair to you, Dr. Cox.  
17 I think I know where that came from. I think it came  
18 from up higher in the paragraph, on the first line  
19 there, "relatively large". Do you think that's where it  
20 came from?

21 A Well, now -- hold on a second. I was so busy  
22 reading for you from the Rosenquist paper that I --

1 Q I'm sorry. I wanted you to be reading to me  
2 from your purported quote of the Rosenquist --

3 A Thank you, yes. The minor effect -- okay.  
4 Now I'm back on track. On the number of CP positive  
5 carcasses. Right. At the end of slaughter, even after  
6 -- you know, I think this is from the -- must be from  
7 the final published form of the paper that I've quoted  
8 here. And I see that you're quoting from the -- well,  
9 article in press shouldn't be different.

10 Q Would you like to find that article?

11 A Yes, I think it might be helpful.

12 Q Is that in the record?

13 A I don't know. I do recognize from the stamp  
14 article in press and the XXXXX at the top of the page  
15 and so forth. These may be galleys. And I know what I  
16 looked at in preparing this.

17 Q So you're sure you got that from the actual  
18 published article.

19 A A copy of the published article, yes.

20 MR. SPILLER: Sorry, your Honor. I don't have  
21 multiple copies of this. It's not in the record,  
22 but --

1 BY MR. SPILLER:

2 Q Dr. Cox --

3 JUDGE DAVIDSON: Let's handle it this way.  
4 We'll go off the record and you can show him what  
5 you're talking about and if there's agreement, we'll go  
6 back on the record and you tell me what it is. If  
7 there's a disagreement, we'll go back on the record and  
8 you can each tell me what it is.

9 MR. SPILLER: Thank you, your Honor.

10 JUDGE DAVIDSON: Off the record.

11 (A discussion was held off the record.)

12 JUDGE DAVIDSON: On the record.

13 MR. SPILLER: Thank you, your Honor.

14 BY MR. SPILLER:

15 Q Now, Dr. Cox, have you and I just, with the  
16 assistance of Bayer's counsel, compared the published  
17 version of this article to the in press version, which  
18 is the exhibit?

19 A Yes, we have.

20 Q And have we found that the words are the same  
21 and in the same order in the -- for this relevant  
22 paragraph for the published version to which you had

1 thought you were referring?

2 A Yes, they are.

3 Q Continuing, then, with our investigation of  
4 how this quote was assembled, in your quote, after the  
5 word "slaughter" in the exhibit, have you inserted the  
6 word "of" in box brackets?

7 A Yes.

8 Q And then after that, have you inserted another  
9 ellipsis?

10 A The first ellipsis, yes.

11 Q And after that, did you move some text from  
12 higher in that paragraph?

13 A I quoted text from higher in the paragraph,  
14 yes.

15 Q And where is the beginning of that material?

16 A Well, as you can see, on the top line under  
17 section 7.2.2, the authors interpret what they're doing  
18 in the following words: "A relatively large reduction  
19 of the number of campylobacter on the chickens."

20 Q So the portion that you moved down there  
21 begins with "a relatively"?

22 A Yes. A relatively large reduction in the

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1 number of campylobacter on the chickens, and they --

2 Q How large a bubble did you take of the text  
3 there?

4 A I continued through, for example -- oh, here's  
5 where the log 10 comes in. "For example, a reduction of  
6 three log 10 colony forming units per chicken." So that  
7 would be a thousandfold reduction is what they're  
8 talking about.

9 Q Down through the word "chicken," is that how  
10 far that bubble extends?

11 A CFU/chicken, yes.

12 Q All right. That comes down to here. And  
13 then you stitch that in after the ellipsis?

14 A I quoted it between the ellipses, yes.

15 Q And then the text continues in the actual  
16 paper that you're including in these quotes, even after  
17 introduction, but your ellipses covered that. So we  
18 struck some words out there. We struck out "even after  
19 introduction of a decrease of three log units"?

20 A Yes. I think that's right. Uh-huh. Yeah.

21 Q And then it continues, "demonstrate," you  
22 added the S, "for quantitative detection methods" and

1 you put in a period there. And then we struck the last  
2 four words out of that line, right?

3 A As the effect of.

4 Q Okay. So then we go -- and for convenience I  
5 have a blowup of that segment from your testimony to  
6 16, and here is another copy of the next page of  
7 Exhibit G-1788, and it's exhibit page 11 now.

8 And on that page, the deletion continues  
9 through the first two lines. That comes out and then  
10 an ellipsis, right, before the "the"?

11 A Well, yes. What I show is not a quote but  
12 which is pertinent and reflects the point there is that  
13 the effect of such a decrease in the number -- it's a  
14 pretty large decrease in the number of campylobacter  
15 would not have been detected by the -- what he refers  
16 to as "qualitative methods," meaning the prevalence  
17 metric.

18 Q So did I understand your testimony correctly,  
19 you agree that's pertinent and you chose not to quote  
20 it?

21 A You give part of what I said. It's pertinent.  
22 It agrees fully with and is covered by what he has

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1 said, and I chose not to belabor it, yes.

2 Q And then you continued, referring to your  
3 quote now, "with the incidence of campylobacteriosis  
4 related to consumption of" -- he said "a chicken meal"  
5 but you deleted "a" and "meal," didn't you?

6 A It sure looks that way, but could you just  
7 hand me the final article one more time? We don't need  
8 to go off and on. I just want to --

9 Q It's up to the Court whether we go off and on.  
10 I'm willing to hand you the published article. I'm  
11 handing you now -- excuse me. I've got to get you that  
12 published article.

13 MR. NICHOLAS: Your Honor, if I may, we would  
14 have no objection to moving the final article into  
15 evidence. CVM's counsel would as well. It just seems  
16 to me it would make this -- would facilitate this and  
17 make it easier rather than going back and forth.

18 JUDGE DAVIDSON: I don't know what's in the  
19 final article, so -- I don't know how it differs, if it  
20 does, what's the difference between the final and this.

21 MR. NICHOLAS: I don't know. That's why I was  
22 suggesting --

1 JUDGE DAVIDSON: Thank you. We'll see what  
2 goes on.

3 BY MR. SPILLER:

4 Q Dr. Cox, do you have before you now the final  
5 published article?

6 A I do.

7 Q And it also says a chicken meal, doesn't it?

8 A Yes, it does, not --

9 Q But you didn't say that in your quote, did  
10 you?

11 A I said consumption of chicken, not consumption  
12 of a chicken meal. Thank you. Was reduced  
13 significantly. Yes. Okay.

14 Q And then continuing, your quote has a comma  
15 after the word "carcasses," not in the original, and  
16 you deleted references to figure 7(c) --

17 MR. NICHOLAS: Excuse me, your Honor. Your  
18 Honor, I'm unsure where counsel is. I'm --

19 MR. SPILLER: I'm on -- I'm sorry, your Honor.

20 MR. NICHOLAS: -- excuse me. He's referencing  
21 Dr. Cox's quote as though he's quoting from the article  
22 and as I see Dr. Cox's testimony, it appears the quote,

1 in this paragraph, at least, appears to end at the top  
2 of page 17, first line, where it says "positive  
3 chickens." So I'm a little confused.

4 JUDGE DAVIDSON: Well, he's still on the  
5 bottom of page 16.

6 MR. NICHOLAS: Thank you, your Honor.

7 MR. SPILLER: Mr. Nicholas makes strong  
8 points, your Honor. This is a quote and we're  
9 continuing to work with the quote and to compare it to  
10 the text from which it was allegedly taken.

11 THE WITNESS: Okay. So where's the comma that  
12 shouldn't be there?

13 JUDGE DAVIDSON: Last line on your page 16.

14 THE WITNESS: I see that.

15 BY MR. SPILLER:

16 Q And the original refers, am I correct, Dr.  
17 Cox --

18 A Reduce the number of -- on the carcasses,  
19 comma -- yes, yes, yes. This is -- yes. I see.  
20 Because he's referring to a figure 7(c) and there is no  
21 figure 7(c) in my --

22 Q And he has a period which you've deleted, so

1 you've run the sentence on. So we'll make it a lower  
2 case E for the "even." Isn't that what you did?

3 A I deleted the reference to figure 7(c) since  
4 I'm not copying or referring to figure 7(c).

5 Q And I hope we will later but let's see, then.  
6 He ended the sentence but you didn't. You make the  
7 quote with the small E in the word "even" there, right?

8 A Uh-huh. Yes.

9 Q And then --

10 A Okay.

11 Q -- we also delete after the word "positive"  
12 chickens the entire rest of -- you had the thing ending  
13 after "the number of campylobacter on the positive  
14 chickens." Is that right? Here? Excuse me. When I  
15 say here, the next to bottom line on Exhibit G-1788,  
16 page 11.

17 A Yes.

18 Q Okay. So we put a period there and we  
19 actually delete not only 7(a) but the rest of that  
20 sentence, because his period is not until here.

21 A Right. Figure 7(c) and figure 7(a) have been  
22 deleted and only his words remain. That's true. With

1 a sentence break change. That's correct. And in fact  
2 -- yes. The sentence you just referred to, "even  
3 though such a reduction had almost no influence on the  
4 fraction of positive chickens," let me go back to my  
5 ellipses, "a relatively large reduction in the number  
6 of campylobacter on chickens."

7 Yes, it was already covered in the preceding  
8 ellipses.

9 Q And to summarize, Dr. Cox, for illustration  
10 purposes, I'm showing you what has been marked and is  
11 not yet in evidence as G-1813.

12 MR. SPILLER: I'll give one to the Court, one  
13 to the reporter, and one to counsel.

14 BY MR. SPILLER:

15 Q I'll be quiet for a moment, Dr. Cox. Would  
16 you look that over and see if that summarizes the  
17 markups you needed to make to convert what that article  
18 said to the quote that you used in your testimony?

19 (The witness examined the document.)

20 A It does not.

21 Q All right. Let's describe -- would you  
22 describe anything that shows on that G-1813 that is not

1 something that was done to convert what the article  
2 said with what you quoted?

3 A Yes. First, I think you'll see that the  
4 quoted extract represents using Rosenquist, et al.'s  
5 words, the meaning, the essential content of what  
6 they've said here.

7 Q Yes. Indeed, in your testimony, you said  
8 Rosenquist -- as stated by Rosenquist -- I'm reading  
9 from your testimony on page 16. So you not only  
10 quoted, you attributed to them, "as stated by."

11 A Yes.

12 Q Okay. We agree on that.

13 A Now, you've crossed out in what you've just  
14 handed me several things that seem to me to be  
15 relevant. One is the less than 10 percent, which I had  
16 put in square brackets, less than 10 percent reduction.

17 Q And that's shown on this copy, isn't it?

18 A Well, with a big X through it. I take it --  
19 you see there's one big X in what you just handed to  
20 me?

21 Q I do.

22 A You'll see that less than 10 percent, in

1 parentheses, in the line that starts with that "less  
2 than 10 percent" in parentheses, I take it that the X  
3 is supposed to strike that entire passage. Is that  
4 right?

5 Q So that could be reflected, instead of the box  
6 bracket, as a bubble of moved text, couldn't it?

7 A Yes. I inserted the word "reduction" for  
8 clarity so it's not it exactly, but yes, I mean, we're  
9 -- it could have been.

10 Then you struck out "on the contrary, the  
11 number of campylobacter on the positive chickens was  
12 significantly reduced," figure 7(b), which, of course,  
13 I don't refer to the figure.

14 JUDGE DAVIDSON: All right. Let's stop for a  
15 second.

16 THE WITNESS: Okay.

17 JUDGE DAVIDSON: Why don't you go through it  
18 again? Remember what the question was.

19 THE WITNESS: He said what are the  
20 differences.

21 JUDGE DAVIDSON: No, no. He asked you if that  
22 adequately reflected your testimony, as it changed the

1 actual language of the Rosenquist exhibit.

2 THE WITNESS: Thank you, your Honor.

3 JUDGE DAVIDSON: You started off by saying no,  
4 because you've got the main -- you meant everything  
5 that's in there, you covered -- but that's not what the  
6 question was.

7 THE WITNESS: I just said because he nuked  
8 this out.

9 JUDGE DAVIDSON: You can note what you want.  
10 I'm going to allow you time to look at it and decide  
11 whether or not that accurately reflects what you just  
12 testified to as far as differences between your  
13 testimony, the quote, and the material in the exhibit.

14 THE WITNESS: Thank you, your Honor.

15 JUDGE DAVIDSON: Okay. Off the record.

16 (Off the record.)

17 JUDGE DAVIDSON: I wasn't eavesdropping, but I  
18 couldn't help hearing what you were talking about and I  
19 guess the answer is the record will speak for itself.  
20 We have everything in here.

21 We have -- and you'll correct me if I'm wrong,  
22 Dr. Cox. Your position is even though the quote is

1 inaccurate as a quote, it doesn't change the meaning of  
2 what you meant to say.

3 THE WITNESS: Yes, your Honor.

4 JUDGE DAVIDSON: Okay.

5 Move on, please.

6 MR. SPILLER: Your Honor, may I preserve this  
7 by moving in evidence what's been marked as G-1813 as  
8 an indication of the difference between that which was  
9 quoted from and the quote that appeared?

10 JUDGE DAVIDSON: No, not this way, because  
11 we've got your scratching on there, which the witness  
12 seems reluctant to accept, although the record does  
13 speak for itself. If you want to put in a copy -- is  
14 G-1813 in the record already without your markings on  
15 it?

16 MR. SPILLER: Yes, your Honor. It is a part  
17 of G-1788 as reflected on that page. It's page 10  
18 there.

19 JUDGE DAVIDSON: Page 10 of 1788. Well, it's  
20 already in the record, so I won't receive 1813, because  
21 I can't get agreement from this side, but I can figure  
22 it out myself whether I like your hand scratching or not.

1 MR. SPILLER: Thank you, your Honor.

2 BY MR. SPILLER:

3 Q And Dr. Cox, after all of this, did the  
4 process that you followed in determining how to quote  
5 this accord with your typical standards for the process  
6 of quoting scientific work?

7 A In the process of trying to give sufficient  
8 information for you to find a cite, read it yourself,  
9 see if what I said is correct, which is -- let me back  
10 up. This is not -- the deletion of figure -- there are  
11 several things on here. The deletions of references to  
12 the figure --

13 JUDGE DAVIDSON: Excuse me, Doctor. I think  
14 you've already explained what's going on. You've  
15 already explained that it doesn't change your testimony  
16 or the import of it, so you don't have to go into that  
17 again.

18 THE WITNESS: Right. But he's saying --

19 JUDGE DAVIDSON: The question was -- the  
20 question was is this the way you quote scientific  
21 articles.

22 THE WITNESS: Right.

1           JUDGE DAVIDSON: And the answer is either yes  
2 or no, and then you can explain.

3           THE WITNESS: Your Honor, I was just about to  
4 give, I hope, a responsive answer. How I quote  
5 scientific articles depends on the purpose and context  
6 of the quote. In all of the cases, if I'm not  
7 referring to figures, specialized to the context such  
8 as 7(a) and 7(b) and something that I pull out, or if a  
9 reference, for example, a number is given, reference  
10 17, that's not pertinent to the content, I would not  
11 feel obliged to repeat those typographical marks in the  
12 quoted section -- for example, in a journal article.

13           However, in a journal article, I would try to  
14 quote in extenso, if necessary, to get the whole thing  
15 in, leaving out only the figure 7(a), figure 7(b),  
16 perhaps numbered references that wouldn't mean anything  
17 in the context of my quote.

18           In this context of giving my direct testimony,  
19 my emphasis was on finding the supporting quote and  
20 giving it in enough detail and adequate citation so  
21 that everyone could see what I was talking about. And  
22 so that's a somewhat different context from a journal

1 article, for example.

2 BY MR. SPILLER:

3 Q I'll ask a slightly different question. Dr.  
4 Cox, for the purpose of your sworn, ratified, written  
5 direct testimony in an administrative hearing before  
6 the Food and Drug Administration, do you consider this  
7 to be an example of a fair quote from you?

8 A I think that correcting the punctuation and  
9 putting in the S -- I think that's fair. The how to  
10 deal with the sentence break around the deleted figure  
11 reference, in light of our long discussion, I question  
12 in my own mind whether it would have been useful to  
13 have quoted the entire thing either though that would  
14 be duplicating material already in there.

15 Substantially, I believe this is a fair quote.  
16 I don't think anything is misrepresented that he said  
17 and I think it's an important and pertinent point.

18 Q So as we look at all of your quotes -- and I  
19 promise the record I will not do this with all of them  
20 -- we should expect this same standard to have been  
21 followed throughout your testimony.

22 MR. NICHOLAS: Asked and answered, your Honor.

1 THE WITNESS: You can expect -- check them  
2 out.

3 BY MR. SPILLER:

4 Q I think that teaches us what we need to know,  
5 Dr. Cox. Thank you.

6 A Uh-huh.

7 Q In that original text, among the omitted text  
8 are the very first four words of paragraph 7.2.2  
9 revealing that all of this is derived from a  
10 simulation, isn't it?

11 A Well, actually, it looks to me that this is  
12 derived from several simulations.

13 Q And simulations isn't revealed in your version  
14 of the quote, is it?

15 A There's a lot of stuff that's in the  
16 Rosenquist article that I didn't quote, yes. Only the  
17 pertinent parts are here.

18 JUDGE DAVIDSON: I think the question was in  
19 your version of the quote -- now, if we have to say the  
20 quote referred to on page 10, then we will, but your  
21 answer dealt with the entire article, and that wasn't  
22 the question.

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1 THE WITNESS: I'm sorry, your Honor. I'll try  
2 to be more responsive.

3 JUDGE DAVIDSON: Thank you.

4 THE WITNESS: No, I did not repeat that this  
5 was a simulation model.

6 BY MR. SPILLER:

7 Q You not only didn't repeat it, you didn't say  
8 it the first time, did you?

9 A I'm not sure what the first time is. I  
10 pointed out I quoted Rosenquist. Many times I've  
11 certainly cited it as an example as a ~~form for~~ <sup>farm-to-fork</sup>  
12 simulation model and I presume some familiarity with  
13 the -- with what's gone before.

14 Q So the linear relationship that Rosenquist  
15 referred to in another part of that same article, you  
16 contend that FDA is in error in depositing a linear  
17 relationship between the ~~flat~~ <sup>flock</sup> prevalence and the  
18 fraction of positive chickens, right? Excuse me. The  
19 ~~flat~~ <sup>flock</sup> prevalence and the incidence of campylobacteriosis  
20 in humans.

21 A That's importantly incorrect. The linear  
22 relationship -- the relationship that I claim is not

1 linear and that Rosenquist demonstrates is not linear  
2 is between microbial load on chicken, not prevalence.  
3 And this is a crucial distinction because it's  
4 microbial ~~load~~<sup>load</sup> and microbial load only that caused  
5 campylobacteriosis. This is the relevant exposure  
6 metric.

7 If Enrofloxacin is used or is not used, it  
8 changes microbial load. Now, he subsequently did a  
9 calculation about prevalence, which is a different  
10 concept. Prevalence says not, <sup>"How</sup> ~~how~~ many microbes is this  
11 chicken <sup>carrying?"</sup> ~~carrying, prevalence~~ says, <sup>"What</sup> ~~what~~ fraction of  
12 flocks in this case have at least some campylobacter  
13 <sup>present?"</sup> ~~present.~~

14 And to me it's fundamental that we can predict  
15 risk from microbial load. We cannot predict risk from  
16 prevalence, as Rosenquist so nicely shows.

17 Q Well, let's see what Rosenquist so nicely  
18 shows. On page 10 of G-1788, in the left-hand column,  
19 the first complete paragraph, Rosenquist says, doesn't  
20 she, that the flock prevalence is 1 to 1 relationship.  
21 That's linear, right?

22 A Actually, no. Unfortunately, any shape is 1

1 to 1; but she does mean any -- I was wrong there, not  
2 any shape, but a great many shapes are also 1 to 1.  
3 She means a direct proportional relationship.

4 Q She means linear, doesn't she?

5 A She means linear, and not only linear, but  
6 direct proportion. But notice she's not changing  
7 microbial load.

8 Q Yes, I do notice that. She says that there is  
9 a 1 to 1 relationship, direct proportional, as you have  
10 described, between the two parameters. And the two  
11 parameters she's talking about is flock prevalence and  
12 human campylobacteriosis cases, right? That's flock  
13 prevalence of campylobacter on the chickens.

14 A This is -- as you read the article, you'll  
15 notice this is specifically in simulation runs where  
16 the microbial load <sup>is</sup> ~~has~~ held constant. So, for example,  
17 it would be irrelevant to any situation that changed  
18 microbial load, such as all the situations I'm looking  
19 at where Enrofloxacin use is contemplated.

20 Q And the linear relationship between flock  
21 prevalence for campylobacter contaminated chicken to  
22 human campylobacteriosis cases is an ingredient of the

1 FDA risk assessment model, isn't it?

2 A No. You're taking this completely out of  
3 context, I believe. Her claim is that if you double  
4 the proportion of flocks that have some campylobacter  
5 in them, so they'd be called campylobacter-positive  
6 flocks, and if you leave microbial load in those flocks  
7 unchanged, so basically you have twice as many flocks  
8 as you did before and they're identical in terms of  
9 microbial load distribution as what you had before,  
10 then you've in essence doubled the size of your problem  
11 and you should expect to double the number of  
12 illnesses, all else being constant.

13 Now, in the CVM risk model there is no choice  
14 but to leave all else constant. In the Rosenquist  
15 model, as this exhibit that you're helpfully putting up  
16 shows, a 10 percent change in microbial load leads to a  
17 30-fold change in illness rates, which is extremely  
18 non-linear. And the reason is that in this model, as  
19 it should be, it's only the high microbial loads that  
20 are causing illnesses.

21 So for you to say that CVM incorporates an  
22 important component is to leave out everything

1 important which is in simulation runs where microbial  
2 load doesn't change, for example, because there's no  
3 manipulation of Enrofloxacin use.

4 Q So referring to G-1788 at page 11 and graphs  
5 that you just mentioned, in figure 6(c), that depicts,  
6 does it not, flock prevalence compared to the number of  
7 human cases per 100,000 population, and we're talking  
8 about cases of campylobacteriosis, right?

9 A It refers to -- if you read the legend you'll  
10 see where it refers to simulation sampling points  
11 around the fitted line. So it refers to it for  
12 specific simulation scenarios that do not include  
13 change in microbial load.

14 The changes in microbial load are described in  
15 7.2.2 in the passage that we so artistically  
16 deconstructed.

17 Q If I ask you about changes in microbial load I  
18 hope you'll answer that. Until then, would you let  
19 your counsel ask you the questions about microbial  
20 load.

21 A Yes, but you asked whether this is what CVM --  
22 whether this component was also an important component

1 of CVM's risk assessment, and the answer is no. CVM  
2 goes far beyond what Rosenquist has done. You're  
3 taking an implicit, and in some places explicit,  
4 assumption of Rosenquist and extrapolating it to an  
5 entire model as if to say microbial loads can never  
6 change.

7 That's what's in the CVM model.

8 Q Dr. Cox, would you listen carefully in the  
9 next question for the terms microbial load or FDA  
10 model?

11 A I will do so, yes.

12 Q In Rosenquist G-1788, page 11, figure 6, am I  
13 right that figure 6(a) depicts a linear relationship  
14 between flock prevalence and fraction of campylobacter  
15 positive chickens at the end of slaughter?

16 A For the simulation runs, yes.

17 Q And similarly, in that same figure, figure  
18 6(c) depicts a linear relationship between flock  
19 prevalence and number of human cases per 100,000  
20 population.

21 A An approximately linear relationship for these  
22 simulations. The reason I'm saying that is it's not a

1 general relationship. It's a relationship conditioned  
2 on what we just talked about, which is holding  
3 microbial load constant.

4 Q And in the bounds discussed in this paper, if  
5 among three relationships A's relationship to B is  
6 linear and if B's relationship to C is linear, isn't it  
7 true that A is linearly related to C?

8 A Actually, not necessarily, but you're falling  
9 into I think just the perhaps confusion that I was  
10 trying to clarify which is these are not general  
11 relationships. These are plots of perhaps 8 different  
12 simulation run outputs.

13 To that, you're trying to attach a general  
14 rule which is that human illness is proportional to  
15 flock prevalence. I'm telling you that general rule is  
16 an incorrect generalization because in general,  
17 microbial loads are not held constant as they are in  
18 these simulations.

19 Q And does Rosenquist use a microbial load  
20 distribution?

21 A Yes, she does, as in the famous paragraph.

22 Q And does Rosenquist have a dose response model

1 in this paper?

2 A Rosenquist uses a dose response model, yes.

3 Q And yet they have the same linear relationship  
4 as the CVM model?

5 A Absolutely not. I mean, look at this  
6 paragraph that we just spent half an hour on. It says  
7 a 10 percent change in microbial load leads to a 30-  
8 fold change in human illness. That's about as non-  
9 linear as you can get. Three log units.

10 Q And in the CVM risk assessment, what explicit  
11 assumption did CVM make about the distribution of  
12 microbial load?

13 A It -- the word explicit there -- actually, I'm  
14 not sure what you're fishing for. What explicit  
15 assumption did they make?

16 Q Please presume that I'm not fishing and just  
17 answer the question.

18 A Sorry. I don't know what assumption you're  
19 referring to.

20 MR. NICHOLAS: Your Honor, I object.

21 JUDGE DAVIDSON: What's the objection?

22 MR. NICHOLAS: If there is a place in the

1 document that counsel is referring to in the risk  
2 assessment, he should do that rather than ask the  
3 witness what the document says.

4 JUDGE DAVIDSON: Well, the witness has been  
5 told more than once that if he's unfamiliar with the  
6 material, he can ask for the document. I know you like  
7 to help him.

8 THE WITNESS: Your Honor, I do feel familiar  
9 with the document, but for explicit -- here's what they  
10 say about microbial load.

11 JUDGE DAVIDSON: Wait a minute. Let's not  
12 just pontificate every time you feel like it's  
13 important to do so. I think you're not answering the  
14 questions precisely. I'll allow you to explain every  
15 answer you give, but every time you get a question, it  
16 seems to me -- and I don't claim any scientific  
17 expertise whatsoever -- it seems to me that what you do  
18 is you anticipate what counsel is trying to show and  
19 you answer that instead of answering the question and  
20 then working on the anticipation of what he's trying to  
21 do.

22 For example, I heard him several times ask you

1 to listen for the words "microbial load." You didn't  
2 hear it, and yet every answer included reference to it.  
3 And I understand why, but the point is I want you to  
4 first answer the question and then if you feel you have  
5 to add some explanation, do so.

6 But the trouble is -- and you just said so  
7 yourself, you don't know what he's driving at so you  
8 can't answer the question. Well, you're not supposed  
9 to worry about what he's driving at at this point. If  
10 you feel that the answer you've given somehow leaves  
11 the wrong inference on the record, you can explain  
12 that.

13 THE WITNESS: Thank you, your Honor.

14 JUDGE DAVIDSON: Please pay careful attention  
15 to the question, try to answer it specifically, and  
16 then if you feel there's more needed, go right ahead  
17 and do so.

18 THE WITNESS: Thank you, your Honor. In this  
19 case your question is what explicit assumption did CVM  
20 make about microbial load. Is that correct?

21 BY MR. SPILLER:

22 Q Yes.

1           A     Okay. I was hung up on which of the many  
2 assumptions, some explicit, some subsequently  
3 described, by CVM as being implicit but not explicitly  
4 stated you were thinking of. And I apologize for  
5 saying "fishing"; it's whatever you're thinking of.

6                     The assumptions that they make -- I'm going to  
7 let "explicitly" go because, as I said, they talk about  
8 implicit later on and it's not clear to me what is now  
9 -- any more what's explicit and implicit. But what  
10 they say about microbial load, if that's your question,  
11 if I'm hitting the right target here, is --

12                    JUDGE DAVIDSON: I'm sorry, Doctor. The  
13 answer is you don't know what he's referring to. You  
14 want to see what explicit -- you don't have to explain  
15 all the rest of it. You've already said you don't  
16 know --

17                    THE WITNESS: I don't know what explicit  
18 assumptions you're referring to. Thank you.

19                    BY MR. SPILLER:

20                    Q     I will try to look up a reference to offer  
21 you, Dr. Cox, and we'll come back to that.

22                    A     Thank you. Okay.

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1 Q Turning to a different exhibit, which is  
2 already in the record, B-1886, the ~~Rodriguez~~<sup>Rodrigues</sup> paper, and  
3 I think to put it in context, in your testimony on page  
4 15 --

5 JUDGE DAVIDSON: I'm going to interrupt you,  
6 Mr. Spiller.

7 MR. SPILLER: Yes, your Honor.

8 JUDGE DAVIDSON: B-1886. It must have another  
9 number, because it's not listed here. It's not moved  
10 into evidence by Bayer.

11 MR. SPILLER: G-1711, I'm told, your Honor, is  
12 the corresponding number. I believe that's one of  
13 those that we discussed this morning that I failed to  
14 remember just now.

15 MR. NICHOLAS: I believe that's correct, your  
16 Honor, G-1711.

17 MR. SPILLER: Thank you, Mr. Nicholas. I  
18 apologize, your Honor, for the delay. I'm groping for  
19 the citation here.

20 JUDGE DAVIDSON: That's okay.

21 BY MR. SPILLER:

22 Q Dr. Cox, on page 15 of your testimony in the

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1 top paragraph, the last sentence of that top paragraph,  
2 do you see a sentence that begins "second, it  
3 incorrectly identifies"?

4 A Uh-huh.

5 Q And the "it" there is a reference to CVM's  
6 risk assessment, specifically its hazard  
7 identification?

8 A Yes.

9 Q And your concern there, the defect that you  
10 see, is that FDA incorrectly identifies domestic  
11 chicken-borne Fluoroquinolone-resistant campylobacter  
12 as the predominant cause of adverse health effects,  
13 right?

14 A In this context, yes.

15 Q And you cite two papers by Cox and one by  
16 ~~Rodriguez~~ <sup>Rodriguez</sup> for -- and specifically ~~Rodriguez~~ <sup>Rodriguez</sup> you're  
17 citing for the fact that these effects are demonstrably  
18 caused by other factors, including foreign travel and  
19 restaurant dining. Am I right?

20 A Almost. The demonstrably is only partially  
21 covered. I'd say for ~~Rodriguez~~ <sup>Rodriguez</sup> it's suggested.

22 Q I hand you now what is printed -- marked with

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1 B-1886 and which I have marked by hand G-1711 so that  
2 it will correspond correctly, and ask you if that's the  
3 ~~Rodriguez~~ <sup>Rodrigues</sup> paper.

4 A Yes. This is the ~~Rodriguez~~ <sup>Rodrigues</sup> paper.

5 Q And it doesn't have restaurant dining factored  
6 as a predominant cause, does it?

7 A I believe that it does. If you look at page 5  
8 of the exhibit, the right-hand column, middle  
9 paragraph, beginning "only two factors were  
10 significantly associated with increased risk of  
11 campylobacteriosis, travel abroad and eating chicken at  
12 a restaurant or a canteen."

13 Q So it mentions chicken in a restaurant or a  
14 canteen, does it?

15 A Yes. That's right.

16 Q And in your quote you said it was restaurant  
17 dining, not including chicken, right? The not  
18 including chicken is my interpretation. In your quote,  
19 you didn't mention chicken like ~~Rodriguez~~ <sup>Rodrigues</sup> did.

20 MR. NICHOLAS: I'm going to object, your  
21 Honor. There's no quotation in Dr. Cox's testimony --  
22 it's not quoting verbatim --

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1 JUDGE DAVIDSON: Sustained.

2 MR. SPILLER: I acknowledge Mr. Nicholas'  
3 *objection*  
~~direction~~. The statement by Dr. Cox was not at that  
4 point purporting to be a quote.

5 BY MR. SPILLER:

6 Q Dr. Cox, I'll restate my question to avoid the  
7 error that I introduced, and I'm sorry for that.

8 A Thank you.

9 Q Do I understand that your allegation in your  
10 testimony is that contrary to FDA's viewpoint, it is  
11 not correct to attribute this to chicken, but you  
12 attribute it to restaurant dining and for that, you  
13 cite *Rodriguez*  
~~Rodriguez~~?

14 A That's a compound sentence. I cite *Rodriguez*  
~~Rodriguez~~  
15 to support the idea travel abroad and consumption of  
16 chicken in a restaurant are associated with being a  
17 cause, but that there is no statistically significant  
18 risk associated with consumption of chicken, other than  
19 in restaurants.

20 Q We'll agree, then, that the *Rodriguez*  
~~Rodriguez~~ article  
21 includes chicken in its attribution of risk to  
22 restaurant dining. Is that correct?

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Rodriguez

1           A     Well, again, what ~~Rodriguez~~ says, being  
2 careful to exactly quote his words, in the abstract on  
3 page 1, fourth line, sentence starting at the end of  
4 that line, where travel, he says two things -- two main  
5 things.

6                     Travel abroad and consumption of chicken in a  
7 restaurant were statistically associated with being a  
8 cause -- so yes, he talks about chicken in a  
9 restaurant. But he continues -- "but" is my  
10 interpolation -- but "there was no statistically  
11 significant risk associated with consumption of chicken  
12 other than in restaurants."

13                    Now, I cite this as suggestive, although not  
14 yet demonstrative, of the fact -- or of the hypothesis,  
15 I should say, that restaurants are the problem,  
16 chickens are not.

17           Q     I wonder -- you say you cited it as suggestive  
18 and not --

19           A     Conclusive. Right. Demonstrative.

20           Q     -- demonstrative, but your testimony is that  
21 these are demonstrably caused by other factors. That's  
22 what your testimony says, right?

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1 A It is. And as I said, I cited myself and my  
2 own causal analysis for the demonstrably part because  
3 Rosenquist didn't demonstrate, he only suggested.

4 Q And in this --

5 A Oh, I'm sorry. Did I say Rosenquist?

6 Q Yes, and I think you meant <sup>Rodrigues</sup> ~~Rodriguez~~.

7 A I meant <sup>Rodrigues</sup> ~~Rodriguez~~. Thank you.

8 Q And in the <sup>Rodrigues</sup> ~~Rodriguez~~ study that we've been  
9 looking at, they actually were able to explain only 20  
10 percent of the Fluoroquinolone-resistant campylobacter  
11 cases. The chicken consumption in restaurants that you  
12 mentioned was the largest of those, and travel was the  
13 next of those, leaving approximately 80 percent  
14 unexplained. Am I right?

15 I'm sorry. I combined questions, didn't I?  
16 Am I right that chicken was -- chicken consumption in  
17 restaurants was the largest factor found by <sup>Rodrigues</sup> ~~Rodriguez~~  
18 in that paper?

19 A I can -- do you want to give me -- are you  
20 looking at table 1?

21 Q Look at page 5.

22 A Yes. Uh-huh.

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1 Q I think in the right-hand column, the  
2 paragraph that begins with only two factors --

3 JUDGE DAVIDSON: That's already been -- it's  
4 on the record. The witness, in answering a previous  
5 question, referred to that, so I don't think we need it  
6 a fourth or fifth time.

7 MR. SPILLER: Sorry, your Honor. Thank you,  
8 your Honor.

9 BY MR. SPILLER:

10 Q Now, moving to a reference also on page 15,  
11 you cite in the -- excuse me -- page 15 of your  
12 testimony, that's B-1901, the second paragraph, you  
13 show -- which I believe is G-1681 in this record --

14 A Uh-huh.

15 Q I'm handing you now a copy of that. I have  
16 one for the Court.

17 A Is it too late for me to add something to my  
18 response to your question about the <sup>Rodriguez</sup>~~Rodriguez~~ paper?

19 Q No, that's why we have redirect, and there  
20 will be an opportunity, I'm sure, when your counsel  
21 asks you questions on that.

22 A Okay. Thank you.

1 Q You cite Michaud a number of times in your  
2 testimony, don't you, Dr. Cox?

3 A Michaud, yes.

4 Q You mention at page 20 of your testimony in  
5 the bottom large paragraph, about halfway down, at the  
6 beginning of the line you have Cox 2001 and then right  
7 after that, a recent prospective control study from  
8 Quebec, and that's where you cite Michaud --

9 A Yes.

10 Q -- identifies poultry as the principal  
11 suspected source of infection in only about 10 percent  
12 of the cases.

13 A Uh-huh.

14 Q You made that comparable to drinking tap water  
15 at home.

16 A He, I think, may have made it comparable.

17 Q And am I correct that that study did not  
18 determine any source in quoting 9 percent of the cases.

19 A Give me a moment, please.

20 (The witness examined the document.)

21 Q And of course read the entire eight-inch tall  
22 article, but if you look at the last line of the text

1 right above "preliminary results."

2 A Yes. Okay. So that sentence, the one we're  
3 looking at, says consumption of poultry, 10 percent and  
4 contaminated water, 9 percent, were the principal  
5 suspected sources of infection. The source was  
6 unknown, he says in 49 percent of the cases, although I  
7 suspect on the basis of what's here that it may not  
8 have been known in the other 51 percent as well, it  
9 says suspected versus known.

10 Q And am I correct, Dr. Cox, that in 48 percent  
11 of the cases the persons involved in this did not clean  
12 their cutting boards after handling raw meat or poultry  
13 and these were the cases and the controls answered that  
14 question, only 18 percent of them?

15 A You've asked me to answer a question that goes  
16 beyond what's shown here. The true percentage of the  
17 consumers who wash their hands after handling raw meat  
18 or presumably raw poultry is reported, but that's not  
19 the same as the true number.

20 So in other words, you have to -- it's as we  
21 were discussing yesterday. You have to bear in mind  
22 that these are responses to the surveys, so I can't

1 answer what was the true number. I can only say what  
2 the people that called --

3 JUDGE DAVIDSON: Doctor, I don't think you  
4 were asked to answer what the true number was. He  
5 referred you to a portion of the exhibit and he said --  
6 I mean, I assume it's preliminary, otherwise why would  
7 he ask? It's already in the exhibit.

8 He asked you does it say that 48 percent of  
9 the cases -- cutting board -- and then you go and tell  
10 me that's not the true number. Well, that's not  
11 answering the question.

12 If it's a preliminary question, he just wants  
13 you to agree that that's what it says. Then he'll ask  
14 another question. If he doesn't, I'll rule the whole  
15 line out, okay?

16 THE WITNESS: But your Honor, it refers --

17 JUDGE DAVIDSON: But you're not testifying to  
18 what's in this exhibit. The exhibit speaks for itself.  
19 He's asking you --

20 THE WITNESS: Well, if he's saying doesn't it  
21 say this and it doesn't say that --

22 JUDGE DAVIDSON: It doesn't say 48 percent are

1 not cleaning --

2 THE WITNESS: It says 48 percent. It doesn't  
3 say 48 percent of cases.

4 JUDGE DAVIDSON: I see it says 48 percent of  
5 cases did not clean the cutting board after handling  
6 raw meat or poultry. Now, is that not what it says? I  
7 don't mean to interrupt or interfere, but the point is  
8 let's get to the question he wants to ask instead of  
9 belaboring what may or may not be the next question.

10 That's's what you're doing again. You're  
11 looking forward to what he's trying to show. Let's let  
12 him do it first.

13 THE WITNESS: Okay. Thank you. Yes, it does  
14 say that.

15 BY MR. SPILLER:

16 Q Dr. Cox -- in the next-to-last sentence,  
17 right?

18 A Yes. Your Honor is correct.

19 Q And isn't the signal in that that one of the  
20 differences indicated by the study is that people who  
21 don't clean the cutting board have a higher likelihood  
22 -- excuse me -- don't clean the cutting board after

1 handling raw meat or poultry have a higher likelihood  
2 of becoming a case instead of a control? And a case is  
3 a person who suffers from campylobacteriosis.

4 A Just a moment.

5 JUDGE DAVIDSON: Certainly.

6 THE WITNESS: Thank you. This article doesn't  
7 discuss or this abstract doesn't discuss whether the  
8 design is prospective, saying if you have poor kitchen  
9 hygiene are you more likely to get campylobacteriosis  
10 or whether it's retrospective, meaning if you got  
11 campylobacteriosis, it's more likely that you had poor  
12 kitchen hygiene.

13 Your question was is it more likely you're  
14 going to get sick if you don't wash your hands, if I  
15 understand it correctly. This may be showing if you  
16 ask people who are sick, hey, did you wash your hands,  
17 more of them will say no, which is the point -- the  
18 distinction I was aiming at before.

19 BY MR. SPILLER:

20 Q Did my question say anything about washing  
21 hands?

22 A Let me see. Washing hands -- so -- excuse me.

1 Cleaning the cutting board. I'm sorry.

2 Q So whether it's prospective or  
3 retrospective --

4 A Same issue.

5 Q It is the same issue, and isn't the signal  
6 here that persons who do not wash the cutting board  
7 after cutting meat or poultry were more likely to be  
8 cases than controls, whether mentioned on something in  
9 the past or prospectively?

10 A No. What it could be showing is that people  
11 who are asked, after they become cases, did you wash  
12 your cutting board, are more likely to respond no.

13 Q On page 56 of your testimony, Dr. Cox, you  
14 refer again to this paper. Let me know when you find  
15 that page.

16 A I'm there.

17 Q There are three paragraphs beginning with the  
18 word note, and in the second of those on line 3, you  
19 refer to the Michaud paper and you say that Michaud  
20 suggests at most a 10 percent fraction, right?

21 A Uh-huh. Yes.

22 Q Didn't we just agree that he only identified a

1 total of 19 percent?

2 A Of suspected --

3 Q I'm sorry. 51 --

4 A Go ahead.

5 Q He only identified a cause for roughly half of  
6 those, right?

7 A I don't believe he's identified any causes.

8 Q He only identified these sources, these  
9 factors.

10 A Yes. That's right.

11 Q And so do you agree it's not fair to say that  
12 at most 10 percent since any of the unattributed 49  
13 percent could fall either in the eventually associated  
14 with poultry column or not?

15 A I don't think that's correct, but -- and the  
16 reason is what exactly does "unattributed" mean here.  
17 you know, is it unattributed because there was no  
18 evidence that this was the source? So let me take a  
19 minute to read this carefully again.

20 JUDGE DAVIDSON: I think we'll take a short  
21 recess. Be back at a quarter of.

22 (A brief recess was taken.)

1 JUDGE DAVIDSON: Mr. Spiller.

2 MR. SPILLER: Thank you, your Honor.

3 BY MR. SPILLER:

4 Q Dr. Cox, would you turn to page 25 of your  
5 written direct testimony, please?

6 A I will. Should I finish answering the  
7 question when -- you were waiting for my answer when we  
8 broke off.

9 JUDGE DAVIDSON: Okay. He's right. I don't  
10 remember the question, but I will have the reporter  
11 read it back.

12 THE WITNESS: Thank you.

13 (The reporter read back the record.)

14 JUDGE DAVIDSON: Okay. You can answer.

15 THE WITNESS: My answer is that I do not  
16 believe that that is unfair, and that I believe that it  
17 is suggested in the first sentence of his conclusion.

18 BY MR. SPILLER:

19 Q Dr. Cox, referring to Michaud Exhibit G-1681,  
20 if any of the cases where the cutting board was not  
21 washed after handling raw meat or poultry were  
22 attributable to not washing the cutting board after

1 handling poultry, wouldn't that raise the factor  
2 related to poultry to above 10 percent?

3 A Not necessarily, no. That's not how  
4 attribution calculations are done.

5 MR. SPILLER: I won't ask further questions  
6 about that exhibit, your Honor.

7 BY MR. SPILLER:

8 Q Now, Dr. Cox, would you turn to page 25 of  
9 your testimony?

10 A Uh-huh. Okay.

11 Q In the second full paragraph of that page, am  
12 I correct you firmly criticize FDA's model by saying  
13 that it lacked widely accepted intellectual  
14 foundations, offered meaningless numbers based upon  
15 concepts that are useless and it incorrectly interprets  
16 these meaningless numbers? You had all of those things  
17 in that paragraph, don't you?

18 A The paragraph is what it is.

19 JUDGE DAVIDSON: You're supposed to answer the  
20 question. We know the paragraph is what it is. We  
21 know it's on the record, but he's asking -- as I told  
22 you before, and I don't want to have to tell you again,

1 it may be preliminary to something else. If it's not,  
2 I'll rule it out myself. But it's a simple question,  
3 it's a simple answer.

4 Either it does or doesn't. You either agree  
5 or you don't agree, and you say it says what it says.  
6 I mean, that's not an answer. It's obvious. Everyone  
7 knows it says what it says. You were asked a specific  
8 question. Answer it or say you don't know or you can't  
9 answer it but you can't avoid it.

10 THE WITNESS: Thank you, your Honor. Those  
11 were fragmentary quotes.

12 JUDGE DAVIDSON: Well, then you don't agree  
13 that you said that.

14 THE WITNESS: Yeah.

15 JUDGE DAVIDSON: Okay.

16 BY MR. SPILLER:

17 Q Did you say within quote marks in that  
18 paragraph that FDA is based on a technically deficient  
19 concept such as, quote, average exposure for an average  
20 individual?

21 A Yes.

22 Q And you know, Dr. Cox, don't you, that FDA's

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1 risk assessment did not rely on average exposures for  
2 average individuals?

3 A I do not know that.

4 Q Would you refer to the risk assessment, then,  
5 at page 69? The risk assessment is Exhibit G-953.

6 MR. NICHOLAS: I'm sorry, your Honor. What  
7 page is that?

8 MR. SPILLER: 69.

9 BY MR. SPILLER:

10 Q And on that page -- Dr. Cox, do you have that  
11 page?

12 A Yes, I do.

13 Q You find a paragraph numbered very near bottom  
14 4(c)?

15 A Yes, I do.

16 Q And does it not there describe an annual value  
17 representing measurable human exposure to ~~chickenless~~<sup>chicken, less</sup>  
18 products and a number of sources?

19 A Yes.

20 Q Does that not describe a cumulative exposure  
21 rather than an exposure only calculated from averages?

22 A It looks to me like it says 50.8 pounds per

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1 capita. Yes, I interpret it as an average.

2 Q And if I heard that right, which you  
3 interpreted as an average.

4 A I didn't say "which I interpreted". Which I  
5 know, as I sit here, interpret as an average, yes, per  
6 capita. Uh-huh.

7 Q And was that the source of your attribution to  
8 the CVM risk assessment in your testimony at page 25,  
9 second paragraph, that CVM average exposure for an  
10 average individual?

11 A It was not.

12 Q I don't want to put you to read through this  
13 now but can you remember and help us find in this  
14 document any place where FDA said that it was the  
15 average exposure to an average individual?

16 A I believe that that phrase came not from this  
17 document but from part of the back and forth on the ~~noo~~<sup>NOOH</sup>  
18 page.

19 Q And so if -- it did, Dr. Cox, and we're  
20 talking about the risk assessment, which do you think  
21 is the most authoritative and prime source of what the  
22 risk assessment said?

1           A     You mean the risk assessment itself or the CVM  
2 assessment?

3           Q     Yes.

4           A     I assume in the context of this hearing that  
5 what they have said about their use of risk assessment  
6 represents their use of what they meant about it.

7           Q     And so knowing that disparity, for your  
8 testimony you chose to rely on an answer which may have  
9 had some attorney's mistake in it and characterized it  
10 to the risk assessment.

11           MR. NICHOLAS: I object, your Honor. There's  
12 no evidence of disparity --

13           JUDGE DAVIDSON: Overruled.

14           THE WITNESS: I don't believe that I relied --  
15 no, I don't think that I did rely on this. Even your  
16 question about total versus average, since we're  
17 dealing with proportions, I have a hard time -- I don't  
18 think I relied on any such distinction.

19           BY MR. SPILLER:

20           Q     So far as you can recall now -- and I  
21 apologize if this is a repeat question -- nothing that  
22 you can direct us to in the risk assessment where you

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1 say it says the average exposure for an average  
2 individual --

3 A Well, let's get to it. If we look at -- I  
4 opened at random at a good place. If we look at page  
5 19, there's a figure showing what kind of exposure is  
6 considered in quantifying human health impacts in this  
7 model.

8 Are we on the same page?

9 Q I'm on page 19. Are you on page 19?

10 A I am.

11 Q Got it. And we're looking for a mention in  
12 quotes of average exposure for an average individual.

13 A No. I'm not looking for those words. I am  
14 looking for these words: human health impact, <sup>lambda</sup>~~lambda~~, is  
15 equal to some constant,  $k$ -res, times the pounds of  
16 chicken consumed with Fluoroquinolone-resistant  
17 campylobacter. And my point is that this is describing  
18 risks to a typical on average a representative  
19 consumer.

20 I know that's been stated and, you know,  
21 what's not here is what is the distribution of  
22 exposures for different people. So it's average

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1 exposure.

2 Q I'll try a different way, Dr. Cox. In your  
3 testimony at page 25, that second paragraph, the quoted  
4 expression average exposure for an average individual,  
5 in quotes, I thought you were attributing that to the  
6 Government Exhibit G-953. I gather for right now we  
7 don't have a source for that.

8 What source did you indicate for that? Am I  
9 correct you indicated no source for that quote?

10 A That's correct.

11 MR. NICHOLAS: Your Honor, I'm going to  
12 object. There's no indication that this is a quotation  
13 from a source. I mean, it appears from the text that  
14 the witness is emphasizing a particular term or setting  
15 it apart, not that he's attributing the quote to the  
16 risk assessment or any other document.

17 JUDGE DAVIDSON: Now that you've said that,  
18 why did you quote it? Why is it in quotation marks?

19 THE WITNESS: Your Honor, I'm pretty sure that  
20 I was using their phrase. I said in some written  
21 comments that this risk assessment doesn't look at the  
22 exposures of individuals and CVM replied in substance,

1 at least in my memory, that they didn't need to look at  
2 the different exposures for different individuals, they  
3 were relying on the average exposure of the average  
4 individual.

5 I stuck that in quotes in my testimony because  
6 it seemed to be an important concept.

7 JUDGE DAVIDSON: Well, excuse me, but when you  
8 put quotes, doesn't that mean that you're putting  
9 something in verbatim?

10 THE WITNESS: It can mean that, and --

11 JUDGE DAVIDSON: Oh, I see. It can mean other  
12 things?

13 THE WITNESS: Yes. For example, you could say  
14 this is a, quote, hypothetical. It wouldn't have to be  
15 that somebody actually said that --

16 JUDGE DAVIDSON: That's one word. I  
17 understand that. But this is a statement, a fact.

18 THE WITNESS: Yes, it is, without attribution  
19 but as a distinguishing phrase. And as I say, I do  
20 believe that it is quoted from part of the record, but  
21 I can't put my finger on it right now.

22 JUDGE DAVIDSON: I hear your explanation.

1 THE WITNESS: Okay.

2 JUDGE DAVIDSON: I can't get away with that in  
3 my decision. I can't quote from something I remember  
4 someone said without being able to attribute it. I  
5 can't quote inaccurately or I'm going to be held up to  
6 ridicule.

7 THE WITNESS: As indeed I sometimes am.

8 JUDGE DAVIDSON: Okay. Thank you.

9 BY MR. SPILLER:

10 Q Dr. Cox, on page 18 of your testimony, in the  
11 last paragraph, do you say that CVM made the utterly ad  
12 hoc and demonstrably incorrect assumption that the  
13 probability of campylobacteriosis in a person is  
14 directly proportional to the quantity of chicken  
15 consumed?

16 A Sorry. I missed that. Page 18?

17 Q We're on page 18 of your testimony.

18 A Right.

19 Q The paragraph fragment on the bottom of the  
20 page.

21 A Oh, here it is. Yes. Absolutely. Yes.

22 Q And in the page that we were working on

1 before, the risk assessment, that's Exhibit G-953 at  
2 page 69, isn't FDA's concern not with only chicken  
3 consumption but with campylobacter-contaminated chicken  
4 consumption?

5 A Yes. And they are proportional to each other.

6 Q And in your allegation, did you mention that  
7 FDA's concern was with the quantity of campylobacter-  
8 contaminated chicken consumed?

9 A No. They're all proportional to each other.

10 Q On page 54 of your testimony, Dr. Cox, you  
11 have a parenthetical reference there, which I won't  
12 reread in the record, concerning AIDS and orange juice  
13 consumption.

14 A Uh-huh. Yes.

15 Q You're not really suggesting that there's a  
16 correlation or biological relationship between AIDS and  
17 orange juice consumption, are you?

18 A Certainly not a biological relationship.  
19 There may or may not be a correlation, and I mean to  
20 make no -- it's pure example.

21 Q And so would the point we should take from  
22 that be that you're reminding us that there needs to be

1 a biologically plausible hypothesis connecting the  
2 things if we want to relate something, for instance,  
3 like campylobacter in chicken to campylobacteriosis in  
4 humans?

5 A No. That's not the point that I intended.  
6 The point was that you can divide any aggregate  
7 quantity, such as number of campylobacteriosis  
8 Fluoroquinolone-resistant campylobacteriosis cases, by  
9 any other, such as pounds of chicken meat or estimated  
10 contaminated chicken meat consumed, and thus come up  
11 with a ratio. And that does not establish a relation  
12 between them, again, quoting from all the written  
13 discussion on this, in any meaningful or useful sense.  
14 This example was intended to demonstrate that point.

15 Q And in your written testimony from last  
16 December and in your testimony today, is it your  
17 testimony that the relationship between campylobacter  
18 on poultry and human campylobacteriosis is as remote as  
19 the connection in your remark about between AIDS and  
20 orange juice?

21 A I believe that the examples are -- I attempt  
22 to suggest that the aggregate -- I'm sorry -- the ratio

1 of aggregate level of campylobacteriosis cases to the  
2 aggregate level of chicken consumption has not been  
3 shown to have any stronger causal connection than other  
4 ratios, including manifestly ridiculous ones.

5 Q Thank you.

6 A Uh-huh.

7 Q On page 18.6 of your testimony --

8 A 18.6.

9 Q -- excuse me. On page 18. I refer to the .6  
10 to help me remember that it's six-tenths of the way  
11 down the page.

12 A Got you. Uh-huh.

13 Q You say in the paragraph beginning dose  
14 response data, the second sentence -- and I just want  
15 you to confirm if I understand you correctly --  
16 nonetheless, for its campylobacter risk assessment, CVM  
17 did not perform any dose response assessment. It has  
18 thus skipped the essential content of the risk  
19 characterization dose response step and failed to  
20 complete the steps required for a risk assessment as  
21 traditionally understood.

22 Did I get that right?

1 A Yes, you did.

2 Q When you reviewed this model in 1999, were you  
3 not aware of the design of FDA's risk assessment?

4 A When I reviewed this model in 1999, was I not  
5 -- when I reviewed the risk assessment I certainly read  
6 what was written about the design.

7 Q So you certainly knew in 1999 before you gave  
8 the evaluation in December of 1999 that we discussed  
9 yesterday that FDA did not have a separate dose  
10 response model within its risk assessment. You knew  
11 that at the time in December '99, didn't you?

12 A I have recommended -- I believe that I knew  
13 that, yes.

14 Q And you didn't say then that FDA had skipped  
15 an essential content and failed to complete a required  
16 step, did you?

17 A Can you please give me a copy of the document  
18 you're looking at?

19 Q You have a copy of the document I'm looking  
20 at, Dr. Cox. It's your testimony.

21 A In my recommendations in 1999, I believe I  
22 stated that the biggest assumption and the biggest

1     invalidated assumption and the biggest assumption that  
2     I recommended should be validated was the use of the  
3     big K in place of a dose response model. I believe I  
4     noted at the time that that assumption might be flawed  
5     and I recommended that it be validated before the model  
6     be used.

7           Q     And you didn't recommend the dose response  
8     model then, did you?

9           A     I did not recommend a specific parametric dose  
10    response model. In previous correspondence to David  
11    Vose that you mentioned yesterday, I had recommended  
12    putting in dose response information although not in  
13    those words. I used mathematical symbols.

14          Q     If I gave you a copy of the transcript of your  
15    remarks there that we discussed yesterday, would you be  
16    able to find in it your explicit recommendation that  
17    the Center have a dose response model in its risk  
18    assessment?

19          A     Not necessarily in those words, but certainly  
20    the concept, yes.

21                   MR. NICHOLAS: Your Honor, Dr. Cox discussed  
22    the correspondence which I believe was G-1809 in the

1 testimony, which was G-1810.

2 JUDGE DAVIDSON: Okay.

3 BY MR. SPILLER:

4 Q Dr. Cox, I'm handing you what's marked with  
5 hand G-1810, copies provided yesterday.

6 A Thank you. This -- I'm sorry. Did you want  
7 me to find that pertinent passage?

8 Q Refer me to the part here where you explicitly  
9 recommend a dose response model.

10 A Beginning at the bottom of page 140, there are  
11 four lines in order. As you will -- I'm sorry -- and  
12 you will notice that the big assumption is that the  
13 incidence of bad outcomes more formally in response  
14 that we don't want is proportional to the volume of  
15 outgoing chicken informally the exposure, or something  
16 proportional to exposure.

17 I mean --

18 Q Dr. Cox, would you -- when you break from  
19 reading the transcript to us, would you let us know  
20 when you're breaking from that and to answer the  
21 question, would you find us the part that has an  
22 explicit reference in so many words to a dose-response

1 model.

2 A I told you I don't believe those words are  
3 there, just the concept.

4 Q Okay.

5 A And this is the place. And the next sentence,  
6 the one that says, I mean, big K is the key assumption  
7 in conjunction with the recommendations that at the end  
8 of this, that assumption be validated. That's what I'm  
9 referring to.

10 Q Dr. Cox, this is a very minor point but I'm  
11 really having trouble relating to your concept of  
12 quotation. I don't see the word "big" here. On 141,  
13 line 2, just now when you were reading to us in front  
14 of everybody, what you said -- did I hear you right?  
15 You said big K.

16 A Sorry. I thought you meant big assumption at  
17 the bottom. Yes, I said big K. Capital K. It's not a  
18 direct quote. It's a description of what's written.

19 Q Thank you. I now understand.

20 A Okay.

21 Q And I can simplify the question now based on  
22 your answer. Have you told me that this is the part

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1 that you believe is the closest you came to an explicit  
2 recommendation that FDA include a dose-<sup>response</sup>~~responsive~~ model  
3 in its risk assessment?

4 A This is the beginning. As I say, you  
5 ultimately take it with the end which makes the  
6 recommendation and a more explicit recommendation was  
7 in my correspondence with David Vose saying if I  
8 translate the math, you've got to look at microbial  
9 load, you've got to look at those responses along with  
10 all these.

11 Q And it's possible we'll get to that but this  
12 was the meeting -- this, what I'm indicating Exhibit G  
13 -- what's the number on that?

14 JUDGE DAVIDSON: 1810.

15 MR. SPILLER: I'm sorry, your Honor.

16 JUDGE DAVIDSON: 1810.

17 BY MR. SPILLER:

18 Q 1810. In 1810, this was a public meeting, not  
19 just a correspondence with a single individual, David  
20 Vose, but this was a meeting at which the Center was  
21 asking and I think you testified had paid you for your  
22 evaluation of this.

1 A Uh-huh.

2 Q And you've told us the beginning of that and  
3 in a minute you're going to tell us the end. And have  
4 you confirmed -- I think you have but I want to make  
5 sure, that dose response model is not actually -- those  
6 words, dose response model are not actually here in G-  
7 1810.

8 A Right. It's exposure and undesirable or bad  
9 effect, not dose response. The words "dose response"  
10 are not there. The concepts are in different words.

11 Q In a risk assessment, Dr. Cox, isn't dose  
12 response in the -- I think you called it a traditional  
13 understanding of very explicit identifiable separate  
14 concept, a term used amongst experts for a specific  
15 thing?

16 A It covers a range of issues.

17 Q If you were speaking to a room that had other  
18 risk assessors, risk analysts in it as well as other  
19 scientists who were not risk analysts, what are the  
20 most descriptive terms you would use for a dose-  
21 response model?

22 A I'd have -- are we speaking about individual

1 level dose-response model, are we talking about a  
2 mixture distribution model for a population  
3 concerning --

4 Q I'm talking about the dose response model that  
5 you now say FDA should have included in its risk  
6 assessment that you were evaluating in December 1999.

7 A Oh, yeah.

8 Q If you're talking to a roomful of people and  
9 you wanted them to understand you were talking about a  
10 dose response model, wouldn't you have called it a dose  
11 response model?

12 A No. As I explicitly stated here, there are  
13 technical terms such as mixture distributions that I  
14 chose not to use. I spoke informally of munging  
15 together different parameters, said this was something  
16 that needed to be checked out.

17 Q Yesterday -- do I correctly recall that you  
18 thought transparency was an important characteristic in  
19 risk assessments, that they be explicit about their  
20 assumptions and that others be able to follow a risk  
21 assessment?

22 A I don't recall your saying that yesterday.

1 I'm trying to be responsive.

2 Q Thank you.

3 A First thing is to be correct.

4 Q If -- do you think it assisted in the  
5 transparency of CVM's risk assessment model for them to  
6 have posted on the Internet so that other people could  
7 see it and run it?

8 A Yeah. I don't like the word transparency but  
9 yes, I think making it open and inspectable and  
10 documenting the assumptions is all good things.

11 Q I'm showing you a copy of a book which I  
12 believe is partially copied in this record as G-1020 --  
13 excuse me -- B, like Bravo, 1020.

14 I'm handing you B-1020.

15 JUDGE DAVIDSON: Your Honor, would you like a  
16 copy?

17 THE WITNESS: I hope the copyright laws have  
18 been observed.

19 BY MR. SPILLER:

20 Q Observing the law is very important, isn't it,  
21 Dr. Cox? You just mentioned that you hope the  
22 copyright laws have been observed.

1           Would it be of concern to you if people didn't  
2 observe the law in exchanging data concerning, say,  
3 drug approvals?

4           A     I think you'd have to tell me more about the  
5 situation.

6           Q     Well, the drug here is Fluoroquinolone, isn't  
7 it?

8           MR. NICHOLAS: I'm going to object, your  
9 Honor. This is beyond the scope of the witness'  
10 testimony. I don't see where it's relevant.

11           JUDGE DAVIDSON: He brought it up.

12           MR. NICHOLAS: I'm sorry?

13           JUDGE DAVIDSON: He brought it up himself. He  
14 just said he hopes the copyright laws are --

15           MR. NICHOLAS: Well, that's not related to the  
16 issue of a drug --

17           JUDGE DAVIDSON: Well, maybe it is, maybe it  
18 isn't. Let's see where it goes. If it's way out of  
19 line, I'll strike it all.

20           THE WITNESS: Okay. So do I believe there are  
21 some -- address the question again.

22           BY MR. SPILLER:

1 Q I'll ask a different question. Is it  
2 important in deciding issues concerning  
3 Fluoroquinolones, Enrofloxacin or Ciprofloxacin, that  
4 there be a truthful description of the circumstances of  
5 the drug as between all the parties?

6 MR. NICHOLAS: Your Honor, I'm going to object  
7 to the vagueness of the question. Trustful description  
8 of the circumstances --

9 JUDGE DAVIDSON: I'll sustain the objection.

10 BY MR. SPILLER:

11 Q Would it affect your testimony, Dr. Cox, if  
12 one of the parties to this hearing had agreed to plead  
13 guilty to a felony involving the intent to defraud or  
14 mislead the Food and Drug Administration concerning  
15 Ciprofloxacin?

16 MR. NICHOLAS: Your Honor, I'm going to object  
17 to that question as well. It's not relevant. There's  
18 nothing in the testimony with respect to that.

19 JUDGE DAVIDSON: Overruled. I want to hear  
20 the answer.

21 THE WITNESS: Nothing that I have testified to  
22 -- unless the fraud involved changing the raw data that

1 I analyzed, that unfortunate circumstance that was  
2 described would not be important to reaching the  
3 conclusions from the raw data that I reached.

4 BY MR. SPILLER:

5 Q What unfortunate circumstance do you mean?

6 MR. NICHOLAS: Your Honor, I'm going to object  
7 to this line of questioning.

8 JUDGE DAVIDSON: You have a continuing  
9 objection?

10 MR. NICHOLAS: It's absolutely irrelevant to  
11 this proceeding and it's prejudicial.

12 THE WITNESS: You said if somebody --

13 JUDGE DAVIDSON: Well, the jury will disregard  
14 it.

15 (Laughter.)

16 MR. NICHOLAS: I certainly hope so.

17 THE WITNESS: If somebody pleads guilty to a  
18 felony for something and it didn't affect the integrity  
19 of the data, would it affect my conclusions? The  
20 unfortunate circumstance was the scenario about the  
21 felony.

22 BY MR. SPILLER:

1           Questions do not constitute evidence. I don't  
2 care how much counsel pontificates. Answers are  
3 evidence. Some of it's good and some of it's  
4 irrelevant, but the answers are the only evidence, not  
5 the questions. So don't tell me I'm receiving evidence  
6 about this yet. I haven't.

7           The question was -- the witness has already  
8 answered it. He said he doesn't know anything about  
9 it.

10           Let's move on.

11           BY MR. SPILLER:

12           Q    A hypothetical. If Bayer had agreed to plead  
13 guilty to that, would that affect your reception of  
14 Bayer's representations with regard to this drug in  
15 this matter?

16           MR. NICHOLAS: What drug is counsel referring  
17 to, your Honor?

18           THE WITNESS: What receptions? I started with  
19 the raw data that I got from CVM, not from Bayer.

20           MR. NICHOLAS: Dr. Cox, there's an objection  
21 pending.

22           THE WITNESS: I'm sorry.

1 JUDGE DAVIDSON: I'll overrule the objection,  
2 but I'm not happy with the tone of the questioning -- I  
3 shouldn't say tone -- the direction you're going in.

4 The witness has already stated on more than  
5 one occasion in response to this line of questioning  
6 that if you have something that says that the data that  
7 he reviewed was somehow tainted, then that might affect  
8 his -- otherwise, a corporation, of course not Bayer,  
9 could have committed holy murder, and it wouldn't  
10 affect his review of the data as long as the data was  
11 what he was looking at and not related to the fact that  
12 they somehow committed a heinous crime.

13 MR. SPILLER: I have and I will recite on this  
14 record -- I have no information that the data in the  
15 situation involved in my question was relayed through  
16 Dr. Cox. I will not ask further questions of Dr. Cox  
17 on this.

18 JUDGE DAVIDSON: Thank you.

19 BY MR. SPILLER:

20 Q In the partial copy of your book before you,  
21 Dr. Cox, that's Exhibit B-1020, on page 24 of the  
22 exhibit -- what page of the book does that correspond

1 to, Dr. Cox?

2 A It looks to me like page 113 here.

3 Q Thank you.

4 A Surely.

5 Q Does it indicate that your simulation model --  
6 excuse me. And you describe at numerous places in this  
7 book your work with respect to campylobacter that AHI  
8 commissioned, right?

9 A On some of it, yes.

10 Q And on that page in the first full paragraph,  
11 third line --

12 MR. NICHOLAS: Excuse me, your Honor. Are we  
13 on 113 of the book or page 24 of the --

14 JUDGE DAVIDSON: They're the same, I believe.  
15 24 of the exhibit and 113 in the book.

16 THE WITNESS: Uh-huh. Okay. I'm with you.

17 MR. SPILLER: I want to be fair to counsel to  
18 make sure that we have given counsel a full deck.  
19 Apparently, like me, counsel got a much abbreviated  
20 copy and I meant to give them the same copy that I had  
21 given to Dr. Cox.

22 Let me offer counsel a copy of Dr. Cox's book

1 which we bought so he can see page 113.

2 BY MR. SPILLER:

3 Q In the first full paragraph there, Dr. Cox, is  
4 there a reference to where your model is said to be  
5 available on the web?

6 A Back in 2001, yes.

7 Q And from your reference back in 2001, we agree  
8 it's not available now?

9 A I was not aware of that but I'll take your  
10 word for it.

11 Q Would you know when it was taken down or when  
12 it became unavailable?

13 A I would like it to be available and I would  
14 have to talk to our webmaster to find out.

15 Q When you used your model, did you ever discuss  
16 in any of your publications concerning that model what  
17 happens if in your model you change the prevalence of  
18 contaminated carcasses while leaving the bacterial load  
19 distributions constant?

20 A First, I don't remember the answer to that  
21 question. There's -- I've done numerous sensitivity  
22 analyses in different publications and showed a great

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1 many curves, and that may have been one of them.

2 But secondly, I'd like to let you know that I  
3 have had more than one model. When you say "your model",  
4 this is an early version.

5 Q In your testimony, you mention your model in  
6 several places. Is the final version of your model the  
7 one reflected in Exhibit A-17, the final report for AHI  
8 dated February 20, 2001?

9 A No, it is not. Not by a mile.

10 Q In your testimony, Dr. Cox, in all of the  
11 references to your model, where did you tell us which  
12 was the final version of your model?

13 A It depends if you're referring to Cox 2002,  
14 then it was the 2002 model. If you're referring to Cox  
15 2001, it was the earlier model. I've worked on a model  
16 over a period of years and different publications would  
17 peg a different version of the model.

18 Q In your testimony, did you say at some point  
19 this is the final model and give a cite to it where --

20 A I don't believe so.

21 Q You agree in FDA's risk assessment FDA did  
22 keep the bacterial load distribution constant?