

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	:
of Approval of Bayer Corporation's	:
New Animal Drug Application (NADA)	:
140-828 (Baytril)	:
-----	x

FDA DOCKET NO.
00N-1571

Monday, April 28, 2003

The hearing in the above-entitled matter commenced at 9:03 a.m., pursuant to notice.

BEFORE:

DANIEL J. DAVIDSON
Administrative Law Judge

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

00N-1571

TR 1

1 17 05 33 -0 11 1

APPEARANCES:

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

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

On behalf of Respondent Bayer Corporation:

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

On behalf of the Animal Health Institute:

KENT McCLURE, ESQ.
1325 G Street, N.W., Suite 700
Washington, D.C. 20005

Also present:

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

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

C O N T E N T S

WITNESSES:	DIRECT	CROSS	REDIRECT	RECROSS
Linda Tollefson	21	23	170	178

BAYER CORP. EXHIBITS:	MARKED	RECEIVED
B-1929 - Draft Testimony Dr. Cray 3-18-03	93	(Withdrawn)

* * *

P R O C E E D I N G S

(9:03 a.m.)

1
2
3 JUDGE DAVIDSON: Come to order. On the
4 record.

5 By the Orders of April 10, 2002 and April 15,
6 2003, this hearing for the purposes of cross
7 examination was set to begin at this time and place in
8 FDA Docket Number 00N-1571, Enrofloxacin for Poultry:
9 Withdrawal of Approval of New Animal Drug Application
10 (NADA) 140-828.

11 Counsel, in announcing your appearances,
12 please state your name, your address, the capacity in
13 which you appear, and whether you have been admitted to
14 practice before the bar or bars of any of these United
15 States.

16 Who appears for the Center for Veterinary
17 Medicine?

18 MS. STEINBERG: Nadine Steinberg. The address
19 is 5600 Fishers Land, Rockville, Maryland 20857. I
20 appear on behalf of the Center for Veterinary Medicine
21 and I'm admitted in the District of Columbia.

22 MR. SPILLER: I'm Robert Spiller. My address

1 is the same as Ms. Steinberg's. I'm also appearing for
2 the Center for Veterinary Medicine, and I'm admitted to
3 the bar of the Commonwealth of Virginia.

4 JUDGE DAVIDSON: Okay.

5 MS. AMBROSE: Candace C. Ambrose. My address
6 is the same as Nadine's. I'm also counsel for CVM, and
7 I'm admitted to the bar of the State of Maryland.

8 MS. ZUCKERMAN: I'm Claudia Zuckerman. My
9 address is the same as Ms. Steinberg's. I'm also
10 counsel for the Center for Veterinary Medicine and I'm
11 admitted to the bar in Maryland.

12 MR. KRAUSS: Your Honor, Gregory Krauss on
13 behalf of Respondent Bayer Corporation.

14 JUDGE DAVIDSON: You didn't me a chance to
15 even ask.

16 MR. KRAUSS: I'm sorry, Your Honor.

17 (Laughter.)

18 JUDGE DAVIDSON: Who appears for Bayer
19 Corporation?

20 MR. KRAUSS: Your Honor, Gregory Krauss on
21 behalf of Bayer Corporation. My address is 600 13th
22 Street, Northwest, Washington, D.C. 20005. I'm

1 admitted to the bars of the States of Maryland, New
2 Jersey, Pennsylvania, and the District of Columbia.

3 MR. NICHOLAS: Your Honor, I'm Robert
4 Nicholas. I appear on behalf of Bayer, the same
5 address as Mr. Krauss. I'm admitted to the bars of
6 Massachusetts and the District of Columbia.

7 JUDGE DAVIDSON: Is there someone here for the
8 Animal Health Institute?

9 MR. McCLURE: Yes, Your Honor. My name is
10 Kent McClure. My address is 1325 G Street, Suite 700,
11 Washington, D.C. 20005. I'm admitted to the bars of
12 the District of Columbia and Texas, and I might add,
13 Your Honor, that I meant no disrespect by not wearing a
14 tie today. I have a broken arm and can't --

15 JUDGE DAVIDSON: That's why we didn't give you
16 a desk.

17 (Laughter.)

18 JUDGE DAVIDSON: Are there any other
19 appearances?

20 (No response.)

21 JUDGE DAVIDSON: Hearing none, let's move on
22 to preliminary matters. I'll let you go first with the

1 preliminary matters. Ms. Ambrose.

2 MS. AMBROSE: Yes, Your Honor. I have one
3 preliminary matter. I ask that I be excused from
4 appearing on time this afternoon after the lunch break.
5 I have a conference call scheduled with one of the
6 witnesses who was to appear on cross examination during
7 the lunch hour, and I'll return to the courtroom as
8 soon as the call is over.

9 JUDGE DAVIDSON: Well, I'll conditionally
10 authorize that, but we may be talking some more about
11 that before we get into actually cross examining the
12 witnesses.

13 Anything else?

14 MS. ZUCKERMAN: Your Honor?

15 JUDGE DAVIDSON: Yes, Ms. Zuckerman.

16 MS. ZUCKERMAN: At this time, the Center for
17 Veterinary Medicine requests reinstatement of certain
18 testimony and exhibits into the evidentiary record that
19 were stricken from the evidentiary record but remain in
20 the administrative record pursuant to Your Honor's
21 Order dated March 3, 2003.

22 The March 3rd Order stated:

1 "The Respondent's motion to strike testimony
2 and exhibits set forth in Appendix D thereto relating
3 to the Sentinel County study is granted solely for the
4 reason that relevant information requested by the
5 Respondent was not furnished by the Center for
6 Veterinary Medicine (CVM) in a timely manner."

7 The Footnote 3 at the end of that sentence
8 reads:

9 "The ruling is without prejudice to the
10 resubmission of the testimony and exhibits at the oral
11 phase of this hearing."

12 CVM seeks reinstatement into the evidentiary
13 record of the following exhibits and related testimony
14 that were part of Appendix D referred to in the March
15 3rd Order.

16 Exhibit B-589, which is the Patent article,
17 describes --

18 JUDGE DAVIDSON: I'm sorry, say that again,
19 the exhibit number.

20 MS. ZUCKERMAN: The Exhibit number is B --

21 JUDGE DAVIDSON: B.

22 MS. ZUCKERMAN: -- as in Bayer --

1 JUDGE DAVIDSON: Okay.

2 MS. ZUCKERMAN: -- 589, and I have copies if
3 Your Honor --

4 JUDGE DAVIDSON: That's all right. Let's get
5 them all listed first.

6 MS. ZUCKERMAN: B-589 is the Patent article
7 describing the Sentinel County study methods;

8 Exhibit G, as in government, 624, which is the
9 Ten-over article describing the Sentinel County
10 susceptibility test results; and

11 Parts of the testimony of CVM witness Fred
12 Angulo, Exhibit G-1452 at Page 14, Lines 2 through 20
13 and Lines 38 through 46, which discuss the methods and
14 the test results of the Sentinel County study.

15 Any concerns regarding Bayer's timely access
16 to documents that are related to the Sentinel County
17 study have now been mooted, for two reasons.

18 First, on January 27, 2003, Bayer received
19 additional Sentinel County related information, a study
20 protocol, and a patient questionnaire that it sought
21 from CDC pursuant to a Freedom of Information Act
22 request. By now, Bayer has had sufficient time, about

1 three months, to review the protocol and questionnaire.

2 Second, CVM is seeking reinstatement into the
3 evidentiary record of only a portion of the exhibits
4 and testimony that relate to the Sentinel County study.
5 CVM is limiting its request to cover only information
6 relating to the susceptibility test results from the
7 study.

8 In other words, CVM is not requesting
9 reinstatement of interview-related data on risk factors
10 and duration of illness that were also generated as
11 part of the Sentinel County study and that were
12 stricken from the evidentiary record by the March 3rd
13 Order.

14 As a result of CVM's narrow request, the
15 patient questionnaire that Bayer received from CDC on
16 January 27th is irrelevant to the exhibits and
17 testimony CVM now seeks to resubmit.

18 With the exception of the study protocol that
19 Bayer received from CDC in January, the relevant
20 Sentinel County information has been in Bayer's
21 possession since at least November 2002.

22 Bayer has had an electronic copy of the

1 susceptibility test results of CDC since November, and
2 in addition, the Patent article, B-589, and the Ten-
3 over article, G-624, were contained in the parties'
4 original 12-A(5) submissions.

5 Finally, although CVM witnesses, in addition
6 to Dr. Angulo, testify in their written direct
7 testimonies to the susceptibility test results of the
8 Sentinel County study, CVM is seeking reinstatement of
9 testimony only from Dr. Angulo, who is scheduled for
10 cross examination on Wednesday.

11 Therefore, to the extent that Bayer is
12 entitled to cross examination on testimony related to
13 the test results from the Sentinel County study, Bayer
14 will still have the opportunity to conduct such cross
15 examination.

16 Therefore, CVM respectfully requests that Your
17 Honor reinstate into the evidentiary record B-589, G-
18 624, and G-1452, Page 14, Lines 1 through 20 and Lines
19 38 through 46.

20 Thank you, Your Honor.

21 JUDGE DAVIDSON: You don't have a chair?

22 MR. KRAUSS: I'm fine, Your Honor.

1 JUDGE DAVIDSON: I know you are, but I'm not.
2 If you want to go back about 20 years --

3 MR. KRAUSS: Thank you, Your Honor.

4 JUDGE DAVIDSON: -- you want to go back about
5 20 years to a hearing we had on something called
6 Catherabol, I removed somebody from the hearing because
7 he insisted on standing up when I wanted him to sit
8 down.

9 MR. KRAUSS: Your Honor, I'm happy to sit
10 down.

11 (Laughter.)

12 JUDGE DAVIDSON: All right. Do you care to
13 respond?

14 MR. NICHOLAS: I would, Your Honor.

15 JUDGE DAVIDSON: Okay.

16 MR. NICHOLAS: We would oppose that motion.

17 We've had a great deal of difficulty, as you
18 know, obtaining information from CDC and/or CVM with
19 respect to the Sentinel County study.

20 It's true that we did receive additional
21 information in early January from CDC. However, we
22 have a pending FOIA appeal with respect to additional

1 information for that study, which we have not received
2 a reply to, notwithstanding many phone calls to CDC,
3 and great efforts on our part to obtain all of the
4 information relevant to that study so we could make a
5 judgment with respect to the credibility of that study
6 and the background of that study.

7 So we would oppose it, Your Honor, because we
8 do not have all the information, even as of this day.

9 JUDGE DAVIDSON: Well, I'd like to see what's
10 in the protocol, because based on what you've, both
11 sides, presented to me when I was faced with this minor
12 task of dealing with 600 pages of motions to strike and
13 replies, all I saw was that they didn't furnish you a
14 protocol. Since you didn't have it, I couldn't expect
15 you to show me what was in it.

16 I still haven't seen it, so I don't know
17 whether it's something that would interfere -- that's
18 why I struck the exhibit, because, and related
19 material, because I had no way of knowing what was kept
20 from you.

21 Until I find out what it was -- and you've
22 received it as of January 27th, so you must now have a

1 copy of it.

2 MR. NICHOLAS: Well, we've received the
3 protocol, Your Honor.

4 JUDGE DAVIDSON: Yeah, and that was --

5 MR. NICHOLAS: But there are other many other
6 things that we've asked for with respect to that, sir.

7 JUDGE DAVIDSON: Well, I understand that's a
8 lot of things you've asked for, a lot of things you
9 haven't gotten, and a lot of information that
10 supposedly has come to me hasn't come to me.

11 I'm not criticizing anybody in particular, but
12 from time to time, I would get e-mails saying that
13 something was faxed to me, and I never got it, and I
14 think I mentioned that to you on the last telephone
15 conversation we had, group conversations.

16 I'm not ready to rule on this until I see
17 what's involved. If I know, if I can see -- the basis
18 for striking the exhibit in the first place, as I said
19 in my Order, was the fact that they hadn't furnished
20 you with what I considered to be important, if not
21 vital information, being the protocol.

22 Now, if I see the protocol and I don't think

1 that that has that much of an impact on whether or not
2 you could adequately understand the exhibit, then I
3 might change my mind, but I haven't seen the protocol,
4 so I still don't know where I am on this.

5 So I'm not ruling until I see it. No one has
6 bothered to give it to me. It may be filed in the file
7 somewhere, but that doesn't help me. There's a lot of
8 stuff in this file that I'll admit I haven't looked at,
9 and until it gets in the evidentiary record, I won't
10 look at it.

11 MR. NICHOLAS: Your Honor, if I may, I'd like
12 to request permission to respond to this motion
13 tomorrow morning.

14 We will go back and be able to provide you a
15 list of what we have not received from CVM or CDC, and
16 so when you have the protocol, you'll have an
17 opportunity to look at these other materials as well,
18 and make a judgment with respect to whether Bayer has
19 been prejudiced in its ability to examine this
20 material.

21 JUDGE DAVIDSON: Sounds like a very reasonable
22 way to proceed.

1 MR. NICHOLAS: Thank you, Your Honor.

2 JUDGE DAVIDSON: Okay. Any other preliminary
3 matters?

4 MS. STEINBERG: No, Your Honor.

5 JUDGE DAVIDSON: Well, I have a couple. Let's
6 see.

7 First of all, after I went home on Friday,
8 apparently somebody dropped this at my door, a motion
9 from CVM to supplement the 1285 and enter Exhibit 1801
10 into evidentiary record.

11 Now, by rule, you have 10 days to respond to
12 that. Are you ready to respond at all at this point,
13 or not? I'm not making you respond.

14 MR. NICHOLAS: Your Honor, we are preparing
15 the response. We did get that letter from Mr. Foster
16 from CDC. It represents, in our view, a one-sided
17 tale, as one might expect, and we are going to present
18 the Court with a full opportunity to understand the
19 circumstances surrounding that.

20 Additionally, with respect to the
21 documentation that we have received by CDC, we have
22 gone back, and I am prepared to represent in that

1 motion that much of the analysis that's contained in
2 the witness's testimony to Bayer is accurate and based
3 upon data that was provided by CDC, but we will address
4 this fully. We don't expect to wait the 10 days, but
5 we just got this late Friday afternoon.

6 In addition, Your Honor, I would say that we
7 have a motion that we will be filing today that will
8 ask to add several recent articles to the documents.

9 JUDGE DAVIDSON: Do you have additional copies
10 of this motion?

11 MS. STEINBERG: We have one copy.

12 JUDGE DAVIDSON: Well, before we finish today,
13 I'd like you to provide one to the court reporter.

14 MS. STEINBERG: Certainly, Your Honor.

15 JUDGE DAVIDSON: I'm going to allow it into
16 the 1285 and reserve judgment on whether it goes into
17 the evidentiary record or not, so that you don't have
18 to deal with the 1285 aspect in your response.

19 Additionally, which witnesses is this going to
20 refer to? Are we going to need a response earlier than
21 the 10 days?

22 MS. STEINBERG: No, Your Honor, I don't think

1 that we will.

2 JUDGE DAVIDSON: Okay. I have one more
3 preliminary matter. It's a wonderful schedule you sent
4 me, but I don't love it.

5 What used to be three hours is now four hours.
6 What was two hours is now four hours. What was two
7 hours original request is now three hours. With Dr.
8 Kassenborg, what was three hours is now four hours --
9 and so on.

10 Now, I don't understand why your original
11 good faith estimate was increased to show additional
12 time. I also don't understand why I have a three-hour
13 witness based on your latest estimate on May 5th and a
14 witness who's supposed to take two hours tomorrow.

15 If I'm going to go to the trouble to put this
16 thing on and come down here, I'd like to work. We
17 could do both of those in one day for sure, and maybe
18 some others.

19 I don't know whether you realize it or not,
20 but I do require -- you've had enough time to prepare
21 for cross examination.

22 I require cross examination to be succinct and

1 to move along and not to have a lot of delays involved
2 in one question to the next question, and I do limit
3 any redirect to what was brought up on cross and I
4 limit, obviously, the cross to what was in direct.
5 I've got an awful lot of direct, I realize.

6 So, I don't know the schedule of your
7 witnesses. I don't know which ones are here or are not
8 here at this present time, but I would like to do some
9 consolidating to shorten this, work, you know, full
10 days, and get this down to where we don't have to spend
11 the entire time waiting for the next witness to come in
12 tomorrow.

13 All right, go ahead, Ms. Steinberg.

14 MS. STEINBERG: I would ask that, at least for
15 today, we keep the witness schedule as originally set.
16 Our witness that is scheduled to appear tomorrow was
17 not told to come today because --

18 JUDGE DAVIDSON: Oh, I understand that part.
19 I issued the order the way you sent it in, but I want
20 to make changes starting from today on.

21 MS. STEINBERG: Thank you, Your Honor.

22 JUDGE DAVIDSON: Have we got any proposals to

1 that, or do you need a recess to talk with opposing
2 counsel, or do you have to check with your witnesses,
3 or what's the story?

4 MS. STEINBERG: I believe we do need to check
5 with our witnesses and make sure they'll be available
6 here in Rockville. A lot of them, several of them are
7 out-of-town witnesses.

8 JUDGE DAVIDSON: I understand.

9 MS. STEINBERG: We can do that now or get back
10 to you after the lunch recess.

11 JUDGE DAVIDSON: I think that would be fine,
12 after the luncheon recess.

13 All right. That's all I have of a preliminary
14 nature. Are we ready for our first witness?

15 MS. STEINBERG: We are, Your Honor.

16 (The witness was sworn by Judge Davidson.)

17 JUDGE DAVIDSON: Please be seated, give your
18 full name and address to the reporter, and then --

19 THE WITNESS: My name is Linda Tollefson.
20 That's T-o-l-l-e-f-s-o-n.

21 Address is 7519 Standish Place, Rockville,
22 Maryland 20855.

1 Whereupon,

2 LINDA TOLLEFSON

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

5 DIRECT EXAMINATION

6 BY MS. STEINBERG:

7 Q Dr. Tollefson, can you state your position for
8 the record?

9 A Yes. I'm deputy director of the Center for
10 Veterinary Medicine in FDA.

11 MS. STEINBERG: Your Honor, may I have
12 permission to show the witness a document, Exhibit G-
13 1478?

14 JUDGE DAVIDSON: That's her testimony?

15 MS. STEINBERG: Yes.

16 JUDGE DAVIDSON: Of course.

17 BY MS. STEINBERG:

18 Q Dr. Tollefson, could you please identify this?

19 A Yes. It's the written direct testimony of
20 mine.

21 Q Can you turn to Page 20? Is that a photocopy
22 of your signature that appears on the original?

1 A Yes, it is.

2 Q Since you submitted, since you signed and
3 submitted that testimony, is there anything -- have you
4 had a chance to review the testimony?

5 A Yes.

6 Q Is there anything in the testimony that you
7 need to correct, typographical errors or other errors?

8 A Yes, there are two issues. The first is on
9 Page 8, the paragraph that's numbered 18, and
10 specifically, it's Lines 36 to 38. That's a mistake.

11 That statement now reads: "The 2001 data on
12 Campylobacter isolates has not been available." That
13 should be 2002. 2001 is available and is actually in
14 the table attached to my testimony.

15 Q Thank you. Is there anything else?

16 A Yes, there is. There's one other thing. It's
17 Page 10, the last sentence, and it's on the top of that
18 page, the paragraph that ends on the top of that page.

19 It's the end of Paragraph 21, and I'm speaking
20 to Campylobacter jejuni and coli, and identification of
21 those, and I say -- I talk about nalidixic acid and
22 fluoroquinolone, and the statement reads:

1 "This is because resistance develops first in
2 nalidixic acid." That is actually not correct for
3 Campylobacter. It's pretty much simultaneous.

4 Q Thank you. Are there any other corrections
5 that you'd like to make?

6 A No, that's all.

7 MS. STEINBERG: Thank you. Your Honor, Dr.
8 Tollefson is ready for cross examination.

9 JUDGE DAVIDSON: Okay.

10 MR. KRAUSS: Thank you, Your Honor. Gregory
11 Krauss on behalf of Bayer Corporation.

12 CROSS EXAMINATION

13 BY MR. KRAUSS:

14 Q Good morning, Dr. Tollefson.

15 A Good morning.

16 Q I'm Greg Krauss and I'm going to conduct your
17 cross examination today. We've already established
18 that you've submitted testimony in this case.

19 You are the deputy director for the Center for
20 Veterinary Medicine; is that right?

21 A Yes.

22 Q You're also assistant surgeon general in the

1 Public Health Service?

2 A Correct.

3 Q Ms. Steinberg showed you your testimony and if
4 you'll -- you have a copy of that; isn't that right?

5 A Yes.

6 Q If you would take a look at Page 20, I think
7 we've already established this, but that's your
8 signature; isn't that right?

9 A Correct.

10 Q You signed it on or about December 6, 2002?

11 A Correct.

12 Q When you signed it, you made a declaration
13 that it was true and correct under penalty of perjury,
14 right?

15 A Yes.

16 Q Dr. Tollefson, did you draft your testimony
17 yourself?

18 A Yes.

19 Q All of it?

20 A Yes.

21 Q Let me just explore your professional
22 background a little bit, please.

1 A Mm-hmm.

2 Q You're a veterinarian?

3 A Yes, I am.

4 Q Do you have a Master's in Public Health?

5 A Correct.

6 Q And your Master's in Public Health emphasized
7 epidemiology?

8 A Yes.

9 Q And biostatistics?

10 A Correct.

11 Q In your testimony, you describe yourself as a
12 veterinary epidemiologist. Is that right?

13 A Yes.

14 Q Your testimony also states that the majority
15 of your career in the Public Health Service has been
16 focused on food safety issues; is that right?

17 A That's correct.

18 Q Dr. Tollefson, you're not a medical doctor?

19 A No, I'm not.

20 Q You do not have any advanced degrees in
21 microbiology, do you?

22 A No, I do not.

1 Q You do not have any advanced degrees in
2 veterinary microbiology, do you?

3 A No, I do not.

4 Q You do not have a Ph.D. in epidemiology, do
5 you?

6 A No.

7 Q You are not a poultry veterinarian, are you?

8 A No.

9 Q You are not a Diplomate of the American
10 College of Poultry Veterinarians, are you?

11 A No.

12 Q You're not a member of the American
13 Association of Avian Pathologists, are you?

14 A No.

15 Q You are one of the designers of the National
16 Anti-Microbial Resistance Monitoring System, right?

17 A Yes.

18 Q That's known as NARMS?

19 A Correct.

20 Q Now, the Notice of Opportunity for Hearing in
21 this matter was filed on October 31, 2000; isn't that
22 right?

1 A That's correct.

2 Q And at that time, you were the director of
3 surveillance and compliance; is that right?

4 A Yes.

5 Q Did you have a role in the decision to file
6 the NOOH?

7 A Yes, I did.

8 Q What was your role?

9 A I guess I was one of the proponents that the
10 time had come to file the NOOH, and I wrote the first
11 draft.

12 Q Did you review data in coming to the decision
13 that the time had come, as you say?

14 A Yes.

15 Q What data did you review?

16 A A number of -- a number of different sources
17 of information.

18 One was the historical record for how we
19 decided to approve Cerofloxacin and Enrofloxacin for
20 use in poultry.

21 I reviewed the transcript of the Joint
22 Veterinary Medical and Anti-Infective Drugs Advisory

1 Committee meeting that took place in May of 1994.

2 I reviewed the National Anti-Microbial
3 Resistance Monitoring System data.

4 I reviewed the Kirk Smith study.

5 I reviewed a number of published literature
6 studies, also some U.K. data that had been coming out
7 around that same time.

8 I reviewed the Campylobacter Risk Assessment
9 that we were -- that was still in draft.

10 I don't think that's an exhaustive list, but
11 it's a general --

12 Q Okay. And your testimony states that:

13 "Taken as a whole, the evidence requires the
14 Center for Veterinary Medicine to act to stop the
15 poultry use of fluoroquinolones; isn't that right?

16 A That's correct.

17 Q Now, Dr. Tollefson, would you agree that this
18 case is about whether Baytril use in chickens and
19 turkeys is causing resistant Campylobacter infections
20 in humans?

21 A Yes, I think that's simplistic. I would say
22 it's about whether fluoroquinolone resistance develops

1 in Campylobacter in poultry and whether those
2 Campylobacter are retained in the carcass, are
3 transferred to humans through a food safety or a food
4 consumption or a handling issue, and cause resistant
5 infections in humans, correct.

6 Q Okay. So the ultimate question is whether,
7 through that chain of events, use of fluoroquinolones
8 in poultry is resulting in resistant Campylobacter
9 infections in humans; isn't that right?

10 A Yes.

11 Q We agree, don't we, that Baytril is used for
12 prescription use only?

13 A Correct.

14 Q And it's not used in any way for growth
15 promotion?

16 A Correct.

17 Q It's only used to treat infections in the
18 birds?

19 A I would disagree with that. The reason that I
20 disagree with that is that the drug is administered in
21 drinking water to a group of chickens. Some of those
22 chickens are ill and have an infection. Others do not.

1 Q Okay. Well, we can get into that, Dr.
2 Tollefson.

3 A Okay.

4 Q You would agree with me that Baytril is not
5 prescribed to treat Campylobacter, right?

6 A Correct.

7 Q It's for, in chickens, E. coli infections,
8 right?

9 A Right.

10 Q And in turkeys for E. coli infections and for
11 Pasteurella multocida?

12 A Mm-hmm.

13 Q In terms of Campylobacter infections in
14 humans, and even resistant infections in humans, for
15 the most part, the disease consequence is diarrhea,
16 right?

17 A Campylobacteriosis in humans causes diarrhea,
18 causes cramping. Yes, I would say for the most part
19 it's a diarrheal illness.

20 Q So, just to put this into perspective here,
21 you know, sometimes in FDA proceedings we're talking
22 about, you know, cancer risk. We're not talking about

1 cancer risk here, are we?

2 A No, we're not.

3 Q Sometimes in FDA proceedings, we're talking
4 about a birth defect risk or something like that.
5 We're not talking about that here, right?

6 A No.

7 Q We're talking about a diarrhea risk, right?

8 A We're talking about a risk of an adverse
9 health event.

10 Q Now, your testimony states that you've
11 examined the data and evidence, and we went through
12 what you looked at and said it wasn't an exhaustive
13 list, right?

14 A Right.

15 Q But what you did look at, you looked at, as
16 you say, as a public health official, right, as a
17 veterinarian, right?

18 A Mm-hmm.

19 Q And as an epidemiologist; isn't that right?

20 A Yes, that's right.

21 Q In your review of the evidence, in addition to
22 what you've already testified that you looked at, did

1 you also look at, in general, literature on food-borne
2 illnesses?

3 A Yes.

4 Q Did you also look at the 1998-1999 Centers for
5 Disease Control and Prevention Campylobacter Case
6 Control Study?

7 A Yes.

8 Q You're familiar with that study?

9 A I'm familiar with it. I'm not intimately
10 familiar with it.

11 Q Now, Dr. Tollefson, I do not have a background
12 in epidemiology, and you do, so I'd like to establish
13 with you some terms.

14 A Okay.

15 Q Epidemiological terms, if you will.

16 A Sure.

17 Q As an epidemiologist, would you agree that an
18 incidence rate for a disease consists of the number of
19 cases over a defined period of time in a defined
20 population?

21 A It's the number of new cases over a defined
22 period of time in a defined population.

1 Q So it's the number of new cases of whatever
2 the incident case, whatever it is you're looking at,
3 the number of new cases --

4 A New cases, correct.

5 Q -- over a defined period of time --

6 A Correct.

7 Q -- in a defined population?

8 A Right. The other is prevalence.

9 Q Right. A prevalence, correct me if I'm wrong,
10 is a snapshot in time of who may have the --

11 MS. STEINBERG: Objection.

12 MR. KRAUSS: Do you have an objection?

13 MS. STEINBERG: Yeah. Counsel is testifying.

14 JUDGE DAVIDSON: Overruled. I'll allow it. Go
15 ahead.

16 MR. KRAUSS: Thank you, Your Honor.

17 BY MR. KRAUSS:

18 Q A prevalence rate would be a snapshot in time
19 looking at a population, what's the level of disease in
20 that population at that moment, right?

21 A Correct. It's the number of existing cases is
22 an easier way to think of it.

1 Q Okay. Thank you.

2 A Mm-hmm.

3 Q Would you agree with me that for food-borne
4 illnesses, incidence rates are often recorded as the
5 number of cases per 100,000 per year?

6 A It depends on the organism. Yes, sometimes
7 it's 10,000, sometimes it's 100,000. Sure. That's a
8 rate.

9 Q Right. We're talking about incidence rates?

10 A Right.

11 Q Annual incidence rates are used by
12 epidemiologists, aren't they?

13 A Mm-hmm.

14 Q And they're used to examine trends of disease
15 incidence over time, aren't they?

16 A Correct.

17 Q Let me shift gears and go into another
18 epidemiological term, please.

19 A Okay.

20 Q As an epidemiologist, would you agree that
21 confounding -- are you familiar with that term?

22 A Yes.

1 Q Would you agree that confounding is the
2 distortion of an exposure/disease association by the
3 effect of some third factor?

4 A No. That's a frequently misused term.
5 Confounding has to affect both the disease and the
6 exposure, not just one.

7 I'm probably not being clear enough here, but
8 ask your question again.

9 Q Are you familiar with the book, Field
10 Epidemiology by Gregg?

11 A No.

12 Q There's a definition in the book, which I'd be
13 happy to show you if you want to see it, that states
14 that confounding is the distortion of an
15 exposure/disease association by the effect of some
16 third factor.

17 A Okay. I'd like to see the definition. In
18 general, a confounding variable has to have an effect
19 on both the exposure and the disease, which makes it
20 very unique. There aren't that many confounding
21 variables.

22 If you're talking of confounding in more of a

1 use of the term in general English, I would agree with
2 you. Okay?

3 Q Okay.

4 A Let me look at the definition --

5 Q I'd be happy to show it to you, Dr. Tollefson.
6 For the record, this is Field Epidemiology by
7 Greg, 2d Edition, Page 157.

8 A Okay.

9 (The witness examined the document.)

10 JUDGE DAVIDSON: Do I get to see it, too?

11 MS. STEINBERG: And also, I would like to
12 know, Your Honor, if this is an exhibit, and if so,
13 what the exhibit number is?

14 MR. KRAUSS: Portions of this book, including
15 this page, are in the record.

16 MS. STEINBERG: And the exhibit number?

17 MR. KRAUSS: B-1912, attached to the Feldman
18 testimony.

19 MS. STEINBERG: Thank you.

20 THE WITNESS: After that statement, he goes on
21 to explain it, which is a better definition.

22 BY MR. KRAUSS:

1 Q Good, because I wanted to go into the
2 explanation.

3 A Okay.

4 Q So if you could clarify it, it would be great.

5 A A third factor in any association may be a
6 confounder and distort the exposure/disease association
7 if it is, two things: associated with the outcome
8 independent of the exposure -- that is, even in the
9 non-exposed group -- okay, so the outcome being the
10 disease in this case; and associated with the exposure
11 but not be a consequence of it.

12 So yes, I would agree with this whole
13 definition.

14 Q Okay. Well, perhaps the confusion was that I
15 split it up, then you took care of part of my outline
16 by doing what you just did. Thank you.

17 A Mm-hmm.

18 Q So with what you said, let me make sure I have
19 this right here, the third factor would be a confounder
20 if the third factor is associated with the outcome --

21 A Correct.

22 Q -- independent of exposure?

1 A Right.

2 Q Or, the third factor is associated with the
3 exposure but not a consequence of the exposure?

4 A No. It's and, not or.

5 Q It has to be both?

6 A It has to be both.

7 MS. STEINBERG: Your Honor, may Mr. Krauss
8 please give the book with the definition to Dr.
9 Tollefson?

10 JUDGE DAVIDSON: I thought he did already.

11 MS. STEINBERG: He's asking questions about it
12 without her being able to look at it.

13 MR. KRAUSS: I'm happy to do that, Your Honor.

14 JUDGE DAVIDSON: Certainly.

15 BY MR. KRAUSS:

16 Q So it's got to be both, in your opinion?

17 A It's got to be both. Yeah. He says that,
18 too.

19 Q Okay. Thank you. Like I said, I'm not an
20 epidemiologist.

21 A Yeah.

22 Q So, Dr. Tollefson, just as an example, there's

1 an example here in the Gregg book where they go through
2 the death rate, the mortality rate in Arizona versus
3 Alaska.

4 A Okay.

5 Q And the death rate in Arizona is 7.9 deaths
6 per 1,000 and in Alaska it's 3.9 deaths per 1,000, so
7 on its face, it looks like there's a higher risk of
8 death --

9 A It's an age adjustment.

10 Q Well, that's the point.

11 A That's right.

12 Q Yeah, that's exactly the point.

13 MS. STEINBERG: Your Honor, can Dr. Tollefson
14 be provided a copy of the book with the example Mr.
15 Krauss is referring to?

16 MR. KRAUSS: I would be happy to.

17 MS. STEINBERG: Thank you.

18 MR. KRAUSS: Once again, we're on Page 157.

19 MS. STEINBERG: Mr. Krauss, do you have
20 another copy of the book?

21 MR. KRAUSS: No. It's in the record, B-1912,
22 attached to Feldman's testimony.

1 THE WITNESS: So it's a crude mortality rate.

2 BY MR. KRAUSS:

3 Q Right, right, without adjustment. But on its
4 face, it would look like you would have a higher risk
5 of death in Arizona than in Alaska, but age is
6 associated with mortality.

7 A Correct.

8 Q The older you are, the greater the chance of
9 dying, and, as it happens, age is associated with where
10 you live. More people are older living in Arizona than
11 in Alaska; isn't that right?

12 A Right.

13 Q So in that instance, age is a confounder,
14 right?

15 A Correct.

16 Q And you have to correct for age?

17 A Right, and you can do that a number of ways.

18 Q Okay. Good.

19 A Okay.

20 Q Now, Dr. Tollefson, one of the things that you
21 testified that you looked at in this case is the study
22 by Dr. Smith?

1 A Kirk Smith, right.

2 Q Kirk Smith.

3 A Of Minnesota, right.

4 Q Right. One of the things that Dr. Smith finds
5 in that study, one of his findings is that he believes
6 there is a longer duration of illness associated with a
7 resistant Campylobacteriosis case compared to a
8 susceptible Campylobacteriosis case --

9 MS. STEINBERG: Your Honor --

10 BY MR. KRAUSS:

11 Q -- and here, we're talking about --

12 MS. STEINBERG: -- I have an objection to the
13 form of the question.

14 JUDGE DAVIDSON: Well, let him finish the
15 question first, then you can object. Are you finished?

16 MR. KRAUSS: No, Your Honor.

17 JUDGE DAVIDSON: Okay. Go ahead.

18 MR. KRAUSS: I may have to start over.

19 BY MR. KRAUSS:

20 Q In the Smith study, one of the things he finds
21 and reports on is an association between having a
22 resistant -- fluoroquinolone resistant Campylobacter

1 infection associated with the longer duration of
2 illness compared to a susceptible, fluoroquinolone
3 susceptible Campylobacter infection; isn't that right?

4 JUDGE DAVIDSON: Is there a problem?

5 MS. STEINBERG: Yes, Your Honor. I object to
6 the form of the question. Mr. Krauss is describing
7 what's in the study and should be providing a copy of
8 the study to the witness.

9 JUDGE DAVIDSON: That's understandable, but
10 the witness didn't seem to have a problem with it.
11 Have you got a copy for her?

12 MR. KRAUSS: I believe I may. We will find
13 one, Your Honor.

14 JUDGE DAVIDSON: While we're waiting, I'd like
15 to remind you that I know you like to see the same
16 thing in the record over and over and over again, but a
17 couple of times you've asked the question, you've
18 gotten the answer, and then you've repeated the answer
19 for the record. And I trust the reporter. You don't
20 have to do that.

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

22 (Pause.)

1 JUDGE DAVIDSON: Are you looking for something
2 that's in the record?

3 MR. KRAUSS: No -- yes, Your Honor. It's G-
4 589, and counsel for CVM requested that we provide the
5 witness a copy --

6 JUDGE DAVIDSON: G-589?

7 MR. KRAUSS: Yes, Your Honor.

8 I'm afraid this is going to be a little bit
9 anti-climactic, but if they want her to have a copy,
10 then she's going to have a copy.

11 THE WITNESS: Thank you. What I recall is
12 that he showed a slight difference between
13 fluoroquinolone resistant the fluoroquinolone
14 susceptible, but that was not a big consideration in my
15 review of data for the NOOH, if that matters.

16 MR. KRAUSS: Okay.

17 THE WITNESS: Okay.

18 BY MR. KRAUSS:

19 Q In terms of a consequence of a resistant
20 Campylobacter infection, the Smith report was not a big
21 factor in your --

22 A No, the difference between the

1 fluoroquinolone, the days of diarrhea for the
2 fluoroquinolone resistant infection as compared to a
3 susceptible, I didn't think that was a large part of
4 this study.

5 Q Okay.

6 A Okay. That was a question that you asked,
7 whether --

8 Q I asked whether it was one of the things that
9 he found, Dr. Tollefson.

10 A Yeah, and I vaguely remember that yes, it was,
11 but the difference was not that great, and -- go ahead.

12 Q Okay. And did you review any other studies,
13 in coming to your decision to file the NOOH, that
14 related duration of, longer duration of illness to a
15 fluoroquinolone resistant infection compared to a
16 fluoroquinolone susceptible infection?

17 A No. Most of those studies were published
18 after we began the NOOH. The Smith study was one of
19 the earliest, and that was 1999. We were writing the
20 NOOH in early 2000.

21 Q Right. Well, let me ask you this, on the
22 issue of confounding.

1 A Uh-uh.

2 Q If -- this is an if -- foreign travel, okay,
3 persons in the study had undertaken foreign travel.

4 Okay, foreign travel is associated with both
5 resistant Campylobacteriosis and with a longer duration
6 of illness. Would foreign travel be a confounding
7 variable in that analysis?

8 A No. The foreign travel isn't causing the
9 illness or the duration of the illness itself, so I
10 would not call it a confounding variable.

11 You should adjust for foreign travel, but it's
12 not the foreign travel itself, it's not the act of
13 traveling that's causing either one of those, so I
14 guess I would not call it a confounder.

15 Q Even though it would be associated with the
16 exposure but not a consequence of the exposure?

17 A Okay, yes. It would be -- so if the person
18 traveled to a foreign country and got the infection
19 there, then it would be associated with the travel, but
20 not a consequence of the actual travel. Yes, that's
21 what I'm saying. And the outcome is not the infection,
22 but the duration.

1 I still, I don't see how the travel itself
2 affects the outcome.

3 Q What I'm saying is if you have a case control
4 study, and you've got persons in your study who have
5 had foreign travel, and they also have a longer
6 duration of illness, and they also have a resistant
7 infection, in that instance, if statistically, when you
8 do your analysis, the foreign travel is associated with
9 both the resistant infection and with the longer
10 duration, wouldn't that be a confounder?

11 A I guess what I'm objecting to is that it isn't
12 associated with both. I don't see how it can be.

13 Q It's a hypothetical, Dr. Tollefson.

14 A It's a hypothetical. Okay. If it's a
15 hypothetical, then, yes, it would be a confounder.

16 Q Okay. I'm going to approach and take that.

17 A Okay.

18 Q Thank you.

19 A If the travel in some way gave you the
20 illness.

21 Q Now, Dr. Tollefson, your career, as you said,
22 is focused on food safety issues, right?

1 A Correct.

2 Q You make an effort to keep current on
3 literature discussing causes of food-borne illness in
4 the United States, don't you?

5 A Yes.

6 Q In doing so, are you familiar with the Centers
7 for Disease Control and Prevention MMWR Reports on the
8 Incidence of Food-Borne Illness?

9 A Yes.

10 Q Would you agree that CDC MMWR Reports on the
11 Incidence of Food-Borne Illness are reliable?

12 A Yes.

13 Q Now, your written direct testimony -- and you
14 have that with you at the stand, right?

15 A Right, mm-hmm.

16 Q -- on Page 3, states: "A recent reliable
17 publication estimates 5,000 deaths and 76 million food-
18 borne illnesses annually in the United States." Isn't
19 that right?

20 A Right, the Mead, et al. article.

21 Q Right. And that recent reliable publication
22 that you refer to is Mead's 1999 article?

1 A Right.

2 Q And that's G-410 in the record?

3 A Correct.

4 Q Now, that 76 million food-borne illnesses,
5 that's not all Campylobacter, is it?

6 A No, no. Not at all.

7 Q In fact, in the Mead report, don't they
8 estimate Campylobacter to be approximately 2.4 million
9 cases?

10 A Correct.

11 Q So --

12 A And it's actually less than that, now.

13 Q Yes. We're going to get to that. Thank you.

14 So for Campylobacter, 2.4 million out of 76
15 million, we're talking about something like 3 percent?

16 A Correct. The 76 million, however, most of
17 those are of unknown source.

18 Q Right.

19 A And some of them are viral. Campylobacter is
20 an important bacterial cause of food-borne illness.

21 Q Right. But Mead's estimates, from what they
22 can estimate versus the total, it's about 3 percent;

1 would you agree with that?

2 A Yeah, I would agree with that. That's --
3 Mead's article, or efforts, were the last time that CDC
4 has tried to do this in such an extensive way. That's
5 why it's frequently cited.

6 Q But isn't it true that for pathogens under
7 active surveillance in the Mead article, he used data
8 from 1996 to 1997 in making his estimates?

9 A Right, he did.

10 Q Now, as someone who keeps current in the food
11 safety literature, are you aware that in April of 2002,
12 CDC publicly reported that during the period 1996 to
13 2001 the estimated incidence of infection with food-
14 borne pathogens has decreased?

15 A Yes.

16 MR. KRAUSS: In fact, I'm going to hand you
17 Government Exhibit G-1791. Your Honor, I have an extra
18 copy, if you would like it.

19 JUDGE DAVIDSON: I got it.

20 (The witness examined the document.)

21 BY MR. KRAUSS:

22 Q Dr. Tollefson, do you recognize this to be

1 that report we just talked about?

2 A Mm-hmm.

3 Q This report states, does it not, that, from
4 the period 1996 to 2001, the estimated incidence of
5 food-borne Campylobacter infections decreased 27
6 percent?

7 A That's correct.

8 Q And as you testified earlier, that previous
9 prediction of, or estimate of 2.4 million has been
10 changed, and now CDC says that Campylobacteriosis is
11 less than 2.4 million, right?

12 A Right.

13 Q In fact, there's evidence in the record that
14 says it's 1.4 million?

15 A About 1.4, that's correct.

16 Q Okay.

17 A Mm-hmm. There's a newer one, actually, for
18 2002.

19 Q And Campylobacter has gone down again, hasn't
20 it?

21 A No, actually, it went slightly up, but not
22 much.

1 Q In the exhibit that I handed you, the overall
2 incidence as of April 2002, the overall incidence of
3 Campylobacter infections was lower than the overall
4 incidence of food-borne Salmonella infections; isn't
5 that true?

6 A Yes, and that's still true. Campylobacter is
7 now second. This is based on the Food Net data.

8 Q Right, based on the Food Net data, and in
9 fact, it's based on Food Net data from 1996 to 2001,
10 right?

11 A Right.

12 Q You would agree with me, wouldn't you, that a
13 report using data from 1996 to 2001 would contain more
14 recent data than one using just data from 1996 to 1997;
15 isn't that right?

16 A That's right, but the Mead, et al. article
17 gives peer review that morbidity, mortality -- well, it
18 goes through a clearance process within CDC, and
19 actually FDA also, but it's not quite as -- it's -- I
20 don't want to call it preliminary, but it's somewhat
21 preliminary, in the effort to get it out as soon as
22 they can.

1 Q Right.

2 A Which is why I think a lot of people rely on
3 the Mead article.

4 Q Well, your written direct testimony states
5 that Campylobacter has been cited as the most common
6 known cause of food-borne illness in the United States,
7 right?

8 A That's true.

9 Q And that is based on a 1992 article, right?

10 A Yes. It's probably -- yeah, it's TOPES
11 article, 1992?

12 Q Right. But as of 2001, and even as you said,
13 as we sit here today, it's no longer true that
14 Campylobacter is the most common known cause of food-
15 borne illness in the United States, right?

16 A I would agree with that. However, it's still
17 a very important cause of food-borne illness.

18 Q But at the time you finalized your
19 testimony --

20 A No, no, wait a minute. I said Campylobacter
21 has been cited as the most common cause of food-borne
22 illness. I was trying to establish that it's an

1 important cause.

2 Q Well --

3 A It's in the section on background on anti-
4 microbial resistance.

5 Q Dr. Tollefson, before 1492, the world had been
6 cited to be flat, and we now know that not to be true,
7 right?

8 A I don't see the relevance.

9 Q Your testimony says Campylobacter has been
10 cited as one of the most important causes --

11 A As the most common known cause.

12 Q -- or as the most common known cause, and on
13 the date of your testimony, that was no longer true,
14 was it?

15 A Correct. That's correct.

16 Q Let me turn your attention to the 1998-1999
17 CDC Campylobacter case control study. Now, you
18 testified that you looked at that, okay?

19 A Mm-hmm.

20 Q Do you recall what aspects of that you looked
21 at?

22 A I looked at aspects of it that were used for

1 the Campylobacter risk assessment.

2 Q Let me hand you an exhibit. This is G-1452,
3 Attachment Number 3. This is attached to Dr. Angulo's
4 testimony, and if I'm not mistaken, it has an
5 independent G-number, but I can't bring it -- is it
6 1488, maybe, do you know?

7 A No, it's 1452, Attachment Number 3.

8 Q Right. Well, what I'm saying is, I think it
9 has its own number now, because it's -- it's not
10 important. We'll use this one.

11 A Okay.

12 Q Thank you. Do you recognize this report, Dr.
13 Tollefson?

14 A Yes. That's an attachment to the exhibit. I
15 didn't see it ahead of time. I recognize it as an
16 attachment to Fred Angulo's testimony.

17 Q Okay. And this is a study by --

18 A It's a draft publication, manuscript.

19 Q Right. As of the time the testimony was filed
20 in December of 2002, it was still in draft, right?

21 A Correct.

22 Q Isn't it true that data from this study on the

1 risk factors of Campylobacteriosis was presented as
2 early as July 2000?

3 A I don't know. That makes sense. We had that
4 data of ruse in that risk assessment, July --

5 Q I'm going to hand you what's Exhibit B-27.
6 It's an abstract by Freedman, et al.

7 A Okay.

8 Q Do you recognize that?

9 A I don't, but it looks like it's a presentation
10 that this manuscript would be the more detailed report.

11 Q Based on looking at Exhibit B-27, if you look
12 at the citation at the end in particular, isn't it true
13 that data from the 1998-1999 CDC Campylobacter case
14 control study was presented as early as July 2000?

15 A Yes, I would have to assume that's true. This
16 is -- it doesn't say where it was presented, but it
17 says "Food Net Presentation." It also says
18 Campylobacter is the most common cause of bacterial
19 gastroenteritis in the United States.

20 Q That was before the 2002 article came out;
21 isn't that right?

22 A 2001.

1 Q April 2002, reporting on --

2 A Right.

3 Q -- data for 2001, right?

4 A Sure.

5 Q Now, you testified earlier that you were
6 familiar with the CDC case control study in relation to
7 its data for the risk assessment.

8 A Mm-hmm.

9 Q Am I characterizing your testimony correctly?

10 A That's correct.

11 Q Isn't it true that one of the things that the
12 CVM risk assessment does is calculate what fraction of
13 Campylobacteriosis cases in the country are associated
14 with poultry, as one of the steps along the way?

15 A Yes. It attempts to do a fraction of the
16 total cases.

17 Q For the record, there's an agreed finding of
18 fact in this case, Bayer's finding of fact B-593, well,
19 Bayer 593, that states that the CVM BOSE risk
20 assessment model relies, to calculate attributable
21 fractions -- let me restart it and just read it
22 directly as it is.

1 "The data that the CVM BOSE risk assessment
2 model relies on to calculate attributable fractions
3 came from two studies from the 1980s, Harris et al. and
4 Deming et al." Then there's some citations.

5 A Right, that's correct.

6 Q And that's your understanding?

7 A Yes.

8 Q So for calculating the attributable fraction,
9 what portion of Campylobacteriosis is attributable to
10 chicken, relied on these studies from the 1980s --

11 A That's true.

12 Q -- and it didn't rely on the 1998-1999
13 Campylobacter Case Control Study for that --

14 A Piece.

15 Q -- piece.

16 A Right. That's true. And I think we took the
17 average of those two, or something --

18 Q You say the average of those two. You're
19 talking about Deming and Harris?

20 A Right.

21 Q Are you familiar with the Deming and Harris
22 studies?

1 A Vaguely.

2 Q You would agree with me, wouldn't you, that
3 they're from the 1980s?

4 A Yes.

5 Q And you would agree with me, wouldn't you,
6 that the data from the 1998-1999 Campylobacter case
7 control study is more recent than the Deming study,
8 right?

9 A Right.

10 Q And it's more recent than the Harris study?

11 A Yes.

12 Q Now, Dr. Tollefson, as someone with a
13 background in epidemiology and biostatistics, do you
14 have an understanding of what a matched odds ratio is?

15 A Yes. Yes, in a matched case control study --

16 Q Correct.

17 A -- is that what you mean? Okay.

18 Q Right.

19 A Right.

20 Q What is your understanding of what a matched
21 odds ratio is?

22 A Well, the -- an odds ration in a case control

1 study is the odds of the cases having the disease to
2 the odds of the controls having the disease. A matched
3 case control study is usually where the controls are
4 matched to the cases on the other risk factors.

5 Q In a matched case control study, the matched
6 odds ratio less than equal to 1.0 has some import,
7 doesn't it?

8 A If it's less than or equal to 1.0, it means
9 that it's not -- it's not a risk factor --

10 Q Would you agree with --

11 A -- 1.0 being null.

12 Q Right. If it's 1.0, the cases are as likely
13 as the controls --

14 A Controls.

15 Q -- to, after having the exposure, to have the
16 outcome.

17 A Right.

18 Q Okay. And with a matched odds ratio of less
19 than or equal to 1, isn't it true that that means that
20 the exposure is associated with a reduced risk of the
21 disease?

22 A Sometimes. Sometimes it's termed as a

1 protective factor, but it usually -- most
2 epidemiologists don't put that much credit in it.

3 Q Now, as someone with a background in
4 epidemiology and biostatistics, do you know what a P
5 value is, Dr. Tollefson?

6 A Yes.

7 Q What's a P value?

8 A It's the probability of that result having
9 occurred. There's usually like a, if it's a P value of
10 less than .05, it means that 95 percent of the time
11 that finding would not have occurred by chance, so it
12 wouldn't have been a spurious finding, for example.

13 Q So you would agree with me that a P value less
14 than or equal to 0.05 is statistically significant?

15 A The 95 percent confidence level, yes.

16 Q And that's what FDA typically uses in that,
17 right?

18 A I think so, yes.

19 Q For a P value of less than or equal to 0.01,
20 that would be even more statistically significant
21 compared to 0.05, right?

22 A Correct.

1 Q In the exhibit that I gave you, which is by
2 Dr. Freedman, which is G-1452, Attachment 3, isn't it
3 true that eating poultry meat at home was associated
4 with a lower risk of illness?

5 A Yes, and that was statistically significant.

6 Q If you would turn, please, to Page 98 of
7 Exhibit 1452 -- and by 98, I'm using the upper right-
8 hand corner number.

9 A I know.

10 Q Okay.

11 A Okay.

12 MS. STEINBERG: Can you repeat those page
13 numbers?

14 MR. KRAUSS: 98, Nadine. It's in the upper
15 right-hand corner.

16 MS. STEINBERG: Okay.

17 BY MR. KRAUSS:

18 Q Dr. Tollefson, this is a table of exposures,
19 among other things, matched odds ratios and P values,
20 isn't it?

21 A Right, it is.

22 Q And this come from the 1998-1999 Campylobacter

1 Case Control Study?

2 A Right.

3 Q If you would now turn to Page 99, it doesn't
4 have that table heading, if you look down the list, you
5 see "8 - Chicken prepared at home" as one of the
6 exposures?

7 A Yes.

8 Q And the matched odds ratio is 0.5?

9 A Correct.

10 Q And the P value is 0.01?

11 A Correct.

12 Q That would mean, wouldn't it, that in this
13 study, persons who ate chicken prepared at home were
14 less likely to be a Campylobacteriosis case?

15 A Yes, that's true.

16 Q In fact, isn't it true that persons who did
17 not eat chicken prepared at home were more likely to be
18 a Campylobacteriosis case than persons who did eat
19 chicken at home?

20 A The converse isn't -- no. The converse, you
21 really can't say that, unless they actually examine it,
22 because you're looking at a number of different

1 exposures.

2 You could say that it's statistically
3 significantly associated with a decreased risk. Could
4 you say that the cases -- say it again, please. I'm
5 sorry. Ask the question again.

6 Q Right. Based on this finding in the Freedman
7 analysis, isn't it true that persons who did not eat
8 chicken prepared at home were more likely to be a
9 Campylobacteriosis case than persons who did eat
10 chicken at home?

11 A I can't answer that. What -- you can go
12 through the different exposures and you can associate
13 it, associate the level of significance with each one
14 of these. A lot of the chicken eaten at a restaurant,
15 for example, has a high association of illness.

16 You can't say that a person who didn't eat
17 chicken prepared at home had a less -- you can't say
18 that. They didn't ask that question.

19 Q But wouldn't that have been the control, in
20 doing the match between a case and a control?

21 A So that --

22 Q Persons who did not eat chicken --

1 A Did not eat the chicken --

2 Q -- prepared at home were more likely to be a
3 Campylobacteriosis case than persons who did eat
4 chicken at home.

5 A So you're just doing a logical converse of
6 what the study found. I guess I'd have to say yes.

7 Q Dr. Tollefson, if you would look at that same
8 table, the fourth one down, "Ate turkey prepared at
9 home," the matched odds ratio is 0.6 and the P value is
10 less than 0.01?

11 A Yes.

12 Q Do you see that?

13 A Yes.

14 Q So in the Freedman analysis, isn't it true
15 that persons who did not eat turkey prepared at home
16 were more likely to be a Campylobacteriosis case than
17 persons who did eat turkey at home?

18 A As an epidemiologist, I would phrase it the
19 other way.

20 Q Tell me how you would phrase it.

21 A I would say that people who ate turkey
22 prepared at home were less likely to be a

1 Campylobacteriosis candidate.

2 Q Compared to persons who did not?

3 A Eat turkey prepared at home, yes.

4 Q Okay.

5 A Yes.

6 Q There's other risk factors here, or exposures
7 here, under "Kitchen and food handling practices." Do
8 you see those, Dr. Tollefson?

9 A Mm-hmm.

10 Q For example, the first one, "Had raw chicken
11 in home refrigerator."

12 A Yes.

13 Q Would you agree with me that the matched odds
14 ratio is 0.7?

15 A Yes.

16 Q And that the P value is less than 0.01?

17 A Yes. I'd also note that almost everybody had
18 raw chicken in a home refrigerator.

19 Q Okay.

20 A It's only a few more -- go ahead.

21 Q Okay. And given that the matched odds ratio
22 is less than 1.0 and that the P value is less than

1 0.01, wouldn't it be true that persons who had raw
2 chicken in their home refrigerator were less likely to
3 be a Campylobacteriosis case compared to persons who
4 did not have raw chicken in their home refrigerator?

5 A Yes -- yes, and the difference is
6 statistically significant, but it's barely, just from
7 eyeballing it.

8 Q P value of less than 0.01, right?

9 A Right.

10 Q Dr. Tollefson, if you'll continue down the
11 list, do you see the one that says, "Touched raw
12 chickens"?

13 A Yes.

14 Q It has a matched odds ratio, does it not, of
15 0.06?

16 A Yes.

17 Q And a P value of less than 0.01?

18 A It's 0.6, not 0.06.

19 Q Thank you.

20 A And yes, the P value is less than .01.

21 Q So would you agree with me that, based on the
22 Freedman analysis, persons in the case control study

1 who touched raw chicken were less likely to be a
2 Campylobacteriosis case than persons who did not touch
3 raw chicken?

4 A Yes.

5 Q I'm just going to do one more of these.

6 If you would look at the very last one in the
7 list, and I'm sorry, the very last one in the list of
8 "Kitchen and Food Handling Practices."

9 It says, "Chicken that was prepared at home
10 required cutting while raw." Do you see that?

11 A Right. Mm-hmm.

12 Q That has a matched odds ratio, does it not, of
13 0.5?

14 A Yes.

15 Q And a P value of 0.01?

16 A Yes.

17 Q So based on Freedman's study, isn't it true
18 that persons who -- for persons who had chicken that
19 was prepared at home that required cutting while raw,
20 those people were less likely to be a
21 Campylobacteriosis case than persons who did not have
22 chicken that was prepared at home that was required to

1 be cut while raw?

2 A Yes.

3 Q The findings we just discussed, those were all
4 statistically significant?

5 A Correct.

6 Q Dr. Tollefson, let me turn your attention to
7 Page 2 of your testimony, Paragraph 4. Do you see,
8 towards the bottom of Page 2, a sentence that starts
9 with, "Resistance traits"?

10 A Yes.

11 Q And your testimony states: "Resistance traits
12 may be passed to human pathogenic bacteria by
13 mechanisms that allow the exchange of bacteria's
14 genetic material."

15 A Correct.

16 Q That's your testimony?

17 A Under "Background on Anti-Microbial
18 Resistance," yes.

19 Q Are you aware of the fact that in this case
20 the parties stipulated, in Joint Stipulation Number 10,
21 "The parties do not have any facts or data
22 demonstrating horizontal gene transfer for

1 fluoroquinolone resistance in Campylobacter"?

2 A That's correct.

3 Q The parties also stipulated, in Joint
4 Stipulation Number 40, " The horizontal transfer of
5 genes conferring fluoroquinolone resistance in
6 Campylobacter has not been demonstrated"?

7 A That's true.

8 Q Do you agree that was stipulated?

9 A Yeah, I agree.

10 Q Okay. And not only do you agree that was
11 stipulated, you agree that that's true?

12 A That's true.

13 Q What this means is that fluoroquinolone
14 resistance cannot be transferred from one existing
15 Campylobacter to another existing Campylobacter through
16 genetic exchange?

17 A Correct. That's correct. It's not plasma
18 mediated.

19 Q Right. And it also means, does it not, that
20 fluoroquinolone resistance from Campylobacter cannot be
21 transferred to some other non-Campylobacter bacteria
22 through transfer of genetic material?

1 A Correct.

2 Q So when you say in your testimony, your
3 testimony about resistance traits passing by exchange
4 of genetic material, that's not relevant to
5 Campylobacter, is it?

6 A That's correct, it's not.

7 Q Dr. Tollefson, if you'll turn to Page 3 of
8 your written direct testimony, you refer to certain
9 "classic studies."

10 A Yes.

11 Q Do you see that?

12 A Yes.

13 Q Those studies are Homberg, G-285; Spika, G-
14 702; Taket; Conan Talkes, B-252; and Edgar and Bivey.

15 A Uh-huh.

16 MR. KRAUSS: Now, I didn't kill another tree
17 by making lots of copies of these. Let me just show
18 these to your counsel, and then I want to ask you about
19 them.

20 (Pause.)

21 MR. KRAUSS: Now, let me approach.

22 BY MR. KRAUSS:

1 Q Let me ask you first about Homberg, G-285,
2 here. That's relates to Salmonella and not
3 Campylobacter; isn't that right?

4 A Right, mm-hmm.

5 Q Let me ask you about G-702.

6 A That's Campylobacter.

7 Q That's not even an article by Spika, is it?

8 A No. The Spika article is -- they got the
9 wrong exhibit -- is an article about Salmonella.

10 Q And the Taket article that you referenced,
11 that has not been submitted to the docket, has it?
12 There's no B or G number?

13 A I don't know.

14 Q And --

15 A It's in the 1285. Whether or not it's in the
16 docket, that's different.

17 Q Well, if it's in the 1285, it would be in the
18 docket, but maybe not in evidence?

19 A Okay.

20 Q All right. And the B-252, Conan Talkes
21 article, this relates to Salmonella and not
22 Campylobacter, right?

1 A Correct.

2 Q And the Edgar and Bivey article has not been
3 submitted to the docket, right?

4 A Correct.

5 Q Dr. Tollefson, let me turn your attention to
6 the joint advisory committee meeting that you
7 referenced. I believe you testified that you were
8 aware of the transcript from this committee meeting?

9 A Mm-hmm.

10 Q Your testimony at Page 4 states: "FDA held a
11 Joint Veterinary Medicine and Anti-Infective Drugs
12 Advisory Committee meeting in May 1994 to discuss the
13 specific issue of approval of fluoroquinolones for use
14 in poultry. There was" --

15 A That's not quite right. I just noticed that.

16 Q I'm sorry. Am I reading it wrong?

17 A No, no, no. That's what I said, but it was
18 actually for use in food-producing animals.

19 Q Oh, so it wasn't specific to poultry?

20 A Uh-uh. No. I'm sorry. I just noticed that.

21 Q So your testimony is wrong here?

22 A It's wrong. It should be food-producing

1 animals in general.

2 Q Okay. In any event, your conclusion drawn in
3 your testimony is that there was no clear consensus
4 among committee members as to whether fluoroquinolones
5 should be used in food-producing animals. That's your
6 testimony, right?

7 A That's correct.

8 Q Okay.

9 A There was agreement that fluoroquinolones are
10 useful in animal medicine, that there's no clear
11 consensus that they should be -- there's a lot of
12 discussion about whether or not they should be approved
13 in food-producing animals.

14 Q Well, in coming to your conclusion that there
15 was no clear consensus, did you review the transcript?

16 A Yes, I was there, first of all, and I reviewed
17 the transcript, and I actually talked to some of the
18 numbers in the committee.

19 Q The transcript is the official record, right?

20 A Correct.

21 Q And the transcript is in evidence?

22 A Yes, that's true.

1 Q And it was a public meeting?

2 A Right.

3 Q And in the official record, the transcript,
4 which I also reviewed, isn't it true that not a single
5 member on record in the transcript of the joint
6 advisory committee took the position that
7 fluoroquinolones should not be used in food-producing
8 animals?

9 A Two members -- it may be semantics. It may be
10 how you interpret that. But two members felt that
11 additional study should be done on, and more extensive
12 evaluation of the benefits in animals versus the risk
13 to humans.

14 So they didn't -- they did not say they should
15 not be approved, but they weren't asked that question.
16 Okay?

17 Q Well, isn't it true that in the transcript, at
18 least nine of the committee members affirmatively state
19 there is a need for fluoroquinolones in food-producing
20 animals?

21 MS. STEINBERG: Your Honor, if Mr. Krauss is
22 going to ask the witness about what is in the

1 transcript, he needs to provide a copy to the witness,
2 and I might also add that the transcript speaks for
3 itself --

4 JUDGE DAVIDSON: Yes, I think it does. It's
5 in the record, isn't it?

6 MR. KRAUSS: Yes, Your Honor.

7 JUDGE DAVIDSON: Let me see it, and ask your
8 question.

9 MR. KRAUSS: And just for the record, on this
10 particular exhibit, the sticker page numbers are not in
11 order, in order to make the transcript page numbers bed
12 in order.

13 THE WITNESS: Yes. I would agree that I think
14 most of the members said that there is a need for
15 fluoroquinolones in animals, in food animals.

16 BY MR. KRAUSS:

17 Q And not a single member, in response to the
18 members saying there's a need, stood up and said, "No,
19 there's not a need"?

20 A I agree with that.

21 JUDGE DAVIDSON: Again?

22 THE WITNESS: Again.

1 JUDGE DAVIDSON: She's agreeing for the second
2 time.

3 MR. KRAUSS: Thank you, Your Honor.

4 BY MR. KRAUSS:

5 Q Now, let me turn your attention to NARMS.

6 A Okay.

7 Q You're one of the designers of NARMS, right?

8 A Yes.

9 Q And planning for NARMS began in 1995; isn't
10 that right?

11 A Planning for what we now know as NARMS began
12 in 1995. We actually started planning a resistance
13 monitoring system a couple of years before that.

14 Q But your testimony at Page 2, Line 19, says
15 planning for NARMS began in 1995?

16 A Correct.

17 Q And that was before the approval of Baytril,
18 right?

19 A Correct.

20 Q And NARMS became operational in January 1996?

21 A Right.

22 Q That was also before Baytril was approved,

1 right?

2 A Correct.

3 Q The NARMS system monitors resistance in food-
4 borne enteric bacteria, right?

5 A Correct.

6 Q There is a human component and then an animal
7 component?

8 A And a retail meat component.

9 Q The retail meat component wasn't added until
10 2001, right?

11 A Correct.

12 Q When NARMS became operational in January 1996,
13 in terms of the susceptibility testing of enteric
14 bacteria, Campylobacter was not included, right?

15 A No, only Salmonella.

16 Q Campylobacter was not added to the human arm
17 of NARMS until 1997, right?

18 A Correct.

19 Q And Campylobacter was not added to the animal
20 arm of NARMS until 1998, right?

21 A Correct.

22 Q Now, let me ask you about, you have some

1 testimony about speciating *C. jejuni* and *C. coli*,
2 right?

3 A Okay. Right.

4 Q I'm going to need to use a whiteboard here.
5 Again, not only am I not an epidemiologist, I'm not a
6 microbiologist, so I don't understand something here,
7 and I want to clarify it.

8 A That's fine. It's very confusing.

9 Q I agree. If I understand the speciation issue
10 correctly, NARMS will collect *Campylobacter* isolates --
11 and here I'm talking about both aspects of NARMS, human
12 and poultry. In general, NARMS collects all
13 *Campylobacters*. It doesn't -- if someone's got
14 *Campylobacteriosis*, at first, they don't know what
15 species of *Campylobacter* it is; isn't that right?

16 A Correct. Okay.

17 Q Okay.

18 A Okay.

19 Q And then, so you start off with all Campy. Do
20 you mind if I use the abbreviation Campy for
21 *Campylobacter*?

22 A No, not at all.

1 Q And NARMS wants to distinguish between
2 Campylobacter jejuni and Campylobacter coli and the
3 other thermophilic Campylobacters; isn't that right?

4 A It's not NARMS on the animal side. It's FSIS.

5 Q Okay.

6 A Okay?

7 Q Okay.

8 A On the human side, I could say yes, those
9 around NARMS partners.

10 Q Okay.

11 A Okay, but --

12 Q But you'd agree --

13 A -- distinction.

14 Q -- with me that somewhere in the NARMS --

15 A Yes, we definitely speciate the Campylobacter
16 organisms, yes.

17 Q Okay.

18 A Okay?

19 Q So we were kind of stepping all over each
20 other here for a minute. Let me just make sure I've
21 got this right.

22 Somewhere in the NARMS process, on both arms

1 of NARMS --

2 A Yes.

3 Q -- there is an attempt made to speciate
4 between Campylobacter jejuni and coli versus the
5 other --

6 A Other thermophilic Campylobacters, okay.

7 Q Okay.

8 A Yes.

9 Q And the way that that was traditionally done
10 -- I know it changed in 2001, or after 2001 -- but --

11 A Go ahead.

12 Q -- the process that was used to speciate was
13 using nalidixic acid and cephalothin; isn't that right?

14 A No. No. That's not correct. As early as
15 1987, it was known that using nalidixic acid in the
16 media to differentiate coli and jejuni was an error,
17 that it was not wise, because of the increasing
18 resistance to quinolones.

19 For some reason, FSIS continued to use that in
20 their isolation procedures to find Campylobacter. The
21 human arm never used that procedure.

22 Q Okay.

1 A Okay?

2 Q So I'm now going to limit this discussion
3 to --

4 A The animal? That's easier. That's easier.
5 Yeah.

6 Q -- the animal part of NARMS. Okay.

7 A Okay. So yes, you're right. For the animal
8 part of NARMS, until 2001, they were using nalidixic
9 acid, susceptibility to nalidixic acid and resistance
10 to cephalothin as identification of jejuni and coli.

11 Q Okay.

12 A That's not the right way to do it.

13 Q Okay.

14 A Okay?

15 Q But nevertheless, NARMS was doing it?

16 A Yes. But no -- no. FSIS was doing it.

17 Q Okay.

18 A We didn't know that.

19 Q Okay. FSIS was doing it?

20 A Yes.

21 Q Okay. And so FSIS would get Campylobacter
22 isolates in and they would have all Campy, and they

1 would use nalidixic acid to speciate between the jejuni
2 and coli on the one hand, and others --

3 A Yes.

4 Q -- primarily lori?

5 A Yeah, any.

6 Q Others?

7 A There's a couple others.

8 Q Okay. And also cephalothin, right?

9 A Yes.

10 Q I'm just going to say "C" for that. Okay?

11 Now, in --

12 A Resistance to that, yes.

13 Q Right. So in the process, there's a split,
14 and these over here, the jejuni and coli, they're
15 determined to be jejuni and coli because they are
16 susceptible to nalidixic acid --

17 A Correct.

18 Q -- and resistant to cephalothin, right?

19 A Yes.

20 Q And that's how you determine that's jejuni and
21 coli?

22 A That's not how I determined it, that's how

1 FSIS determined it.

2 Q That's how FSIS determined it. Okay. And
3 then, after this process, these same isolates are
4 tested --

5 A Okay. Now, all the isolates are sent, then,
6 to Paula. The jejuni and coli, those are sent to ARS
7 Laboratory in Athens, Georgia.

8 Q Okay.

9 A FSIS does not do any susceptibility testing.

10 Q Okay.

11 A Okay.

12 Q So when you say Paula, you mean Dr. Paula
13 Fedorka-Cray?

14 A Right. Correct.

15 Q And you're saying when they -- when those
16 isolates arrive at FSIS on the poultry arm of NARMS,
17 they've already gone through this process?

18 A Yes, they have, until 2001.

19 Q Right.

20 A Okay.

21 Q And now, the jejuni and coli isolates that
22 arrive to Dr. Fedorka-Cray's lab have already been

1 determined through this process to be susceptible to
2 nalidixic acid, right?

3 A Yes. It's somewhat of a screening test. They
4 use a disk to select the colony, so it's not 100
5 percent in either case, the susceptibility to nalidixic
6 acid and the resistance to cephalothin, but it's the
7 majority of them.

8 Q So it's not 100 percent, so what you're saying
9 is when the isolates are then chosen to be nalidixic
10 acid susceptible, it's not 100 percent, some of them
11 might be resistant?

12 A Correct.

13 Q But they're called C. jejuni or C. coli?

14 A Correct.

15 Q And then all of these isolates have already
16 been determined to be jejuni --

17 JUDGE DAVIDSON: Excuse me, Mr. Krauss.
18 You're playing fast and loose with my record.

19 MR. KRAUSS: I'm sorry.

20 JUDGE DAVIDSON: I mean, I know you're doing,
21 and I understand and I appreciate the aid that you're
22 using there, but when you say "these isolates," "this

1 process," the record doesn't show what you're talking
2 about, even though I see what you're talking about and
3 the witness sees what you're talking about.

4 I don't like to delay this any more than you
5 do, but if you have to explain it again, you know, you
6 have to go through and name the process you're talking
7 about. Otherwise, the record is not going to show it.

8 MR. KRAUSS: I appreciate it, Your Honor.
9 Thank you. So I'm going to get rid of the theses and
10 thoses and thats.

11 BY MR. KRAUSS:

12 Q In the speciation process, using nalidixic
13 acid as development, the jejuni and coli isolates have
14 already been determined to be susceptible to nalidixic
15 acid. That's why they are determined to be jejuni and
16 coli, right?

17 A That's correct.

18 Q And then these isolates are sent to, on the
19 poultry side now, sent to Dr. Paula Cray's
20 laboratory --

21 A Yes.

22 Q -- for susceptibility testing?

1 A Right, and --

2 Q And they --

3 A -- they re-identify them as being jejuni or
4 coli, but not --

5 Q Using some other method?

6 A Right, exactly. Yeah.

7 Q But they've already been determined to be
8 susceptible to nalidixic acid?

9 A Yes.

10 Q These jejuni and coli?

11 A Correct.

12 Q And then, susceptibility testing is performed
13 in the laboratory of Dr. Paula Fedorka-Cray, and some
14 of these isolates are then determined to be resistant
15 to nalidixic acid --

16 A Mm-hmm.

17 Q -- and some are also determined to be
18 resistant to Cipro --

19 A Right.

20 Q -- even though they already have been
21 determined to be susceptible to nalidixic acid, right?

22 A Right. The procedure isn't 100 percent.

1 Q Now, still talking about NARMS here, Dr.
2 Tollefson, you weren't the only designer of NARMS,
3 right?

4 A No.

5 Q In fact, Dr. Frederick Angulo from CDC was one
6 of the designers, too?

7 A Yes.

8 Q And his role related primarily to the human
9 arm of NARMS, right?

10 A Correct.

11 MR. KRAUSS: I don't even know if he's in the
12 room, Your Honor, but I'm going to ask this.

13 BY MR. KRAUSS:

14 Q You respect him as a scientist, don't you?

15 A Yes.

16 Q He submitted testimony in this matter?

17 A Mm-hmm. Yes, he did.

18 Q And Dr. Paula Fedorka-Cray of USDA was also
19 one of the designers of NARMS, isn't that right?

20 A Yes.

21 Q She's a veterinary microbiologist, right?

22 A She's a microbiologist, she's not a

1 veterinarian. Is that what she calls herself? That's
2 fine. I don't -- she works with animal isolates.

3 Q Okay. So she's a microbiologist?

4 A Correct.

5 Q And she works with animal isolates?

6 A Yes.

7 Q She has a Ph.D., doesn't she?

8 A Yes, she does.

9 Q And her role was mainly with the animal arm of
10 NARMS; isn't that right?

11 A Correct.

12 Q You testified that your testimony is based in
13 part on your knowledge and experience as a co-author
14 with Dr. Fedorka-Cray on several abstracts and papers;
15 isn't that right?

16 A Yeah, that's right.

17 Q And you respect Dr. Fedorka-Cray as a
18 scientist, don't you?

19 A Yes.

20 Q Now, Dr. Fedorka-Cray did not submit testimony
21 in this matter, did she?

22 A No, she did not.

1 Q She was originally on CVM's witness list,
2 wasn't she?

3 A Yes.

4 Q She was?

5 A Yes.

6 MS. STEINBERG: Objection, Your Honor.

7 JUDGE DAVIDSON: Yes?

8 MS. STEINBERG: What relevance does it have
9 who was on our witness list?

10 JUDGE DAVIDSON: Well, I assume he's going to
11 get to it sooner or later, but let him go for now.

12 MR. KRAUSS: I'll get to it now, Your Honor.

13 JUDGE DAVIDSON: Okay.

14 BY MR. KRAUSS:

15 Q Now, Dr. Tollefson, are you aware that Dr.
16 Fedorka-Cray completed a draft of testimony for this
17 hearing?

18 MS. STEINBERG: Objection, Your Honor.
19 Relevance.

20 JUDGE DAVIDSON: Overruled. Go ahead.

21 BY MR. KRAUSS:

22 Q Do you want me to repeat the question?

1 A No. She completed several drafts. We went
2 back and forth drafting testimony. I actually wrote
3 them first --

4 Q Okay.

5 A -- based on things that she had told me
6 orally and things that we had done in abstracts and so
7 on, as I said in testimony.

8 Q Okay.

9 A Yes. So we worked on testimony together.

10 Q And at some point in time, she had what was
11 referred to as a completed draft?

12 A She -- the way I recall it, she thought -- she
13 felt it was completed. We disagreed. She had added
14 another paragraph that we thought wasn't relevant; and
15 time ran out.

16 So we put most of what Paula was going to
17 testify in mine.

18 Q Right.

19 A It has do with a lot of this stuff.

20 Q Right. And you reviewed the completed draft
21 of Dr. Cray's testimony; isn't that right?

22 A I wouldn't call it reviewed it.

1 Q You reviewed drafts?

2 A Yes, definitely, I reviewed drafts.

3 MR. KRAUSS: Let me hand you -- first counsel,
4 and then you -- would you take a look at this, please?

5 The first page -- Your Honor, let me hand her
6 the copy.

7 THE WITNESS: (Examining) Yes, this is one of
8 the drafts that I remember.

9 BY MR. KRAUSS:

10 Q You reviewed this draft?

11 MS. STEINBERG: Objection, Your Honor.

12 JUDGE DAVIDSON: Okay.

13 MS. STEINBERG: This document was not mailed
14 to us.

15 JUDGE DAVIDSON: I understand that.

16 MS. STEINBERG: It's not in the record.

17 JUDGE DAVIDSON: I assume if it has some
18 relevance, it will be moved into evidence.

19 MR. KRAUSS: It will, Your Honor.

20 BY MR. KRAUSS:

21 Q In fact, Dr. Tollefson, you testified that you
22 recognized this document?

1 A Yes.

2 Q And you recognize this to be a draft of
3 testimony prepared by Dr. Fedorka-Cray?

4 A Right, but we objected that not everything in
5 here was factual.

6 Q Okay. We'll get into that.

7 A Okay. Okay.

8 Q Do you have any reason to believe that the
9 draft, what's referred to as "Completed Draft
10 Testimony" that's attached to the cover letter, do you
11 have any reason to believe that it's not a true and
12 accurate copy of Dr. Paula Fedorka-Cray's completed
13 draft testimony that you reviewed at some point in
14 time?

15 A We never had anything marked "Completed
16 Draft," so I couldn't -- I really can't -- I don't
17 know, because I don't know, word-for word --

18 Q But you reviewed drafts along the way?

19 A Yes, I did. I never saw this with "Completed
20 Draft" stamped on it, but it looks, in general, sort of
21 the penultimate draft, because we objected in one
22 particular paragraph and some minor things.

1 MR. KRAUSS: Okay. Your Honor, we would move
2 this document into evidence.

3 JUDGE DAVIDSON: Do you have a number?

4 MS. STEINBERG: Your Honor, we object.

5 JUDGE DAVIDSON: They haven't given me a
6 number yet.

7 MR. KRAUSS: Your Honor, it would be B-1929.

8 (Bayer Exhibit No. B-1929 was
9 marked for identification.)

10 MS. STEINBERG: We object. This is a non-
11 witness statement.

12 JUDGE DAVIDSON: Well, I'm going to reserve
13 ruling on it's admission into evidence. It will go
14 into the 1285 file, until I hear more what we're
15 talking about.

16 MR. KRAUSS: Okay.

17 JUDGE DAVIDSON: Because obviously, if there's
18 something in here you think is of evidentiary nature,
19 you have to get Dr. Cray to testify. If you think it's
20 just something that you're going to use with respect to
21 Dr. Tollefson's testimony, then I'll allow it. You
22 know, that's the difference. Okay

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

2 BY MR. KRAUSS:

3 Q Now, would you agree with me that -- I think
4 you testified that you drafted portions of this
5 completed draft testimony?

6 A Mm-hmm.

7 Q Would you agree that the subject matters
8 covered in Dr. Fedorka-Cray's completed draft testimony
9 were incorporated into Pages 9 to 12, and in
10 particular, Paragraphs 20 to 29, of your testimony?

11 Take your time to look at your testimony.

12 A Yes, that's correct. Some of it was from
13 Carolyn Minnick's and Geraldine Ransom's testimony,
14 from which I then, in order to help Dr. Cray with time
15 constraints, drafted and sent to her, she looked at it,
16 and saw it.

17 So I don't know if everything in here, from 20
18 to 29, was primarily Dr. Cray's.

19 Q Would it help you to have a comparison between
20 your Paragraphs 29 to 29 and Dr. Cray's completed draft
21 testimony?

22 A Well, the problem is that I'm not saying who

1 wrote the first -- you know, who put in what. I would
2 say that most of what is in here, from Paragraphs 21
3 through 29, are in Paula's area. I'd say that. Okay?

4 Q Okay.

5 A FSIS and AR -- the USDA portion of NARMS.

6 Q Now, portions of Dr. Fedorka-Cray's completed
7 draft testimony reference certain phenomena that she
8 and others performing Campylobacter susceptibility
9 testing were experiencing, and she raised questions
10 about the accuracy of the poultry NARMS results; isn't
11 that right?

12 MS. STEINBERG: Objection, Your Honor.

13 JUDGE DAVIDSON: Okay. What are you putting
14 it in for? Remember, that's what I said before. If
15 you're trying to get this in the record as evidence, I
16 got to have --

17 MR. KRAUSS: Your Honor, for right now, I'll
18 withdraw my motion to move it into evidence, and I'm
19 just going to use the document with the witness.

20 JUDGE DAVIDSON: All right. But you realize,
21 my ruling means that you're talking about whether this
22 witness's testimony is going to be affected by what was

1 in this document as opposed to whether or not this is
2 going to be on the record as evidence.

3 MR. KRAUSS: I understand that, Your Honor.

4 JUDGE DAVIDSON: Okay. Thank you.

5 MR. KRAUSS: Your Honor, I withdraw my motion
6 without prejudice.

7 JUDGE DAVIDSON: I understand, counsel.

8 BY MR. KRAUSS:

9 Q Now, let me re-ask my question, since it got
10 interrupted.

11 Isn't it true that portions of Dr. Paula
12 Fedorka-Cray's completed draft testimony referenced
13 certain phenomena that she and others performing
14 Campylobacter susceptibility testing were experiencing
15 and that raised questions about the accuracy of the
16 poultry NARMS results?

17 MS. STEINBERG: Your Honor, objection to the
18 form of the question. There's no evidence that this is
19 the completed testimony, completed draft testimony.

20 JUDGE DAVIDSON: I think we can solve that
21 problem, if you stop referring to it as the completed
22 draft testimony. It is in 1285 as Exhibit B-1929, and

1 you just use that --

2 MR. KRAUSS: No, Your Honor, I did not make
3 that representation. It is not in the docket as D-
4 1929.

5 JUDGE DAVIDSON: It is now.

6 MR. KRAUSS: Oh, it is now. Thank you.

7 JUDGE DAVIDSON: As B-1929, so if you stop
8 referring to it as completed draft testimony, you'll
9 obviate the necessity for objections from the other
10 side.

11 MR. KRAUSS: Thank you, Your Honor.

12 JUDGE DAVIDSON: Okay.

13 THE WITNESS: Okay, but I've got another
14 objection, as well, that's more technical.

15 You're asking two questions. Let me answer
16 the first part, did she have this paragraph that talked
17 about phenomena in isolating Campylobacter.

18 And that's the paragraph we objected to,
19 because our laboratory at FDA did not have that
20 problem. The CDC food-borne disease laboratory did not
21 have that problem. Many other laboratories that deal
22 with Campylobacter do not have the problem. So we

1 objected to her statement about "and others."

2 Now, your second part of your question was,
3 doesn't that invalidate the animal NARMS data.

4 BY MR. KRAUSS:

5 Q Well, that wasn't my question. My question
6 was, didn't she raise questions about the accuracy of
7 the poultry NARMS results?

8 A Okay. And my answer to that is, I consider
9 this, as an epidemiologist and a person used to
10 reviewing data, as a much more minor issue than the
11 issue with the nalidixic acid susceptible isolates only
12 coming from Dr. Cray's lab.

13 So in my mind, questions were raised about the
14 animal -- poultry isolates from NARMS before this
15 testimony was ever drafted.

16 Q Okay.

17 A Okay?

18 Q When you used the word "this," you had the
19 same problem I had earlier --

20 A Yeah, right.

21 Q -- you were pointing to something in the
22 document, and we don't know what that is for the

1 record.

2 You apparently -- there's two issues. There's
3 the "this" and there's the speciation. What was the
4 "this"?

5 A Dr. Cray had said that she has problems in her
6 laboratory with aggregation of colonies and mixed
7 cultures, and those are two different issues, but the
8 one, the mixed culture issue, we think is not really a
9 problem. Most infections are due to a mixture of
10 organisms.

11 For example, if somebody has a fluoroquinolone
12 resistant Campylobacter infection, it doesn't mean that
13 all of their Campylobacter are resistant, by any means.
14 They will have a mixed infection of susceptible and
15 resistant. Okay? So we didn't think of that as a
16 phenomenon.

17 And then the issue of aggregation, other
18 people, other laboratories have not had that problem,
19 so we did not want to introduce that into her testimony
20 as a major item. I mean, we just didn't agree with it.

21 Q What do you understand --

22 A Our microbiologists did not agree with it.

1 Q What do your understanding the aggregation
2 issue to be?

3 A Well, when she talks about aggregation of
4 isolates, she was thinking that it meant -- Dr. Cray
5 was thinking that it means that you can't speciate the
6 isolates very easily, and that you can't susceptibility
7 test them very easily.

8 Susceptibility testing of isolates is a
9 probability issue. Okay? There's a certain number
10 resistant, there's a certain number susceptible. Which
11 isolate you pick from the plate has more to do with
12 whether or not it's going to show up resistant or
13 susceptible, until that resistance reaches something
14 greater than 50 percent, right, as a prevalence.

15 So it's always -- we're sort of always
16 underestimating resistance, if you will, until
17 resistance becomes so common that your limit of
18 protections are no longer there, so the aggregation
19 issue, I just didn't think it was an issue at all, and
20 our microbiologists didn't, either.

21 Q And who is that?

22 A Doctors Dave White, Pat McDermott, and Bob