

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA : CIVIL ACTION  
ex rel., STEPHEN A. : NO. 2:10-04374(CDJ)  
KRAHLING and JOAN A. :  
WLOCHOWSKI, :  
Plaintiffs, :  
vs. :  
MERCK & CO., INC., :  
Defendant. :

\_\_\_\_\_ : Master File No.  
IN RE: MERCK MUMPS : 2:12-cv-03555(CDJ)  
VACCINE ANTITRUST :  
LITIGATION :

THIS DOCUMENT RELATES TO: :  
ALL ACTIONS :

- - -  
May 2, 2017

HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY

- - -  
Videotaped deposition of STEPHEN  
KRAHLING, taken at the offices of Morgan Lewis  
& Bockius, 1701 Market Street, Suite 18-F,  
Philadelphia, Pennsylvania 19103, beginning at  
9:37 a.m., before LINDA ROSSI-RIOS, a  
Federally Approved RPR, CCR and Notary Public.

- - -  
VERITEXT LEGAL SOLUTIONS  
MID-ATLANTIC REGION  
1801 Market Street - Suite 1800  
Philadelphia, PA 19103

Page 2

1 APPEARANCES:

2

3 On behalf of the Private Plaintiffs

4 SPECTOR ROSEMAN KODROFF & WILLIS, P C

5 BY: JOHN A MACORETTA, ESQUIRE

6 1818 Market Street

7 Suite 2500

8 Philadelphia, PA 19103

9 215 496 0300

10 jmacoretta@srkw-law.com

11

12 On behalf of the Relators

13

14 KELLER GROVER LLP

15 BY: JEFFREY F KELLER, ESQUIRE

16 1965 Market Street

17 San Francisco, CA 94103

18 415 543 1305

19 jfkeller@kellergrover.com

20

21 On behalf of Relators and the Witness

22 Stephen Krahling

23

24 CONSTANTINE CANNON LLP

25 BY: GORDON SCHNELL, ESQUIRE

and

MARLENE KOURY, ESQUIRE

335 Madison Avenue

New York, NY 10017

212-350-2700

gschnell@constantinecannon.com

mkoury@constantinecannon.com

Page 3

1 APPEARANCES (cont'd):

2

3 On behalf of the Defendant, Merck & Co ,

4 Inc

5 MORGAN LEWIS & BOCKIUS LLP

6 BY: LISA DYKSTRA, ESQUIRE

7 and

8 MELINA R DiMATTIO, ESQUIRE

9 1701 Market Street

10 Philadelphia, PA 19103

11 215 963 5000

12 lisa.dykstra@morganlewis.com

13 melina.dimattio@morganlewis.com

14

15 On behalf of the Defendant, Merck & Co ,

16 Inc

17

18 VENABLE LLP

19 BY: DINO S SANGIAMO, ESQUIRE

20 750 E Pratt Street

21 Suite 900

22 Baltimore, MD 21202

23 410 244 7400

24 dssangiamo@venable.com

25

ALSO PRESENT:

20 TIMOTHY K HOWARD, ESQUIRE

21 Merck in-house counsel

22 AMANDA HEARY, Videographer

23 - - -

24

25

Page 4

1 I N D E X

2

3 WITNESS PAGE

4 STEPHEN KRAHLING

5 By Ms Dykstra 10

6

7 E X H I B I T S

8 MARKED DESCRIPTION PAGE

9 Krahling-1 10/10/00 Memo, 24

10 MRK-KRA00331424 - 00331433

11 Krahling-2 CDC Manual for the 75

12 Surveillance of

13 Vaccine-Preventable

14 Diseases

15 Krahling-3 Amended Complaint for 80

16 Violations of the Federal

17 False Claims Act

18 Krahling-4 MMR II label, 87

19 RELATOR\_00002094 - 00002105

20 Krahling-5 6/23/98, IND submission, 112

21 MRK-KRA00624345 - 00624446

22

23 Krahling-6 Relator Stephen A 116

24 Krahling's Responses and

25 Objections to Defendant

Merck's Requests for

Admission

Krahling-7 6/21/16 Letter 117

Krahling-8 Letter, 123

MRK-KRA00001446 - 00001469

Krahling-9 12/1/99 Letter, 131

MRK-KRA00001222 - 00001230

Krahling-10 12/30/99 IND submission, 139

MRK-KRA00001470 - 00001924

Page 5

1 E X H I B I T S (cont'd)

2 Krahling-11 3/12/11 Response to FDA 155

3 Request for Information,

4 MRK-KRA00018864 - 00018937

5 Krahling-12 8/1/00 Letter, 171

6 MRK-KRA00048418

7

8 Krahling-13 Employee Initialization, 174

9 MRK-KRA00582401

10 Krahling-14 10/24/00 Letter, 176

11 RELATOR\_00001058 - 00001060

12

13 Krahling-15 E-mails, 215

14 MRK-KRA00048342

15 Krahling-16 Compilation of e-mails, 218

16 RELATOR\_00000731 - 00000735

17

18 Krahling-17 4/8/01 Letter, 223

19 RELATOR\_00000328 - 00000331

20 Krahling-18 7/17/01 E-mail, 251

21 MRK-KRA00002243

22

23 Krahling-19 Handwritten notes, 272

24 RELATOR\_00001068 - 00001070

25 Krahling-20 Resume, 287

RELATOR\_00002770 & 00002771

Krahling-21 Relator Stephen A 290

Krahling's Responses and

Objections to Merck's

Revised First Set of

Interrogatories

Krahling-22 Handwritten notes, 304

RELATOR\_00001072 - 00001080

Krahling-23 9/25/01 E-mail, 318

RELATOR\_00000745

Krahling-24 E-mail string, 320

RELATOR\_00000747

Page 6

1 EXHIBITS (cont'd.)  
 2 Krahling-25 Handwritten notes, 291  
 RELATOR\_00001044 - 00001047  
 3  
 Krahling-26 10/29/01 Letter, 327  
 4 MRK-KRA00002013 - 00002016  
 5 Krahling-27 Letters, 332  
 RELATOR\_00001086 - 00001090  
 6  
 Krahling-28 11/30/01 Agreement, 336  
 7 MRK-KRA00582394 - 00582397  
 8  
 9  
 10  
 11  
 12  
 13  
 14  
 15  
 16  
 17  
 18  
 19  
 20  
 21  
 22  
 23  
 24  
 25

Page 7

1 DEPOSITION SUPPORT INDEX  
 2  
 3 DIRECTION TO WITNESS NOT TO ANSWER  
 4 Page Line  
 5 (None)  
 6  
 7  
 8  
 9 REQUEST FOR PRODUCTION OF DOCUMENTS  
 10 Page Line  
 11 331 9  
 12  
 13  
 14  
 15 STIPULATIONS  
 16 Page Line  
 17 (None)  
 18  
 19  
 20  
 21 QUESTIONS MARKED  
 22 Page Line  
 23 (None)  
 24  
 25

Page 8

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL  
 2 - - -  
 3 VIDEOGRAPHER: We are now on  
 4 the record. Please note microphones  
 5 are sensitive and may pick up private  
 6 conversations. Please turn off all  
 7 cell phones and place them away from  
 8 the microphones as they can interfere  
 9 with the deposition's audio.  
 10 My name is Amanda Heary  
 11 representing Veritext Legal Solutions.  
 12 The date today is May 2, 2017,  
 13 and the time is 9:37 a.m. This  
 14 deposition is being held at Morgan,  
 15 Lewis & Bockius, located at 1701 Market  
 16 Street, Philadelphia, Pennsylvania.  
 17 The caption of this case is In Re:  
 18 Merck Mumps Vaccine Antitrust  
 19 Litigation and United States of America  
 20 ex rel. Stephen A. Krahling and Joan  
 21 Wlochowski versus Merck & Co., Inc.  
 22 This case is being held in the United  
 23 States District Court for the Eastern  
 24 District of Pennsylvania. The Case  
 25 Number 2:12-cv-03555(CDJ). The name of

Page 9

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL  
 2 the witness is Stephen Krahling.  
 3 At this time attorneys present  
 4 in the room and everyone attending will  
 5 identify themselves and the parties  
 6 they represent.  
 7 MR. SCHNELL: Gordon Schnell  
 8 from Constantine Cannon. Counsel for  
 9 Mr. Krahling.  
 10 MR. KELLER: Jeffrey Keller  
 11 from Keller Grover. Counsel for the  
 12 Relators.  
 13 MS. KOURY: Marlene Koury from  
 14 Constantine Cannon. Counsel for  
 15 Relators.  
 16 MS. DYKSTRA: Lisa Dykstra from  
 17 Morgan Lewis. Counsel for Merck.  
 18 MS. DIMATTIO: Melina DiMattio  
 19 from Morgan Lewis. Also for Merck.  
 20 MR. SANGIAMO: Dino Sangiamo,  
 21 Venable, for Merck.  
 22 MR. HOWARD: Timothy Howard,  
 23 in-house counsel for Merck.  
 24 VIDEOGRAPHER: Our court  
 25 reporter Linda Rossi representing

Page 10

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Veritext Legal Solutions, will swear in

3     the witness and we can proceed.

4     - - -

5             STEPHEN KRAHLING, after having

6     been first duly sworn, was examined and

7     testified as follows:

8     - - -

9             EXAMINATION

10    - - -

11  BY MS. DYKSTRA:

12    Q.    Good morning, Mr. Krahling.

13  Krahling, right?

14    A.    Krahling, right.

15    Q.    Krahling. I'm going to go over

16  some just general information just to make

17  sure we're on the same page as far as how

18  we're going to proceed today. We have two

19  full days of deposition. We'll take breaks

20  whenever you need them. You'll let us know us

21  know if you need a break. If you need a

22  break, we'll take a break.

23           If I speak too quickly because

24  sometimes I do or you don't understand a

25  question and you need me to repeat it, just

Page 11

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2  let me know as we go forward. Okay?

3     A.    Yes.

4     Q.    You have to make verbal answers

5  so the court reporter can get that down.

6           I need you to respond to each

7  question fully to the best that you're able

8  to. I don't want you to guess. But if you

9  don't know the answer, that's okay. But give

10  me your best answer and your most honest

11  answer. Okay?

12    A.    I understand.

13    Q.    We'll try not to speak over

14  each other so the court reporter can get

15  everything down, make sure she gets it down

16  accurately. If I ask you a question and you

17  answer it, I'm going to assume that you

18  understand it. So if you don't understand my

19  question, I'm happy to rephrase it or have her

20  read it back to you. Okay?

21    A.    Okay.

22    Q.    You understand what being under

23  oath means. Correct?

24    A.    Yes, I do.

25    Q.    That you must tell the truth,

Page 12

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2  and if not, you're violating the law?

3     A.    I got that.

4     Q.    We can take breaks, as I said,

5  but not when a question is pending, so we'll

6  take them appropriately.

7     A.    I understand that also.

8     Q.    Let me ask you a couple of

9  questions. Have you ever testified before in

10  a deposition?

11    A.    I don't think so, no.

12    Q.    Have you ever testified under

13  oath before?

14    A.    I don't recall. I don't think

15  so.

16    Q.    Have you ever been involved in

17  a -- as a plaintiff or a defendant in any

18  other lawsuits?

19    A.    I mean, those are legal terms.

20  I don't think that I have.

21    Q.    Have you ever sued anybody?

22    A.    No. It's crossing my mind as

23  traffic ticket type stuff. No.

24    Q.    Have you ever filed any other

25  cases under the False Claims Act other than

Page 13

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2  this one?

3     A.    No.

4     Q.    Have you ever discussed with

5  the Department of Justice any other cases

6  potentially to be filed under the False Claims

7  Act other than this one, even if it wasn't

8  necessarily filed?

9     A.    If I had done that, it would

10  have been with these guys present, my counsel.

11  But I don't recall doing that.

12    Q.    Okay. Well, if you do recall

13  later on and it comes to your mind, you can

14  let us know.

15    A.    You mean if I recall outside of

16  conversations with my lawyers?

17    Q.    No. You can tell me if you had

18  a conversation with the Department of Justice

19  about a potential False Claims Act case,

20  whether it was filed or not. Just don't tell

21  me the content, just tell me whether the

22  conversation occurred.

23    A.    Outside of my lawyers being

24  present?

25    Q.    No. With your lawyers or

Page 14

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     without. That's not a privileged statement

3     whether it occurred or not.

4     A.    I got it. I didn't mean to

5     speak over you.

6     That, I don't quite recall

7     because it's a legal thing whether a case

8     would go forward. I don't recall.

9     MR. SCHNELL: I don't think he

10    understands. She's talking about other

11    than this case. Do you understand

12    that?

13    THE WITNESS: Yeah. I don't

14    believe we did, but we talked about

15    other Merck products and we didn't talk

16    about anything else except this case.

17    So I don't think my memory is

18    responsive to the question. I don't

19    believe we did, but to say flat out

20    no -- do you understand my answer?

21    BY MS. DYKSTRA:

22    Q.    Not entirely.

23    A.    I believe that we didn't, but I

24    don't know what would be responsive because

25    Merck has more than one vaccine. So, for

Page 15

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     instance, mumps, MMR, ProQuad, and you start

3     talking about anything else I see or happened

4     in the context of other litigation, I don't

5     believe those conversations took place, but I

6     was discussing them in front of the Department

7     of Justice with my lawyers there, they're

8     lawyers and I'm not, so I don't understand --

9     Q.    Let me ask --

10    A.    -- what legal avenue any of

11    that was running down, but we focused on this

12    case or the issues of this case.

13    Q.    Let me ask this: Have you ever

14    had a conversation with the Department of

15    Justice about another pharmaceutical company

16    in connection with a potential False Claims

17    Act case?

18    A.    No.

19    Q.    Have you ever had discussion

20    with the Department of Justice or any other

21    government agency in connection with a

22    potential False Claims Act case other than

23    related to a mumps product?

24    A.    What are you getting at there,

25    I don't -- can you --

Page 16

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q.    Have you ever had a discussion

3     with the government about a potential False

4     Claims Act case unrelated to the mumps

5     vaccines, related to another product?

6     MR. SCHNELL: Are you talking

7     about outside the discussions involving

8     this case?

9     MS. DYKSTRA: Correct. I'm

10    trying to say other vaccines to

11    clarify. We're not talking about mumps

12    vaccines or this case.

13    BY MS. DYKSTRA:

14    Q.    Any other situation where you

15    pursued or had discussions about a potential

16    False Claims Act case putting aside anything

17    related to the mumps vaccine?

18    A.    I'm pretty sure the answer to

19    that is no, if I am understanding you

20    correctly.

21    Q.    Let me ask -- let's turn to

22    something else about your preparation for

23    today.

24            So tell me what you did to

25    prepare for today. Without discussing what

Page 17

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     you talked with your counsel about, tell me

3     who you met with and when.

4     A.    So you want to know who I met

5     with and when?

6     Q.    To prepare for today.

7     A.    I met with Marlene and Gordon

8     who are both there, in New York City, Midtown

9     Manhattan. I think it was exactly a week ago

10    today. Today is Tuesday, right?

11    Q.    Yes.

12    A.    So it would have been Tuesday.

13    Maybe I drove on Tuesday. For three days last

14    week. I drove home on a Friday.

15    Q.    Where do you live?

16    A.    The middle of Pennsylvania,

17    State College, PA.

18    Q.    About how long did you meet

19    each day, all day long for three days?

20    A.    What do you mean "all day

21    long"? Business hours?

22    Q.    Business hours.

23    A.    A little late start each day

24    for the first two days and then an early

25    cutoff each day. Friday was just a couple of

Page 18

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     hours because I wasn't going to drive in the

3     morning traffic and I wanted to miss the

4     evening traffic. So just to get in in the

5     afternoon, maybe two or three hours Friday,

6     the final day.

7     Q. Other than --

8     A. I have one more. That was

9     that. We also got into town Sunday, two days

10    ago, and I met with Marlene, Gordon and

11    Jeffrey who are all here, and we -- that

12    would -- yesterday, for -- I think we got a

13    late start again. And we cutoff a little

14    early. That was yesterday. And that's the

15    entire time I met with them for preparation

16    for this deposition.

17    Q. Thank you. I assume you looked

18    at documents during those sessions?

19    A. Yeah, I looked at some documents.

20    I review documents.

21    Q. Did any documents in particular

22    refresh your recollection about what occurred

23    in connection with this lawsuit?

24    A. I reviewed the complaint.

25    MR. KELLER: I don't --

Page 19

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     THE WITNESS: I reviewed the

3     complaint. I think they showed me the

4     package insert, but I didn't review it.

5     I didn't look at the interrogatories.

6     I didn't look at the RFAs. Those are

7     the two -- well, I reviewed -- had the

8     complaint in my hands. That was the

9     only document I had that I reviewed.

10    So to what -- I mean, I don't

11    understand your question. Refreshed

12    memory, can you be more specific?

13    BY MS. DYKSTRA:

14    Q. That's okay. I think that's a

15    good enough answer for right now.

16    Let me ask you a question about

17    when you filed the complaint. When you filed

18    the complaint originally, did you draft the

19    complaint or did your lawyers draft the

20    complaint?

21    MR. SCHNELL: Object to form.

22    THE WITNESS: What do you mean

23    by "draft"?

24    BY MS. DYKSTRA:

25    Q. Put pen to paper and write the

Page 20

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     words out on the page or type it up?

3     MR. SCHNELL: Object to form.

4     THE WITNESS: I don't know that

5     anybody put pen to paper, but you're

6     talking type it up. If you can define

7     content, what do you mean, who came up

8     with certain sentences or the

9     sentences?

10    BY MS. DYKSTRA:

11    Q. How did you draft the

12    complaint? Let me ask you that. How was the

13    complaint drafted?

14    MR. SCHNELL: Object to form.

15    THE WITNESS: I mean, the most

16    general way I can say is I worked with

17    my law team to draft the complaint. If

18    there's anything I can answer more

19    specific than that, I don't quite

20    understand. I was involved heavily in

21    it.

22    BY MS. DYKSTRA:

23    Q. And was Joan involved heavily

24    in preparing the complaint as well?

25    A. I can't speak to that.

Page 21

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q. Was she not in the meetings

3     with you and your attorneys when you drafted

4     the complaint or prepared what would be in the

5     complaint generally?

6     A. The reason behind some of those

7     decisions would reveal the decisions made by

8     my counsel and I. Should I answer that?

9     Q. I don't want to know -- I just

10    want to know whether when you met with your

11    counsel and talked about -- to your counsel

12    about drafting the complaint, whether Joan was

13    part of those discussions or meetings?

14    A. She was involved in drafting

15    the complaint, but my lawyers did a very good

16    job of trying not to bias what we were saying

17    by keeping us apart so that we told our

18    stories and didn't try to coordinate or rely

19    on each other. So I didn't get to see her or

20    understand what she was saying. They kept us

21    completely separate.

22    Q. When you drafted -- when you

23    helped to draft or prepare the complaint, did

24    you review the package inserts in connection

25    with that work?

Page 22

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     A.    I don't recall.

3     Q.    Other than meeting with your

4   counsel for today to prepare, did you do

5   anything else, like on your own or with

6   friends or with colleagues, did you do

7   anything else to prepare yourself for today?

8     A.    Could you be more specific?

9   Like I did the laundry.

10    Q.    Did that prepare you for today?

11    A.    Yeah, because I had three

12   outfits to wear in case a bird crapped on me

13   on the way here. I mean, you want something

14   more than that. I don't understand what

15   you're asking for more than that or aside from

16   that.

17    Q.    Did you review any other

18   documents on your own?

19    A.    No.

20    Q.    Did you talk to any of your

21   colleagues about what happened in the lab in

22   preparation for today?

23    A.    No.

24    Q.    Did you talk to your family or

25   friends about getting ready for today?

Page 23

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     A.    I mean, I had talked to my son

3   about the reason I couldn't golf 18 holes with

4   him on Saturday. That's about the extent of

5   that, because I wanted to not be around the

6   hustle and bustle of a normal Saturday when I

7   was leaving the next day. Are you looking for

8   something more than that?

9     Q.    If there is anything more than

10   that, that's --

11    A.    No.

12    Q.    Let me go through, if I can,

13   your educational and -- your education and

14   your work experience so I can understand the

15   chronology of that.

16         MS. DYKSTRA: Speaking to

17   counsel for a second. As you know in

18   this case we had labeled some of the

19   rHA documents highly confidential AEO.

20   There was a document that was labeled

21   that way. I'm going to de-designate it

22   for purposes of this deposition because

23   his resume was attached to it.

24         So we are marking as Exhibit

25   Krahling-1.

Page 24

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     - - -

3     (Exhibit Krahling-1, 10/10/00

4     Memo, MRK-KRA00331424 - 00331433, was

5     marked for identification.)

6     - - -

7   BY MS. DYKSTRA:

8     Q.    This is a document relating to

9   your hiring at Merck, and your resume is

10   attached to it. So if you can just -- you

11   don't have to read the whole letter, I'm not

12   going to ask you about the front page, I'm

13   just going to focus on your resume and your

14   grades which are attached.

15    A.    Can I read the whole thing?

16    Q.    The front letter?

17    A.    All of it.

18    Q.    Sure. You may read anything

19   you need to.

20         MS. KOURY: Lisa, are you

21   redesignating this confidential?

22         MS. DYKSTRA: Confidential,

23   yes.

24   BY MS. DYKSTRA:

25    Q.    I'm not going to go past the --

Page 25

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     A.    There it is.

3     Q.    I'm not going past this page.

4   I'm not going to look at the rest of it.

5     A.    This?

6     Q.    Just that, yeah.

7     A.    It's hard to read.

8     Q.    I'm not going to ask questions

9   about anything else in the document.

10    A.    That's fine. I don't have to

11   look at that page.

12    Q.    And I'm not going to ask

13   questions about that either.

14    A.    We don't want this to refresh

15   my memory at all?

16    Q.    No, it has nothing to do with

17   the --

18    A.    I shouldn't read it?

19    Q.    -- rest of the questions.

20    A.    I don't know.

21         MR. SCHNELL: Ask your question

22   and if you think you need to, then you

23   can read it.

24         THE WITNESS: Maybe I didn't

25   write this page. Oh, this is a letter

Page 26

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 of recommendation, isn't it?

3 BY MS. DYKSTRA:

4 Q. Yes, you have the letter of

5 recommendations attached, and I'm not going to

6 ask --

7 A. Okay. So you're not going to

8 ask me about this letter of recommendation?

9 Q. I'm not going to ask you about

10 any of the letters of recommendation.

11 A. I don't have to review that.

12 Q. So the first page is your

13 resume.

14 A. The first page is --

15 Q. Not the letter, the first --

16 second page is your resume.

17 A. The first page looks like

18 something David Krah wrote.

19 Q. Correct.

20 A. So we're moving to the second

21 page?

22 Q. Yes. Did you prepare this

23 document to provide to Merck when they were

24 going to hire you or when you were looking for

25 a job?

Page 27

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 A. I don't recall when I prepared

3 this document. It likely was something I had.

4 But I believe that I gave this to Dave Krah to

5 apply for a permanent position in his lab.

6 Q. And your education here states

7 that you went to Penn State and have a BS in

8 microbiology. Is that accurate?

9 A. That is accurate.

10 Q. Do you have any other degrees?

11 A. Beyond a bachelor's degree?

12 What do you --

13 Q. Yes, beyond a bachelor's or in

14 addition to another BS from another school.

15 A. No.

16 Q. Have you taken any college

17 courses, graduate courses or any other type of

18 post-college courses past this time frame of

19 1995 when you graduated from Penn State?

20 A. No.

21 Q. If you turn to the second page

22 which is your transcript, it says at the

23 bottom -- halfway down there's an intro to

24 micro lab that you got a D in. Have you taken

25 any other classes at all with respect to

Page 28

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 microbiology?

3 A. Hold on. I'm looking for it.

4 Q. Sure.

5 A. So now what's your question?

6 Q. If you've taken any other

7 microbiology classes other than this one?

8 A. I did not take any classes

9 other than what is listed in this transcript.

10 Q. If you go all the way to the

11 bottom, it says you have a D in viruses. Do

12 you see that?

13 A. Yep.

14 Q. And I assume you took no other

15 classes in viruses other than what's here?

16 A. These are the classes I took at

17 Penn State.

18 Q. If you go back to your resume,

19 which is 1426 at the bottom, is this resume

20 that you submitted to Merck an accurate

21 representation of your work experience?

22 MR. SCHNELL: Object to form.

23 THE WITNESS: Yes. At the

24 time, yes, it would have been.

25 BY MS. DYKSTRA:

Page 29

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 Q. And it lists all the places you

3 worked when you applied?

4 A. All the places that I worked

5 that were relevant.

6 Q. So you worked at Penn State for

7 approximately five years. Is that correct?

8 MR. SCHNELL: Object to form.

9 THE WITNESS: At the time I had

10 worked at Penn State for five years.

11 BY MS. DYKSTRA:

12 Q. From 1993 to 1998?

13 A. Yeah, but I mean, beyond that,

14 that's actually the amount of time I was --

15 because I wasn't getting paid. In 1993 to

16 1995 I worked summers and got paid a wage for

17 doing that. During the semester, I got class

18 credit for working there. So when you say

19 work, I'm not -- I mean, there's different

20 ways of being compensated for your labor.

21 From 1995, when I graduated,

22 until 1998, I got paid as a professional.

23 When I left there and went to Merck, I was

24 still available to help the graduate students

25 with the projects they were doing, teaching



Page 30

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     them techniques and things like that. So that

3     would be considered work, but I didn't draw a

4     wage for it.

5     Q.    What generally did you do at

6     Penn State? If there's different positions

7     that you had, describe those for me, what your

8     responsibilities were.

9     A.    I think I only had one position

10    there, as a research technician. I mean, the

11    label may have changed from an undergraduate,

12    but I worked on the same project which was

13    what the lab was working on in support of

14    that. Generally speaking, we were trying to

15    characterize the mechanics of the phospholipid

16    membrane bilayer in eukaryotic cells. Do you

17    want some more depth than that?

18    Q.    No. That's fine, thanks.

19        After you left Penn State, did

20    you have another position, another work

21    experience after you left Penn State in 1998?

22    A.    Yes.

23    Q.    Where did you go after Penn

24    State? Who were you employed by after Penn

25    State?

Page 31

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     A.    A company called ViroPharma.

3     Q.    How long were you at ViroPharma?

4     A.    About six months.

5     Q.    What did you do there?

6     A.    I did tissue culture work in

7     support for cell-based assays.

8     Q.    And I'm sorry, why did you

9     leave Penn State in 1998?

10    A.    I was young. I had gone to

11    college there. I kept getting a year older,

12    everyone else stayed the same age. Just felt

13    like I should leave at some point.

14    Q.    Did you leave on good terms?

15    A.    Very good terms.

16    Q.    When you took the job at

17    ViroPharma, what was the position that you had

18    there?

19    A.    I don't remember off the top of

20    my head what the title would be, but it was

21    applicable to the experience I had from Penn

22    State.

23    Q.    Why did you decide only to

24    remain there for six months?

25    A.    Why didn't I spend my entire

Page 32

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     career there?

3     Q.    Why did -- what made you leave

4     after six months? Or why did you leave after

5     six months?

6     A.    I guess the best way to say it

7     was that it was a lateral move at best from

8     Penn State, and it was a small company and

9     they were expanding and having more and more

10    work done. So I was doing more and more work

11    in support of other people's assays, not

12    running many assays. And I was young and

13    mobile. So I thought I could move or find

14    another position that would be something more

15    in the line of doing research. So, I guess,

16    the best answer was there wasn't enough to

17    keep me there. It wasn't a higher level

18    research job like Penn State's.

19    Q.    Were you running assays at

20    ViroPharma?

21    A.    Yes.

22    Q.    What type of assays did you

23    work on?

24    A.    They were cell-based assays.

25    Q.    Any more detail than that?

Page 33

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     A.    I had an agreement with them

3     not to disclose what I was working on.

4     Q.    Let me ask it this way so we

5     won't tread there: Were any of the assays you

6     worked on plaque neutralization assays?

7     A.    No.

8     Q.    Were any of the assays you

9     worked on ELISA assays?

10    A.    May have been. They were

11    cell-based assays with viruses and viral

12    infection assays, potency toxicity. Generally

13    that's all I can say. That's the kind of

14    thing that companies do.

15    Q.    What do you mean "that's the

16    kind of thing" --

17    A.    I don't want to say specifically

18    what chemical -- what they were trying to do

19    with a chemical because I signed -- that's

20    what I mean. I did assays and I want to

21    define them in a way that -- they're general

22    assays. People -- when you say ELISA, I don't

23    know what you mean by ELISA necessarily, we

24    haven't defined the term. But I assume you're

25    speaking very generally. So I very generally

Page 34

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     did assays that would require you to put cells

3     on tissue culture plates.

4     Q.    Were you fired from ViroPharma?

5     A.    I don't think you could

6     characterize it like that.

7     Q.    Were you -- did somebody at

8     ViroPharma tell you need to leave or ask you

9     to leave?

10    A.    I went in and tried to resign,

11    and they had given me -- when I started there,

12    they had given me, like, money to be able to

13    move there but it was like a loan so that I

14    would pay it back out of each paycheck. When

15    I tried to resign, they said I would have to

16    pay the balance of that back to them. And I

17    couldn't so I had to stay until the six

18    months. And then they informed me that time

19    to go. So it was my idea to leave. I don't

20    know how they took that. But then when the

21    money was close to where it could be paid off,

22    I felt it was a mutual agreement that you can

23    go, you don't want to be here, go.

24    Q.    When did you first tell them

25    that you -- when did you make the decision and

Page 35

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     tell them you wanted to leave?

3     A.    That was a long time ago.

4     Q.    How many months were you there

5     or weeks were you there?

6     A.    I was there six months. So the

7     best guess -- no, I shouldn't guess. Before

8     they came to me and said, all right, you can

9     go.

10    Q.    Where was ViroPharma located

11    that you had to relocate?

12    A.    That's off the turnpike. I got

13    this. I think I took the Exton exit of the

14    turnpike. Somewhere around there. It was

15    where Route 100 closes the turnpike, very

16    close to that.

17    Q.    When you left ViroPharma -- let

18    me ask one question. Sorry.

19            Why did you not list ViroPharma

20    on your application or your resume that you

21    provided to Merck in connection with your

22    application to work at Merck?

23    A.    There were other jobs I also

24    didn't list. My experience at Penn State was

25    so strong, if you look at the publications, I

Page 36

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     had averaging more than one publication per

3     year since I had graduated with a BS. When I

4     interviewed at Merck, I remember one guy

5     saying you have more publications than I do.

6     And he was running the interview. So this is

7     apparently very impressive. Working at six

8     months for some other place where you only did

9     basic tissue culture isn't really a strong

10    point. It didn't add anything to the resume.

11    Q.    And, I guess, it could have

12    taken something away that you were only there

13    for six months?

14            MR. SCHNELL: Object to form.

15            THE WITNESS: I disagree with

16    that characterization. By the time I

17    had turned this in to Dave Krah, I had

18    already worked at Merck for a year and

19    a half.

20    BY MS. DYKSTRA:

21    Q.    After ViroPharma, where did you

22    go for employment?

23    A.    It was a contract agency. I

24    don't know how to describe it. Merck hired

25    people through -- people call it a temp agency

Page 37

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     or a contract agency. And I think that agency

3     set up -- gosh, actually I don't recall how I

4     got there, but I got to Warner-Lambert. I'm

5     not sure if it was through the contract agency

6     that mediated meeting Merck or not.

7     Q.    But after you left ViroPharma,

8     your next position as a professional was at

9     Warner-Lambert?

10    A.    Yeah.

11    Q.    What did you do at Warner-Lambert?

12    A.    I was only there a week. I

13    don't recall what I did for a week.

14    Q.    Why were you only there a week?

15    A.    Because I was offered the job

16    at Merck. Merck was in research. If I

17    recall, Warner-Lambert was more quality

18    control perhaps. Merck was much more aligned

19    with my experience at the time.

20            Just to volunteer information,

21    I didn't feel that that was negative either.

22    It didn't matter so I didn't put it on the

23    resume, one week. But I left there with very

24    positive feelings. I went to the people at

25    Warner-Lambert at the time and said it's been

Page 38

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     one week, I feel bad leaving after a week.

3     And they said, you know what, we understand.

4     This is more in line with your experience, you

5     got to do it. I would do it too. So even

6     though I left after only one week, it was on

7     very good terms.

8     Q.   And then from Warner-Lambert

9     you went to your first position at Merck?

10    A.   Yes.

11    Q.   What was the title of that

12    position?

13    A.   I don't recall because it was

14    through a contract agency. So that the people

15    at Merck called them -- sometimes they

16    officially called them contract employees,

17    sometimes they called them temps. So I don't

18    know if that -- they -- how that would be

19    designated.

20    Q.   Who did you work for when you

21    first went to Merck?

22    A.   I'm pretty sure it was Dave

23    Krah.

24    Q.   Anyone else?

25    A.   Nope.

Page 39

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q.   And tell me about your first

3     experience at Merck working for Dave Krah.

4     MR. SCHNELL: Object to form.

5     THE WITNESS: That's really

6     general. What do you mean "first

7     experience"?

8     BY MS. DYKSTRA:

9     Q.   When you first went to work for

10    David Krah, what did you do?

11    A.   What did I do?

12    Q.   And this was -- what year are

13    we in, beginning of 2000?

14    A.   1999.

15    Q.   1999. So what did you do

16    working Dave Krah when you were at Merck in

17    1999?

18    A.   Formed cell-based assays to

19    characterize Merck's live virus vaccines.

20    Q.   What was your job? What

21    specifically did you do?

22    A.   Ran the cell-based assays. We

23    did VZV, varicella zoster virus potency

24    assays. I helped out with the -- some early,

25    I don't know whether he characterize them

Page 40

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     validation, but he was doing -- Dave Krah was

3     doing experiments with neutralization assays.

4     Cultured cells. My responsibilities from when

5     I worked at Merck the first year and a half

6     to -- are you ready?

7     Q.   Yes, I'm sorry.

8     A.   I wanted to make sure you heard

9     it.

10    My job responsibilities as a

11    contract employee to the second part where

12    they hired me full time didn't change. It was

13    the same position, it's just Merck formally

14    qualified it as staff virologist. I did all

15    the same things, all the same things were

16    expected of me. Krah told me that the reason

17    Merck hired people as contract employees first

18    was so that they could get an idea if they

19    could work there, if they were good. And that

20    if they weren't, it was easier to fire them if

21    they were contract employees. That once

22    someone is permanent, it's a little tougher to

23    fire them.

24    So Merck was using this idea of

25    having temps as a way to filter out people

Page 41

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     that they didn't think would be good at the

3     job.

4     Q.   So the entire time you were at

5     Merck, either as a contract employee or as a

6     full-time permanent employee, you always

7     reported to David Krah?

8     A.   I reported to David Krah up --

9     what do you mean by "reported"?

10    Q.   Was he your direct supervisor?

11    A.   There you go. Okay. So direct

12    supervisor from the time I started until

13    October 2001. There was a time I came back

14    for a few weeks where it was somebody else.

15    Q.   What time frame are you talking

16    about?

17    A.   The time that Merck's lawyers

18    contacted me and told me I had to come back.

19    Q.   Toward the end, I guess, of

20    October -- September, October, best time

21    frame?

22    A.   It could have been November. I

23    can only bookend it by between October and

24    December.

25    Q.   Who did you report to at that

Page 42

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     time?

3     A.    I don't know his name.

4     Q.    Let me ask you before we go

5     into your employment at Merck, you left Merck

6     in 2001. Correct?

7     A.    Yes.

8     Q.    Between 2001 and today, tell me

9     chronologically what other positions you held

10    for employment.

11    A.    I went back to Penn State, the

12    lab I had worked at before, and helped develop

13    graduate students in Dr. Schlegel's lab.

14    Q.    What time frame was that?

15    A.    2002 and then to 2004. I

16    believe we had a publication in 2004. And

17    then it faded as in I was -- I made myself

18    available if they had questions, but I didn't

19    draw a wage. There was no other place of

20    employment after that.

21    Q.    So between 2004 and 2017 you've

22    been unemployed?

23    A.    What do you mean by that

24    characterization? Doesn't that imply seeking

25    employment?

Page 43

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q.    I'm not implying that.

3     A.    I didn't have a job that paid a

4     wage.

5     Q.    What did you do between 2004

6     and 2017?

7     A.    Got married, had kids. Can I

8     ask a quick question?

9     Q.    Sure.

10    A.    That sun is blasting off of

11    that, can we close that blind?

12    Q.    Absolutely.

13    A.    If I could just -- you can open

14    it later when the sun leaves, but it's

15    blasting into my eyes so I can't look over

16    this way. I didn't want to do it while a

17    question was pending. Thank you.

18           - - -

19           (A discussion off the record

20           occurred.)

21           - - -

22    BY MS. DYKSTRA:

23    Q.    Is that better?

24    A.    Yes. Still seeing something.

25    It will clear up in a bit. I just can't see

Page 44

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     clearly out of my left eye.

3     Q.    So between 2004 and 2017, were

4     you looking for employment outside the home?

5     A.    No.

6     Q.    When did you get married?

7     A.    I should be able to answer this

8     faster.

9     Q.    You should.

10    A.    2002. October 26, 2002.

11    Q.    How many children do you have?

12    A.    Two.

13    Q.    When were they born?

14    A.    November 19, 2003.

15    February 18, 2006.

16    Q.    Are you the primary caretaker

17    of your children?

18    A.    Yes.

19    Q.    Are you still married?

20    A.    Yes.

21    Q.    What does your wife do?

22    A.    She's a pharmacy owner and a

23    pharmacist.

24    Q.    So between 2004 and 2017 you

25    weren't looking for employment outside the

Page 45

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     home?

3     A.    Not that I recall. I may have

4     thought about it from time to time, but I

5     didn't actively say I need to get a job.

6     Q.    When did you first consider

7     bringing a case against Merck in connection

8     with your work in Dr. Krah's lab?

9     A.    Can you define what you mean by

10    "case"?

11    Q.    When did you consider filing a

12    complaint of any kind against Merck in

13    connection with your work in Dr. Krah's lab?

14    A.    Can you be more specific?

15    There's two answers to that. When I worked at

16    Merck and Shaw informed me that Dave was going

17    to continue to make life hell for me and he

18    said I could maintain that status quo -- he

19    gave me two options, Shaw said you can

20    maintain the status quo, in which case I

21    wouldn't get paid bonuses that were owed, and

22    that Dave would most likely give me a poor

23    performance review and that things would be

24    very stressful for me. He advised me not to

25    do that. He said take option number two and

Page 46

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     you can resign voluntarily.

3             As a rebuttal to that, I told

4     him that I felt that if he understood that

5     Krah was retaliating against me, that perhaps

6     I had a harassment claim. And he told me that

7     he wanted me to consider voluntarily resigning

8     and that they would give me the double bonus

9     that Emimi spoke of. I rejected that and said

10    I had to maintain status quo for now. He was

11    adamant that I needed to at least admit that I

12    would consider taking the double big bonus and

13    resigning. And we left it unresolved at that

14    point.

15            So that would be responsive to

16    your question, but that's not the same as this

17    case. So you also want to know when I first

18    thought of bringing this type of case?

19    Q.    Yes.

20    A.    That would have been in 2003

21    when I met a lawyer who made me aware that

22    these type of cases exist.

23    Q.    What do you mean by these types

24    of cases?

25    A.    Qui tam lawsuit. I didn't know

Page 47

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     what these were. I didn't know it was an

3     avenue I could go forward with.

4     Q.    Who is the lawyer you met in

5     2003 that made you aware of these cases?

6     A.    Jim Moody.

7     Q.    I'm sorry, how do you spell his

8     last name?

9     A.    Jim Moody.

10    Q.    Moody?

11    A.    Yes.

12    Q.    Did you retain him as your

13    counsel?

14            MR. SCHNELL: Object to form.

15            THE WITNESS: I'm not sure what

16    you mean by "retain." I sought legal

17    counsel from him and I viewed him as my

18    lawyer, but I'm not sure what you mean

19    by "retain."

20    BY MS. DYKSTRA:

21    Q.    That's fine. As your lawyer,

22    did you and Mr. Moody draft a complaint or do

23    anything else to pursue a qui tam action in

24    2003 or thereafter?

25            MR. SCHNELL: At this point, I

Page 48

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     just want to caution the witness not to

3     disclose what could be confidential

4     attorney-client communications or work

5     product. If you want to be more

6     specific. That's kind of a question

7     that can get --

8            THE WITNESS: I can answer

9     whether we were doing that?

10    BY MS. DYKSTRA:

11    Q.    Uh-huh.

12    A.    I was working with him to

13    pursue that.

14    Q.    That was in 2003?

15    A.    2003.

16    Q.    And how long did you work with

17    Mr. Moody?

18    A.    In or around 2009. Maybe 2008.

19    That's give or take a year.

20    Q.    Did Mr. Moody file a false

21    claims or qui tam complaint on your behalf

22    with any court or any government agency?

23    A.    No.

24    Q.    Why not?

25            MR. SCHNELL: Again, I want to

Page 49

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     caution the witness not to get into

3     areas that may disclose confidential

4     communications or work product.

5            THE WITNESS: I can't answer

6     that.

7    BY MS. DYKSTRA:

8    Q.    In 2008 or 2009, did you fire

9    Mr. Moody or stop using him as your counsel?

10   A.    I moved on to find counsel that

11   would be more effective in bringing the case

12   right around that 2009 mark.

13   Q.    Who was your next counsel in

14   connection with the case?

15   A.    Jeffrey Keller. Gordon

16   Schnell, Constantine Canon. Keller Grover,

17   Melissa Hartnett.

18   Q.    That was around 2009 that they

19   became your counsel?

20   A.    Yeah. I'm not sure if it

21   started 2008. Definitely by 2009.

22   Q.    Let me go back to your -- come

23   back to that. Let me go back to your work.

24   Actually, let me go back -- let me stay on

25   this topic for a second.

Page 50

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2             Tell me in general your -- why

3 you are bringing this case against Merck, in

4 your own words.

5     A.    That's such a broad question.

6 I mean, you want me to boil it down to the

7 most fundamental aspect of the case?

8     Q.    Sure.

9     A.    Back then? The reason I

10 brought the case is because it seemed the most

11 effective avenue forward to expose the fraud

12 that was committed at Merck and to get

13 information in front of the FDA and CDC which

14 are the regulatory agencies that I felt would

15 be better served having that information,

16 which I knew they didn't have.

17     Q.    And "that information," you

18 mean what?

19     A.    Oh, God, that's so broad.

20 Everything in -- a lot of it is outlined in

21 the allegation if you want to go through it.

22 I mean, I imagine we can spend two days

23 talking about it.

24     Q.    Is it fair to say that the

25 complaint generally focuses on your work at

Page 51

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 Merck for Dr. Krah and running the plaque

3 neutralization assay, and that was where you

4 believe the fraud to have occurred?

5             MR. SCHNELL: Object to form.

6             THE WITNESS: It didn't focus

7 on that. It encompassed the company

8 and what they called their marquis

9 vaccine. I mean, when they call it a

10 marquis vaccine, they're talking about

11 the entire image of the company and

12 what it is. And it didn't encompass

13 just that time there. It encompasses

14 right now today.

15 BY MS. DYKSTRA:

16     Q.    Were you aware of any fraud in

17 any other lab other than the one that Dr. Krah

18 ran at Merck?

19             MR. SCHNELL: Object to form.

20             THE WITNESS: Do you mean fraud

21 as a legal term or do you mean

22 scientific misconduct?

23 BY MS. DYKSTRA:

24     Q.    I mean scientific misconduct.

25     A.    People told me about scientific

Page 52

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 misconduct, but if you want to talk about what

3 I saw with my own eyes, I'd have to really sit

4 and think about it. But I was aware of

5 scientific misconduct in other labs.

6     Q.    Which other labs were you aware

7 of scientific misconduct that other people

8 told you about?

9     A.    I don't recall what the lab

10 name would be. But it was the lab where they

11 developed their HPV vaccine. I'm really

12 saying scientific misconduct in a general

13 sense. What I knew is that one of the women

14 that was helping develop the vaccine was

15 uncomfortable with the vaccine or how the data

16 was being used. That type of thing.

17     Q.    Let's focus for the moment on

18 the mumps vaccine. When I say mumps vaccine,

19 can we agree that it includes any vaccine

20 Merck manufactures that contains the mumps

21 component that would include MMR II, Mumpsvox

22 and ProQuad generally?

23     A.    That's a great definition.

24     Q.    So are you aware of, you worked

25 in Dr. Krah's lab in connection with the mumps

Page 53

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 vaccine running the plaque neutralization

3 assay. Correct?

4     A.    That was one of the things that

5 I worked on in connection with mumps vaccine.

6     Q.    What else did you work on in

7 connection with the mumps vaccine at Merck

8 other than the plaque neutralization assay?

9     A.    Well, you're designing the

10 assay as if the assay exists by itself. But I

11 worked on the Protocol 007 testing which was

12 used to characterize so many different things.

13 For instance, Krah made us aware that the

14 neutralization assays were used -- that we

15 worked closely with manufacturing because the

16 neutralization assays were used to change

17 process development. That the Protocol 007

18 testing that his lab and the results from it,

19 that we worked closely with release testing,

20 which is manufacturing, and that we worked

21 with process development in general closely.

22 And also that we had to work closely with

23 regulatory.

24             So I think it would be a

25 mischaracterization to say I focused on doing

Page 54

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     an assay and the assay was the end result of

3     the assay. Not that you were characterizing

4     like that, but that's my -- that's how it

5     sounded.

6     Q.   No, that's okay. I just want

7     to make sure I understand your testimony and

8     what you're saying.

9             So you worked on the plaque --

10    let's go through it one by one. You worked on

11    the plaque neutralization assay with Dr. Krah

12    or reporting to Dr. Krah. Correct?

13    A.   That was one of the things I

14    worked on in his lab.

15    Q.   So you ran -- you worked on the

16    plaque neutralization assay as part of

17    Protocol 007 with Dr. Krah. Correct?

18    A.   I worked on -- it would be more

19    accurate to say I worked on Protocol 007

20    testing with Krah and the other members of his

21    lab. Now, by Protocol 007 testing, that means

22    the PRN assay which -- if I call it a PRN,

23    that's plaque reduction neutralization assay,

24    and I'm talking about the mumps neutralization

25    assay.

Page 55

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2             So we worked on the PRN assay.

3     We also worked to validate the ELISA assay.

4     It was the same thing. So when I say Protocol

5     007 testing, I mean the PRN and the ELISA

6     testing.

7     Q.   When you say you worked on the

8     PRN assay, you actually worked in running the

9     assay itself, conducting the assay. Correct?

10    A.   If you mean by running we

11    handled the plates that had the cells, the

12    supernatant in it, yes.

13    Q.   What do you mean when you say

14    you worked to validate the ELISA assay?

15    A.   Krah let me know that the PRN

16    assay is time consuming, bulky, requires lots

17    of materials. The idea was that they would

18    only have to do this PRN assay this one time

19    and the ELISA would be pegged to it. So the

20    PRN was used to validate the assay but he

21    often used the word "calibrate," because the

22    PRN assay was used to be able to read the

23    ELISA. There's two results that come out of

24    an ELISA when the test is done correctly,

25    positive or negative. The PRN determined what

Page 56

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     was positive or negative in the ELISA. In his

3     words, it was fundamental to the ELISA and it

4     was important and our lab was entrusted with

5     it. The PRN also -- how did he say it? The

6     ELISA -- the indicator strain used in the

7     ELISA had to match the PRN. So all of the

8     validation testing done for the PRN to choose

9     an indicator strain was also choosing the

10    strain that would be used in the ELISA.

11             So the two assays were so

12    fundamentally connected that we didn't talk

13    like you do and, oh, you did PRN, you didn't

14    do ELISA. I was told that we were validating

15    use of the ELISA so that in future studies

16    protocols after 07, they wouldn't have to do

17    the PRN again because the ELISA would have

18    been linked to a functional, better assay such

19    as the PRN.

20    Q.   When you say that the PRN was

21    used to calibrate the ELISA, let's put that

22    aside for a second, did you actually work in

23    the ELISA lab running the ELISA assay?

24    A.   The ELISA plates and running

25    them through a plate reader, that was not

Page 57

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     done, I did not partake in that.

3     Q.   That was in a separate lab.

4     Correct?

5     A.   I don't recall.

6     Q.   But that was not run by Dr. Krah,

7     the ELISA testing?

8     A.   I don't know if it was run by

9     him or not.

10    Q.   But you didn't take part in

11    that testing, the actual running of the assay

12    itself?

13    A.   If running of the assay itself

14    means running the plates through the reader, I

15    took part in the sense that I validated and I

16    helped do the assays for how you read those

17    results. But I didn't shove them through the

18    plate reader, no.

19    Q.   Just to be clear, the PRN assay

20    was run in Dr. Krah's lab. Correct?

21    A.   Yes.

22    Q.   The ELISA assay was run in a

23    different lab?

24             MR. SCHNELL: Objection. Asked

25    and answered.

Page 58

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL  
 2 BY MS. DYKSTRA:  
 3 Q. Are you aware --  
 4 A. I don't know that.  
 5 Q. You're not aware where the  
 6 ELISA assay was run? That's fine. You're not  
 7 aware of where the ELISA assay was run itself,  
 8 the actual running of the plates and counting --  
 9 A. When you say run, I don't know  
 10 what you're talking about. I'm defining run  
 11 as that last step where -- ah, you know what,  
 12 the other way they were linked. They had to  
 13 be run on the same serum. So we had to show  
 14 in the PRN that using these same serum, using  
 15 the same indicator strain, that PRN, a  
 16 functional, more specific assay, the ELISA  
 17 could correlate to it so that in the future  
 18 they wouldn't have to keep doing the PRN. So  
 19 all of the results from the ELISA were  
 20 unreliable because they were based on the PRN.  
 21 So when you say -- I'll tell  
 22 you this: The plate reader was in a different  
 23 lab probably that they used. I don't know. I  
 24 cannot say for certain the plate reader they  
 25 used. So I don't want to keep jumping back to

Page 59

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL  
 2 some generalization. I don't know where the  
 3 plate reader was that they used for the ELISA  
 4 assays.  
 5 Q. You also noted in your answer  
 6 that you worked closely with release testing  
 7 and manufacturing. Can you explain what you  
 8 mean by that?  
 9 A. That's hard to say.  
 10 MR. SCHNELL: Objection. I'm  
 11 sorry, in his answer?  
 12 MS. DYKSTRA: Just now.  
 13 THE WITNESS: I did --  
 14 MS. DYKSTRA: Just in his  
 15 answer here.  
 16 THE WITNESS: Krah provided us  
 17 with that information on what exactly  
 18 our -- the importance of our lab was.  
 19 So he would -- he wrote that down and  
 20 gave it to us and said this is what we  
 21 do, we work closely with that. So he  
 22 would have to communicate with  
 23 manufacturing because they relied on  
 24 information he had.  
 25 BY MS. DYKSTRA:

Page 60

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL  
 2 Q. When you say Dr. Krah wrote  
 3 that down, what do you mean, he wrote what  
 4 down?  
 5 A. He wrote it down. It's in a  
 6 document. We -- it's got to be in a document  
 7 somewhere. I'm sure we produced it. He -- to  
 8 our lab, he would give us, it looked like  
 9 outlines. They would say how our lab fits in  
 10 it, why it's important, how we make money  
 11 for -- you know, implied how we make money and  
 12 how we incorporate to the rest of the company.  
 13 And he stressed that we work closely with  
 14 manufacturing release testing. He wanted to  
 15 show us, in his words, why we mattered to the  
 16 rest of the company. Which was a good thing  
 17 in my eyes, that he would let us know how we  
 18 functioned with the rest of the company.  
 19 Q. But you said in your request in  
 20 connection with discovery in this case that  
 21 you never worked in the manufacturing division  
 22 at Merck. Correct?  
 23 MR. SCHNELL: Objection to  
 24 form. If you're going to refer to  
 25 something, you should really --

Page 61

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL  
 2 BY MS. DYKSTRA:  
 3 Q. Did you ever work in the Merck  
 4 manufacturing division?  
 5 A. It depends on what you mean by  
 6 "division." I just said that --  
 7 Q. Did you ever work for anybody  
 8 who reported up through Merck's manufacturing  
 9 division?  
 10 A. Reported up? I don't know the  
 11 chain of command. Here's what I can tell you:  
 12 According to Krah and according to what I  
 13 understand, the work we were doing impacted  
 14 manufacturing. How much goes into the  
 15 vaccine. To that level. So what they would  
 16 report to regulatory. But there's a building  
 17 somewhere where they make it. My job was not  
 18 to report to that building and make it.  
 19 Q. That's fair. So you didn't  
 20 have any responsibility in the actual  
 21 manufacturing process of the vaccine?  
 22 A. That's too broad. Any  
 23 responsibility? The work we were doing  
 24 impacted what happened in that building. I  
 25 just didn't personally go to the building.



Page 62

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q.    You understand that there is a

3    manufacturing division of Merck that actually

4    creates the vaccine, mechanically creates a

5    vaccine and markets that vaccine.  Correct?

6     A.    That's a good characterization,

7    yeah.  Mechanically makes it.

8     Q.    You weren't involved in that

9    process of manufacturing the vaccine itself?

10    A.    See, now you're saying process.

11   Krah said that what we do in that lab affects

12   how much goes in the vial because they were

13   putting too much -- he didn't say too much.

14   He said they were putting more in it.

15   Q.    More what?

16   A.    More virus.

17   Q.    In what?

18   A.    The mumps vaccine because it

19   didn't work.

20   Q.    When did he tell you that?

21   A.    Starting in around 2000.

22   Q.    Tell me again what he said.

23   A.    He said it so many times, where

24   do you want to start?

25   Q.    Well, tell me how it came up

Page 63

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2   the first time and exactly what he said about

3   what Merck was doing.

4     A.    He said it in support of the

5   reason we were doing the testing in the first

6   place.  He said that there was an FDA mandate,

7   they call it a mandate.  We had to show this

8   vaccine worked at lower potencies because they

9   were putting more in the vaccine, that it

10   degraded.  I mean, I could talk about this all

11   day.  So I can only give you an ostensive

12   example right now.  If you want me to

13   enumerate at all, we should go through the

14   interrogatories.  There's a lot of meat there.

15   I mean, every day this is what we're doing.

16   He indicated that he was under stress from

17   those above him to get it done by fall.  He

18   said we were protecting the marquis vaccine

19   and keeping it on the market.

20   Q.    What did Dr. Krah tell you

21   about why Merck was putting more virus in the

22   vaccine and when?

23   A.    I remember one conversation in

24   particular, and it had to do with why I

25   wouldn't cross out results on the assay.  And

Page 64

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2   he was going back to something he had already

3   discussed, that they had to put more in the

4   vaccine because it degraded and there was

5   potency loss.  And potency loss, lower potency

6   means it doesn't work as well, or at least

7   they didn't have proof that it worked.  And he

8   had theories for the effect of those degraded

9   vaccines.  I don't know if those were the

10   company's theories or not.  But he indicated

11   that when the vaccine was passaged more or at

12   least more recently manufactured vaccine, had

13   more potency degradation in it.

14            I pointed out that that might

15   not be the only reason.  That maybe it didn't

16   work that well to begin with regardless of the

17   potency, meaning the release testing might not

18   work either.  And he said regardless, we

19   needed to show that this vaccine had 95

20   percent efficacy or Merck would lose its

21   exclusive licensing rights to this vaccine.

22   He even said -- he stressed what an important

23   project this was because he normally worked on

24   research and development which is trying to

25   bring a vaccine to market, but he said that

Page 65

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2   this was so important because it was a vaccine

3   that was already on the market.

4     Q.    Do you know whether Merck put

5   more vaccine in its product during this time

6   frame because the FDA required that?

7     A.    When you say "more vaccine,"

8   you --

9     Q.    You used the word "more

10   vaccine" to make the vaccine more potent,

11   that's what he told you?

12    A.    Well, then let's be clear on

13   that.

14    Q.    Okay.  Let's.

15    A.    He said that they had to put

16   more mumps virus in the vaccine.

17    Q.    Correct.  I'm sorry, I

18   misspoke.  Yes.

19    A.    No, no.  I may have said

20   vaccine, I don't know, but let's clear that

21   term out.

22    Q.    More virus in the vaccine to

23   make it more potent.

24    A.    Okay.  So can you -- sorry to

25   talk over each other.

Page 66

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2             Can you restate your question --

3     Q.    Sure.

4     A.    -- with that cleared up?

5     Q.    Dr. Krah -- let me start it

6 this way: Dr. Krah told you that Merck had to

7 put more virus in the vaccine to make it more

8 potent. Correct?

9     A.    He indicated that they had

10 recently had to put more virus in the vaccine

11 to cover for a loss of efficacy. The loss of

12 efficacy he linked to degradation, meaning a

13 lot of dead virus in the vaccine. And he used

14 the word potency. So sometimes he would say

15 we have a problem with degradation. That

16 means a lower potency because the potency is

17 less. So to cover for a loss of potency which

18 he tied to efficacy because that's the test we

19 were doing, we were doing efficacy test, it

20 had to be more in -- had to be more mumps

21 virus in the vaccine.

22             So the importance of our lab

23 was to be able to say that this thing worked

24 at lower amounts because that would affect how

25 much goes in the vaccine.

Page 67

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q.    Are you aware one way or the

3 other whether the FDA approved putting more

4 virus in the vaccine at that time?

5             MR. SCHNELL: Object to form.

6             THE WITNESS: What do you mean

7 by "approved"?

8 BY MS. DYKSTRA:

9     Q.    Whether the FDA was aware and

10 approved putting more virus in the vaccine.

11     A.    Let's go with aware. Krah

12 indicated that they were aware of it. And

13 that was the point of why we had to show that

14 this thing worked at lower potencies.

15             MS. DYKSTRA: Should we take a

16 quick break?

17             MR. KELLER: Sure.

18             MS. DYKSTRA: Great.

19             VIDEOGRAPHER: The time is

20 10:40. We're going off the video

21 report.

22             - - -

23             (A recess was taken.)

24             - - -

25             VIDEOGRAPHER: The time is

Page 68

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     10:56. We're back on the video record.

3 BY MS. DYKSTRA:

4     Q.    Mr. Krahling, I have a couple

5 of follow-up questions on what we just

6 discussed.

7             Did you and Mr. Moody file a

8 False Claims Act case anywhere when he was

9 your lawyer?

10     A.    No.

11     Q.    Did he recommend against it?

12             MR. SCHNELL: Objection. That's

13 pure attorney-client communication.

14             THE WITNESS: I can't answer

15 it.

16 BY MS. DYKSTRA:

17     Q.    Did you want to file a case

18 when he was your lawyer? Did you want to file

19 a False Claims Act case between the period of

20 '03 and '08 while Mr. Moody was your lawyer?

21     A.    That's a well stated question.

22 Yes, I did.

23     Q.    You said you started working

24 with Mr. Moody in or around 2003?

25     A.    It was in the year 2003.

Page 69

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q.    Did you retain and save all of

3 your documents that you took from Merck or

4 related to your work at Merck since that time?

5             MR. SCHNELL: Object to form.

6             THE WITNESS: I didn't take

7 documents from Merck.

8 BY MS. DYKSTRA:

9     Q.    You produced documents that you

10 took from Merck. Correct?

11             MR. SCHNELL: Object to form.

12             THE WITNESS: God, I didn't

13 take documents from Merck. How could I

14 produce something I didn't have? You

15 can define documents. I didn't take

16 documents.

17 BY MS. DYKSTRA:

18     Q.    Documents in my mind mean

19 pieces of paper, lab notebooks, e-mails, assay

20 runs. Did you take any of that type of

21 information from Merck when you left?

22     A.    When I was at Merck I preserved

23 photocopies of documents that I had in my

24 possession.

25     Q.    And you retained them when you

Page 70

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 left Merck?

3     A. I retained the photocopies of

4 documents that were being destroyed in Merck's

5 lab when I left -- I had them before I left

6 Merck, I had them after I left Merck.

7     Q. And did you produce to your

8 counsel in connection with requests for

9 documents in this discovery in this case all

10 of the documents that you had photocopied

11 while you were at Merck?

12     A. Yes.

13     Q. You also mentioned that you

14 worked at ViroPharma for a short period of

15 time, six months?

16     A. Yes.

17     Q. Did you ever make any

18 accusations when you were there of any

19 scientific misconduct?

20     A. I don't recall.

21     Q. You don't recall if you ever --

22 did you witness any scientific misconduct at

23 ViroPharma?

24     A. I wasn't there that long. I

25 don't recall much about the job except that I

Page 71

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 worked in cell-based assays.

3     Q. So you don't recall one way or

4 the other whether there was scientific

5 misconduct or you made allegations of

6 scientific misconduct while were you there?

7     A. What I'm saying is I -- I don't

8 recall very much about the time I worked

9 there.

10     Q. You also noted that you said

11 you had heard from other people, not witnessed

12 yourself, that there were scientific

13 misconduct in other Merck laboratories.

14 Correct?

15     A. Yeah, defining scientific

16 misconduct as the person talking to me wasn't

17 happy with how the data was coming in being

18 interpreted.

19     Q. And you mentioned that

20 occurred -- by the way, you heard that

21 information from somebody in HPV lab?

22     A. My understanding was that's

23 where she worked. That's the vaccine she

24 was -- said she was working on and talking

25 about.

Page 72

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q. Who was this person?

3     A. DeeMarie Skulsky. No, wait.

4 DeeMarie Watson was her name when I first met

5 her. She got married and it became DeeMarie

6 Skulsky.

7     Q. Was there anybody else who ever

8 told you about scientific misconduct in any

9 other lab, not Dr. Krah's lab, but any other

10 lab at Merck?

11     A. I need a moment to think about

12 that. So any other lab, not Krah's lab other

13 than DeeMarie. I can't recall any other off

14 the top of my head.

15     Q. Did anybody that worked in the

16 lab that was working on the ELISA assay as

17 part of Protocol 007, ever tell you that they

18 thought that assay was being run improperly?

19     A. But I told you I don't know who

20 was doing the ELISA in the context of using

21 the plate reader. If we define it as did

22 anyone that used the plate reader reading the

23 assay, reading the ELISA plates communicate

24 with me, I don't know who was doing that

25 testing.

Page 73

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q. So no one that was doing that

3 testing on the ELISA assay, reading the plates

4 and running the assay in that other

5 laboratories, nobody ever told you -- you

6 never talked to anybody in that other

7 laboratory, I guess, is my question?

8     A. I don't know who worked there.

9 How would I know because I can't define who

10 did that?

11     Q. So the answer is no?

12     A. It's not a simple no. Here's

13 how I encompass it: I did not -- I was not

14 aware or I don't recall any reports of

15 scientific misconduct from people who hadn't

16 worked in Krah's lab. Now, you can figure out

17 who worked in Krah's lab and then you should

18 be able to figure out it wasn't the other

19 people. DeeMarie.

20     Q. Being the one exception?

21     A. No, she's not an exception.

22     Q. Well, she didn't work in Krah's

23 lab?

24     A. Yes, she worked in Krah's lab.

25     Q. All right. You mentioned

Page 74

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     that -- tell me if I got this correct, that

3     you were doing efficacy testing in Krah's lab.

4     Is that correct?

5     A.    Where do I say that?

6     Q.    You just said that earlier

7     today.

8     A.    Yeah. Yes.

9     Q.    How do you define efficacy, a

10    clinical efficacy study?

11    A.    How do I define it? When I'm

12    using the term?

13    Q.    Yes.

14    A.    I'm defining efficacy the way

15    we use it in the complaint, as how well the

16    vaccine works.

17    Q.    The CDC uses the following

18    definition. And I want you to tell me if you

19    agree with this definition. They define

20    efficacy as the ability of a vaccine to

21    provide protection against disease under ideal

22    circumstances, for example, during a clinical

23    trial. Do you agree with that definition of

24    efficacy?

25    MR. SCHNELL: I object to form.

Page 75

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     If you're reading it from something, a

3     website or a book, he should see what

4     you're reading it from, because it

5     could be different definitions in

6     different contexts.

7     MS. DYKSTRA: Sure. Hold on

8     one second.

9     Can we mark this?

10    - - -

11    (Exhibit Krahling-2, CDC Manual

12    for the Surveillance of

13    Vaccine-Preventable Diseases, was

14    marked for identification.)

15    - - -

16    BY MS. DYKSTRA:

17    Q.    What I've given you is a CDC

18    Manual for the Surveillance of Vaccine

19    Preventable Diseases. I'm going to ask you --

20    obviously this covers a lot of different

21    acronyms, but I'm going to ask you if the last

22    page, it has vaccine efficacy is the last term

23    defined in the CDC manual. In that the CDC

24    states that vaccine efficacy is "The ability

25    of a vaccine to provide protection against

Page 76

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     disease under ideal circumstances (for

3     example, during a clinical trial)." [As

4     read.] I want to know whether you agree with

5     that definition?

6     A.    What page are you on?

7     Q.    The very last page, very last

8     term.

9     MR. SCHNELL: Are you

10    introducing this as an exhibit?

11    MS. DYKSTRA: Yes.

12    THE WITNESS: Where is

13    chapter 9? There's a table of contents

14    and there's a chapter 9 that says

15    "Mumps." I don't see chapter 9 here.

16    BY MS. DYKSTRA:

17    Q.    I don't have chapter 9 here.

18    I'm just going to the CDC's definition of

19    terms. So the entire manual is not here.

20    It's just portions of the manual. The last

21    page is a definition of terms that the CDC

22    uses.

23    A.    They produced an entire chapter

24    on mumps. And you're just showing me

25    something that is not in that chapter. Is

Page 77

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     this in chapter 9 where they talk about mumps?

3     Q.    No.

4     A.    Do you have chapter 9 with you?

5     Q.    No.

6     A.    How do I know that they don't

7     use some different term in chapter 9?

8     Q.    To define efficacy, is that

9     your question?

10    A.    My question is, how do I know

11    what's in chapter 9, it's not here? Here's

12    what I can give you.

13    Q.    Okay.

14    A.    Chapter 9, there's a whole

15    chapter on it. I can't tell you what this

16    cherry picked thing means when the entire

17    chapter is missing. I don't feel comfortable

18    talking -- of giving you an interpretation

19    what the CDC meant based on just what looks to

20    be a glossary.

21    Q.    Putting aside the glossary, do

22    you agree that an efficacy trial or efficacy

23    itself is the ability of a vaccine to provide

24    protection against disease under ideal

25    circumstances? Do you agree with that

Page 78

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     statement?

3     A.    I agree that's one definition

4     of efficacy.

5     Q.    What's other definitions of

6     efficacy that you have?

7     A.    In my pocket?

8     Q.    In your head.

9     A.    I mean, they're published.

10    They're published. I mean, there's actually

11    reviews written on all the different ways the

12    term is used and applied. And then there's

13    practical uses also. I could tell you how

14    Krah used the word.

15    Q.    Sure. Why don't you tell me

16    that.

17    A.    He meant how well the vaccine

18    worked and what we were doing in our lab.

19    Immunogenicity is a bit of a burdensome word,

20    so he used the word efficacy. Sometimes he

21    used the word efficacy when he was talking

22    about potency because we weren't doing potency

23    assays, we were doing efficacy assays and his

24    focus was on getting 95 percent efficacy. To

25    him he said that we had an FDA mandate to show

Page 79

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     that the efficacy was 95 percent as reflected

3     in the label. That was the reason that the

4     entire Protocol 007 project existed. And also

5     it's important to safeguarding the marquis

6     vaccine. So there was a practical sense in

7     which he used efficacy. And in the complaint

8     we used it as how the vaccine works. But I

9     can admit that there are more definitions of

10    efficacy and that they're published in

11    research of the different ways that the term

12    is used. Hopefully that answers your

13    question.

14    Q.    Do you understand that there is

15    a difference between immunological testing,

16    testing for seroconversion and actual efficacy

17    trial where you are providing a placebo to one

18    arm and a vaccine to the other?

19    A.    I understand that there are

20    different usages of the word efficacy. I do

21    understand that there are immunogenicity tests

22    that can test for immunological markers. And

23    I am aware of -- that you can have trials

24    where a placebo is used.

25    Q.    In your complaint you used the

Page 80

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     term "diminished efficacy." Can you tell me

3     what you mean by that?

4     A.    Can you show me in the

5     complaint where I may have used that term?

6     Q.    Sure.

7     MS. DYKSTRA: Mark this,

8     please.

9     - - -

10    (Exhibit Krahling-3, Amended

11    Complaint for Violations of the Federal

12    False Claims Act, was marked for

13    identification.)

14    - - -

15    BY MS. DYKSTRA:

16    Q.    So we've marked as Exhibit 3

17    your amended complaint. Correct? You may

18    take that off, yes. Is that what you were

19    asking?

20    A.    Yes. And yes.

21    Q.    So there's many places where

22    you use the term diminished efficacy. I think

23    the first may be paragraph 3. You state that

24    "...Merck knew about the vaccine's diminished

25    efficacy."

Page 81

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     A.    All right. So what's the

3     question?

4     Q.    What do you mean when you use

5     the term diminished efficacy?

6     A.    I mean efficacy as in how well

7     the vaccine works and I mean diminished as in

8     -- that it has changed from something that was

9     relatively higher to something that is

10    relatively lower.

11    Q.    So when you use the term

12    efficacy, you're using it in the phrase, I

13    think I'm quoting you, "how well the vaccine

14    works"?

15    A.    Yes.

16    Q.    Do you equate, then, the term

17    efficacy with the term effectiveness?

18    A.    Equate is -- I can't say I

19    equate it.

20    Q.    What's the difference in your

21    mind between efficacy and effectiveness?

22    A.    Practical usage that in Merck's

23    lab the terms efficacy and effectiveness were

24    often interchangeable, and the word efficacy

25    was most often used, best practical usage,

Page 82

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     that I was familiar with in the lab.

3     Q.   If we stick looking at your

4     complaint for a moment, in paragraph 19 on

5     page 6, you note that "In order to obtain its

6     original government approval to sell the mumps

7     vaccine, Merck conducted field studies of

8     vaccinated children and concluded that the

9     vaccine had an efficacy rate of 95 percent or

10    higher." [As read.]

11    Do you see that?

12    A.   I do see it.

13    Q.   What are you referring to here?

14    A.   This line refers to the package

15    label. Well, it would be the package insert,

16    I guess you'd call it.

17    Q.   Are the studies that you are

18    talking about here Dr. Hilleman's studies back

19    in the late '60s and '70s?

20    A.   I believe that's what they're

21    referring to.

22    Q.   Do you allege that there was

23    any fraud in connection with those studies?

24    A.   I can't say, I wasn't there

25    back then.

Page 83

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q.   So you don't have any reason to

3     believe that there was fraud in connection

4     with those studies in the late '60s, early

5     '70s that warranted the product's original

6     approval?

7     A.   Are you talking about legal

8     fraud?

9     Q.   Scientific misconduct.

10    A.   I don't have reason to know or

11    not know. I couldn't make a claim one way or

12    the other.

13    Q.   So you're not making a claim

14    today that Dr. Hilleman's studies in the late

15    '60s, early '70s, were conducted in any

16    improper way? That's not what you're alleging

17    here?

18    A.   I'm not alleging that those

19    people who ran those tests did something

20    improper like mentally they were doing

21    something that we've been referring to or I've

22    been referring to as scientific misconduct.

23    What happened back then, what I would claim or

24    what I -- what is true is that the testing

25    methods available to them back then were less

Page 84

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     rigorous than what are available today. The

3     sample size run are smaller than the things

4     Merck did in Protocol 007. So less rigorous,

5     not as good a test or accurate a test isn't

6     scientific misconduct.

7     Q.   You understand that Dr. Hilleman

8     ran a double-blinded clinical trial where one

9     arm received a vaccine and the other arm

10    received a placebo. Correct?

11    A.   That's referenced in that

12    package insert?

13    Q.   Yes. You understand that, right?

14    A.   Yes.

15    Q.   Do you understand that that

16    type of clinical trial where you give one arm

17    of children placebo and one arm vaccine for

18    mumps could not be run today in the United

19    States. Correct?

20    A.   You can replicate the same

21    thing. You can get information about that

22    without having not to inject the child.

23    That's what a pre-vaccination sample is. It

24    represents a child that hasn't had the vaccine

25    yet. So in lieu of a placebo control, that

Page 85

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     gives you information that is relevant to what

3     Hilleman found back then. But Hilleman also

4     didn't have large sample sizes either. But I

5     understand that according to some guidelines,

6     I think research guidelines, that it's

7     unethical to withhold a vaccine today, it

8     would be unethical to withhold the vaccine and

9     do the placebo, clinically controlled placebo

10    trial that you're talking about.

11    Q.   So to boil that down to my

12    question, you understand that it would be

13    unethical today to do a double-blinded

14    clinical trial where there were two arms, one

15    given a placebo and one given the mumps

16    vaccine?

17    A.   If you knew that the vaccine

18    worked, yes.

19    Q.   You're not aware of any other

20    double-blinded clinical trial of the mumps

21    vaccine other than the one Dr. Hilleman did in

22    the United States, are you?

23           MR. SCHNELL: Object to form.

24    BY MS. DYKSTRA:

25    Q.   I'll restate.

Page 86

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2             Are you aware of any other

3 clinical trial following Dr. Hilleman's of the

4 mumps vaccine in the United States?

5             MR. SCHNELL: Object to form.

6             THE WITNESS: Yes.

7 BY MS. DYKSTRA:

8     Q.    Clinical -- I'm sorry, clinical

9 efficacy trial?

10    A.    It depends on how you're doing

11 the -- Krah said that what we were doing was a

12 clinical efficacy trial. I mean, I'm aware of

13 the one I worked on and 13 or 14 more that

14 Merck published.

15    Q.    You stated that the trial you

16 were working on was in lieu of a

17 placebo-controlled trial. Correct?

18    A.    I said that the pre-vaccination

19 serum can be used in lieu of not having a

20 placebo control to give you a good idea of the

21 same information, especially when on the

22 package label the field efficacy is linked

23 specifically to immunogenicity data.

24             MS. DYKSTRA: Mark this as the

25 next exhibit.

Page 87

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2             - - -

3             (Exhibit Krahling-4, MMR II

4 label, RELATOR\_00002094 - 00002105, was

5 marked for identification.)

6             - - -

7 BY MS. DYKSTRA:

8     Q.    What we've marked as Exhibit 4

9 is the MMR II label prior to 007. Are you

10 familiar with this label?

11    A.    Yes, I've seen it before.

12             MR. SCHNELL: Can we get copies

13 of it?

14             Did you say what year this was?

15             THE WITNESS: 2007.

16             MS. DYKSTRA: This is prior to

17 submission of the 007 results.

18 BY MS. DYKSTRA:

19    Q.    Did you look at this label

20 prior to filing your complaint?

21    A.    The 2007 one? I looked at the

22 labels available to me at the time.

23    Q.    Can you point to me in this

24 label the language that you believe

25 misrepresents the efficacy of the product?

Page 88

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     A.    How are you using efficacy?

3 Strike that.

4             I'll tell you what, I can go

5 through this and give you the language that I

6 think misrepresents the product --

7     Q.    That would be great.

8     A.    -- including efficacy.

9     Q.    Yes, please do.

10    A.    I'm going to need time to read

11 it.

12    Q.    Well, you raised the complaint

13 and you wrote the complaint. I just want you

14 to tell me what in this complaint misrepresents

15 the efficacy or effectiveness or

16 immunogenicity of the vaccine?

17    A.    My question was can I read the

18 complaint -- can I read the package insert or

19 do you want me to just pull it out from the

20 last time I've seen it?

21    Q.    Well, we can go off the record

22 if you want to read the entire package insert,

23 yes.

24    A.    Here's what I can do: I can

25 read it front to back and when I see one, I

Page 89

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 can point it out.

3     Q.    Why don't we go off the record

4 because the entire label doesn't relate to

5 efficacy. There's all sorts of things about

6 precautions and contraindications and

7 warnings.

8     A.    But I said I could give you the

9 language that misrepresents the product

10 including the way it represents efficacy and

11 you said that was okay to do.

12    Q.    I would like you to focus right

13 now on what language, you think, in this label

14 that misrepresents the efficacy, effectiveness

15 or immunogenicity of the vaccine.

16    A.    What were the three things?

17    Q.    Effectiveness, efficacy or

18 immunogenicity.

19    A.    Limited to your definitions of

20 those terms?

21    Q.    However you define those terms

22 is fine. I want you to tell me what you think

23 with respect to those three terms is false in

24 the label.

25    A.    But -- okay. I'd like to do

Page 90

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     that, but you don't want me to read the whole

3     thing.

4     Q.    You can. We'll go off the

5     record if you think you need to read the

6     entire label to identify those statements.

7     A.    No, I'll take a run at it. Can

8     I write on this or not? This is your copy.

9     I'll just go through front to -- start to

10    back. 20,000 TCID50 of mumps.

11    Q.    You're reading the one, two,

12    three, four, fifth paragraph?

13    A.    It might be. It's in the first

14    section.

15    Q.    The paragraph beginning, "The

16    reconstituted vaccine...?"

17    A.    Yes.

18    Q.    What is false and misleading

19    around statements that the vaccine contained

20    20,000 TCID50 of mumps virus?

21    A.    But that is linked to how well

22    the vaccine works. The statement on here is

23    that the vaccine provides protection at that

24    level and Krahl said that it didn't. That's

25    why we had to show that it worked at a lower

Page 91

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     level. So that level, 20,000 TCID50 of mumps,

3     does not provide protection. Not only that,

4     but Krahl said there was a problem that there

5     wasn't that much in the vials when it expired.

6     Which is why we had to show that the lower

7     amounts in the vial still worked according to

8     this label.

9     Q.    Thank you. Now, can I ask you

10    a specific question, please? Is the statement

11    that each .5-milliliter dose -- I'm reading

12    right above that, "Each .5 milliliter dose

13    contains not less than..." [as read] I'll

14    skip the measles, "...20,000 TCID50 of mumps

15    virus..." is that a true or false statement

16    according to you?

17    MR. SCHNELL: Object to form.

18    THE WITNESS: First of all,

19    that number is linked to the efficacy

20    claims in the next section. Second of

21    all, the label says that there's a

22    24-month expiry. Krahl told me that

23    some of the lots don't have that much

24    in them when they expire. So it would

25    be false for two reasons. Not every

Page 92

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     lot had that much in it when it

3     expired. And they had no proof, which

4     he was trying to find, that it would

5     work at the lower amounts that might be

6     in it. So that's the first false

7     statement.

8     BY MS. DYKSTRA:

9     Q.    Okay. The second?

10    A.    ".. mumps neutralizing

11    antibodies in 96 percent..." [As read.]

12    Q.    That's the very last paragraph?

13    A.    Yes.

14    Q.    So is the statement clinical

15    studies of 284 triple seronegative children

16    11 months to 7 years of age demonstrated that

17    MMR II is highly immunogenetic and generally

18    well tolerated? Is that true or false, in

19    your opinion?

20    A.    It omits the fact that Merck

21    had more recent data with a larger sample size

22    and a more specific test or accurate test that

23    that number was not true, that the number was

24    significantly lower than that.

25    Q.    So it's not that this number --

Page 93

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     I didn't read the whole thing. Let me read

3     the whole thing.

4     "Clinical studies of 284 triple

5     seronegative children, 11 months to 7 years of

6     age, demonstrated that M-M-R II is highly

7     immunogenetic and generally well tolerated.

8     In these studies, a single injection of the

9     vaccine induced.. mumps neutralizing

10    antibodies in 96 percent..." [As read.]

11    You're saying that that

12    statement is not false on its face, it's just

13    false by -- because it omits other more recent

14    information?

15    A.    I can't make a claim to whether

16    the -- whether they really got 96 percent

17    antibodies in an immunogenicity test back

18    then. What I'm saying is that Merck had more

19    recent data with an assay methodology they

20    considered better on a larger sample size and

21    they got nowhere close to that number.

22    Q.    Any other misstatements in this

23    portion of the label?

24    A.    Yeah. Page 2, third paragraph

25    down, the setup is the first sentence where it



Page 94

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     discusses efficacy of measles, mumps, and

3     rubella in that double-blind controlled field

4     trials. And then the next sentence says,

5     "These studies also establish that

6     seroconversion in response to vaccination

7     against measles, mumps, and rubella paralleled

8     protection from these diseases." Merck has

9     more recent information that seroconversion

10    does not parallel what Hilleman found back

11    then.

12    Q.    So your -- just so I am clear,

13    your allegation is not that the language in

14    paragraph 3 of the label regarding

15    Dr. Hilleman's studies is false, it's just

16    that there is more information beyond that

17    that should be in the label as well?

18        MR. SCHNELL: Object to form.

19        THE WITNESS: Yeah, they know

20    that the second part is false today.

21    They know that -- I don't know if you

22    want to call it false or outdated, they

23    know that that is completely

24    inaccurate, because they're saying we

25    have efficacy, and now in the second

Page 95

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     part, and our seroconversion results

3     parallel that.

4     BY MS. DYKSTRA:

5     Q.    Well, it actually doesn't say

6     that. It says, these studies also established

7     that seroconversion rate in response to

8     vaccination paralleled protection. It was

9     talking about these studies in its footnote.

10    So we're talking about Dr. Hilleman's studies.

11    I understand --

12    A.    That's what I said.

13    Q.    No, it's not what you said.

14    Are you saying that Dr. Hilleman's studies

15    were false or are you saying that the label is

16    false because it does not include additional

17    information from later studies?

18        MR. SCHNELL: Object to form.

19        THE WITNESS: What I said was

20    that the second part, which is

21    reference 13 to 15, is Merck knows that

22    that's not true today. It may have

23    been true back then, I don't know. But

24    Maurice Hilleman's studies where the

25    seroconversion of Hilleman paralleled

Page 96

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     what Hilleman found in the field.

3     Merck knows that the second part, which

4     is Hilleman and is what I said, is not

5     true today because they have a more

6     accurate test they claim and they have

7     -- where they measured seroconversion

8     and it no longer parallels what

9     Hilleman found. So they had --

10    Hilleman found what he considered high

11    efficacy and high immunogenicity. And

12    that second statement is Hilleman

13    saying these parallel each other,

14    they're both high. I imagine the point

15    of that connection is that they

16    paralleled each other. So now with

17    Protocol 007, Merck has immunogenicity

18    data that says they're nowhere near the

19    number that Hilleman found. There is

20    no parallel anymore. That's -- so this

21    makes this a false statement. They

22    know that this statement by Hilleman --

23    that they reference in Hilleman, the

24    second sentence, no longer accurately

25    describes or does not accurately

Page 97

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     describe the product they're putting on

3     the market today.

4     BY MS. DYKSTRA:

5     Q.    Because there are more recent

6     studies that show lower rates of seroconversion?

7     A.    Protocol 007.

8     Q.    Are there any other tests that

9     you believe show lower seroconversion rates of

10    the mumps vaccine besides Protocol 007?

11    A.    It's tough to say. I don't

12    know. I can't think of any off the top of my

13    head. But I don't know that a lot have been

14    done.

15    Q.    You don't know that a lot of

16    tests of the mumps vaccine have been done

17    since --

18    A.    A lot of tests have been done

19    where they can replicate this.

20    Q.    Say that again, I missed it?

21    A.    I'll make it clear. I know

22    that Merck tested their mumps vaccine after

23    this and did immunogenicity trials. But they

24    used the Protocol 007 ELISA, the one that was

25    validated and used according to the PRN. So

Page 98

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     when there are protocols after 007, they're

3     using that wild type ELISA which used the PRN

4     to establish the cutoff. So the Merck assays

5     which would look at immunogenicity are

6     unreliable. The data from those is unreliable

7     because it relied on the falsified PRN results

8     of Protocol 007. Are there others done by

9     other companies on other products, I don't

10    know.

11    Q.    You haven't looked at any other

12    studies by other companies that have tested

13    other products including the Merck's mumps

14    vaccine?

15    A.    Not that I can recall today

16    sitting here.

17    Q.    I think you said this, but I'm

18    not sure so I want to make sure I understand.

19    Why is it that you believe the mumps vaccine,

20    the efficacy or the effectiveness of the

21    vaccine, however you define it, is diminished

22    since Hilleman's studies?

23    A.    You're moving on from my list

24    of false statements here. Are we done?

25    Q.    No, we'll go back to that in a

Page 99

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     second.

3     I just want to understand why

4     you think these statements are false?

5     A.    So we're putting this aside for

6     a second. Can you repeat the question,

7     please? Sorry.

8     Q.    Sure. Sure. Why is it that

9     you think the vaccine's efficacy or

10    effectiveness has diminished since the time

11    that Hilleman ran his studies on the mumps

12    vaccine?

13    A.    Krah told me it did. We were

14    working to try and -- I shouldn't say we. He

15    and his lab and some members of his lab were

16    working to try and say the vaccine worked as

17    well as they state it did in the label. He

18    said the FDA mandate that we show 95 percent

19    efficacy was based on what they were

20    representing in the label. And that if they

21    couldn't show it, they would either have to

22    change the label or they would lose their

23    market, their exclusive license for it. So I

24    mean, do you want reasons beyond that he told

25    me?

Page 100

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q.    Yes, I would like to know

3     whether there are any other reasons beyond

4     what Dr. Krah told you that you believe the

5     vaccine has a diminished efficacy or a

6     diminished effectiveness?

7     A.    Emini mentioned the same thing.

8     He said we had to use rabbit secondary

9     antibodies in order to get these results

10    combined with Krah doing his thing with these

11    data so that they could get the results for

12    financial reasons.

13    Q.    Any other -- what other

14    information, if any, are your allegations

15    based on if the vaccine has diminished

16    efficacy other than what Dr. Krah and

17    Dr. Emini told you?

18    A.    You want an enumerative

19    response on that?

20    Q.    Yes.

21    A.    It could take a while. The

22    continued mumps outbreaks in highly vaccinated

23    populations. The fact that the number of

24    reported mumps cases to the CDC since I left

25    work have increased over 1,000 percent. The

Page 101

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     fact that I saw seroconversion numbers

3     reported to the European medicine agency that

4     were based on Protocol 007 that said the

5     vaccine worked when the statements given to me

6     at the lab I worked at said that it didn't

7     work. So I know those falsified numbers were

8     being reported and the outbreaks are happening.

9     Q.    How do you know that there has

10    been reports to the CDC that outbreaks have

11    increased over 1,000 percent?

12    A.    Because mumps is a notifiable

13    disease and the CDC tracks it.

14    Q.    So the CDC is aware of the

15    number of outbreaks and the diminished

16    efficacy of the vaccine?

17    MR. SCHNELL: Object to form.

18    BY MS. DYKSTRA:

19    Q.    Based on your statement, is the

20    CDC aware of the outbreaks of the vaccine --

21    of the virus?

22    A.    The CDC is aware of the number

23    of reported cases of mumps in the United

24    States. They track it.

25    Q.    Is the CDC aware of the,

Page 102

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     quote/unquote, diminished efficacy or

3     diminished effectiveness, as you refer to it

4     in your complaint?

5             MR. SCHNELL: Object to form.

6             THE WITNESS: Diminished, I

7     don't think the CDC is aware of the

8     problems with the vaccine which is one

9     of the reasons to bring the case. I

10    don't think they have enough

11    information to make a decision about

12    the vaccine.

13             You know what, that's not

14    perfectly accurate. I think if they

15    had the information I had, they

16    wouldn't buy it. Perhaps the FDA

17    would -- Merck would lose their

18    exclusive license that Krah was afraid

19    of. That's all I got.

20    BY MS. DYKSTRA:

21             Q. I'm going to move on for a

22    second to finish the label. Is there anything

23    else in the label, we don't have to go past

24    the -- into the indications and usage. Let's

25    focus right now on the clinical pharmacology.

Page 103

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Is there any other statements in the clinical

3     pharmacology section that you believe is false

4     or misleading?

5             MR. SCHNELL: If you're going

6     to talk about that section, it's only a

7     page, should he read it so he can be

8     complete or do you want him to read it

9     at the next break?

10            MS. DYKSTRA: The clinical

11    pharmacology section. He can read it

12    in full. I think he has read --

13            MR. SCHNELL: The description

14    in the clinical pharmacology section.

15            MS. DYKSTRA: I think -- I

16    thought he did read the description.

17    BY MS. DYKSTRA:

18            Q. I thought that you were going

19    through it line by line what you thought was

20    false and misleading.

21            A. No. You told me that -- I was

22    doing a quick scan.

23            Q. Why don't you take time to read

24    the description in clinical pharmacology and

25    other than the sections you've identified, the

Page 104

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     three, let me know if there's anything false

3     or misleading in those sections?

4             A. Stopping at "INDICATIONS AND

5    USAGE."

6             Q. Correct.

7             VIDEOGRAPHER: The time is

8     11:37. We're going off the video

9     record.

10            - - -

11            (A recess was taken.)

12            - - -

13            VIDEOGRAPHER: The time is

14     11:39. This begins disc two in the

15     videotape deposition of Stephen

16     Krahling.

17    BY MS. DYKSTRA:

18            Q. Mr. Krahling, is there

19    something else other than the paragraph you've

20    identified that you believe is false and

21    misleading in the section of -- description of

22    clinical pharmacology of the MMR II label?

23            A. Second to the last paragraph,

24    before indications and usage start.

25    "Following vaccination, antibodies associated

Page 105

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     with protection can be measured by

3     neutralization assays, HI, or ELISA (enzyme

4     linked immunoabsorbent assay) tests.

5     Neutralizing and ELISA antibodies to measles,

6     mumps, and rubella viruses are still

7     detectable in most individuals 11 to 13 years

8     after primary vaccination."

9             I think that's misleading.

10            Q. In what way is that misleading?

11            A. The ELISA tests that Merck uses

12    today are based on unreliable data because of

13    the falsified PRN. So it's unclear to me

14    whether, when they make this reference,

15    they're trying to refer to the testing done in

16    Krah's lab with that ELISA because it says

17    reference 16 to 18, and 17 isn't a real

18    citation. It says unpublished files.

19            Q. So you're not sure whether

20    section -- paragraph 17 in that referenced

21    footnote might relate to Dr. Krah's tests?

22            A. Merck has more updated recent

23    information with their Protocol 007 testing

24    that shows -- that may show neutralizing

25    antibodies or ELISA antibodies aren't

Page 106

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     detectible. Krahl informed me that the testing

3     done on samples one year after vaccination and

4     in the future on any after the PRN would be

5     using the ELISA based on the Protocol 007 PRN

6     calibration. So this seems to be misleading

7     and then it's unpublished.

8     Q.    We're going to move on --

9     A.    I'm not done.

10    Q.    Okay.

11    A.    The first page, the package

12    insert is making a retrospective claim that

13    the vaccine appears to have quality based on

14    the decline in incidents of reported diseases.

15    And it says, "...cases reported in a given

16    year prior to vaccine use...." And then if

17    you go to mumps it says, "152,209 cases

18    reported in 1968 compared to 840 cases

19    reported in 1995 resulted in a 99.45 percent

20    decrease in reported cases...." [As read.]

21            1968 is not a year before the

22    vaccine was used -- licensed. It looks like

23    that number is cherry picked from an outbreak

24    year so that you can pick a high year and then

25    a low year after it. So it's misleading in

Page 107

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     the sense that the number of reported cases

3     did decline and it was after the fact that the

4     vaccine was licensed. But if you pick any

5     other section of time, it's increased.

6     Q.    I'm sorry, you think --

7     A.    Not any other section of time,

8     but, for instance, this says any given year.

9     Well, let's pick the year I left Merck versus

10    last year for which there is the most recent

11    -- that there's full data. It's gone up.

12    Q.    Do you believe that there was a

13    year prior to licensing of the product when

14    the vaccine was not available on the market

15    that it had more -- it had less -- I'm sorry,

16    let me restate that.

17            Are you aware that the CDC

18    monitors outbreaks of mumps?

19    A.    I'm aware that they will

20    monitor reported cases.

21    Q.    Correct. CDC tracks reported

22    cases of mumps?

23    A.    Got it.

24    Q.    And you're aware they've

25    tracked reported cases prior to the licensing

Page 108

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     of the vaccine and for every year after.

3     Correct?

4     A.    I don't think that's true.

5     What did you say?

6     Q.    They tracked the number of

7     reported cases prior to licensing and compared

8     it to the number of cases they've tracked

9     every year after licensing?

10    A.    Are we talking about MMR II?

11    Q.    Yes.

12    A.    Okay. They have tracked that,

13    yes.

14    Q.    Are you aware that according to

15    the CDC, the incidence of mumps has decreased

16    over 95 percent from prior licensure of any

17    mumps vaccine to post licensure of any mumps

18    vaccine? Are you aware of that or not?

19    A.    You just switched it.

20    Q.    It's a new question. Are you

21    aware of that or not?

22            MR. SCHNELL: Object to form.

23            THE WITNESS: The MMR was

24    licensed in 1977. The drop there is

25    not 95 percent. That would make this

Page 109

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     statement false. If you go by the

3     number reported here of 152,209 in

4     1968, that is not a year that is before

5     the monovalent was licensed. So in

6     that sense, this statement is false.

7     BY MS. DYKSTRA:

8     Q.    How about answering my question?

9     A.    I thought I did.

10    Q.    My question is that you're

11    aware the CDC tracks reported mumps cases

12    every year. Correct?

13    A.    Yes, they do.

14    Q.    Okay. Are you aware that they

15    have measured the decrease in mumps since any

16    Merck mumps vaccine has been licensed to

17    today?

18            MR. SCHNELL: Object to form.

19            THE WITNESS: You're saying

20    they have monitored any Merck mumps

21    vaccine since any Merck mumps vaccine

22    has been licensed?

23    BY MS. DYKSTRA:

24    Q.    You know what, we'll skip it,

25    I'll get you an exhibit and you can look at it

Page 110

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 and tell me if you agree.

3 A. But I can tell you right here.

4 Q. Is there anything else in the

5 label that you want to point to that you think

6 is false and misleading? I want to make sure

7 we get it all.

8 A. I want to be clear on this.

9 Cases reported in a given year prior. 1968 is

10 not prior. That's all I'm getting at. We can

11 argue why it says that or how it's a mistake.

12 But we're done with that on the package insert

13 up to indications and usage.

14 Q. Nothing else you want to point

15 to that you think is false and misleading

16 other than the things you've just identified?

17 A. Not in those two first

18 sentences right now off the top of my head.

19 Q. First two sections, right?

20 A. Yeah, first two sections.

21 Q. We'll come back to that.

22 I want to switch over to the

23 development of the assay. So you joined Merck

24 you said in 2000?

25 A. 1999.

Page 111

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 Q. And what was the date of your

3 employment, when you first were hired?

4 A. I think it was March 1999.

5 Q. And you left in November of

6 2001?

7 A. I think at some point during

8 November 2001 may have been the last time I

9 was physically present at the place.

10 Q. To what extent, if at all, were

11 you involved in the design and development of

12 the actual PRN assay?

13 MR. SCHNELL: Object to form.

14 THE WITNESS: That's such a

15 broad question. I mean, the design and

16 development of the assay, I worked

17 there when it was designed and

18 developed by Krah in his lab.

19 BY MS. DYKSTRA:

20 Q. I'm going to show you a series

21 of documents that some predate your employment

22 but I want to just confirm that you were not

23 involved in these particular discussions with

24 the FDA around the development of 007. The

25 first one I'm going to show you we'll mark as

Page 112

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 Krah-5.

3 MR. SCHNELL: Krahling.

4 MS. DYKSTRA: Krahling-5.

5 Sorry.

6 - - -

7 (Exhibit Krahling-5, 6/23/98,

8 IND submission, MRK-KRA00624345 -

9 00624446, was marked for identification.)

10 - - -

11 BY MS. DYKSTRA:

12 Q. This is a June 23, 1998, IND

13 submission from Merck to the FDA. Can you

14 take a look at that, you don't have to read

15 the whole thing. I just want to know, this is

16 before you were employed by the company.

17 Correct?

18 A. June 23, 1998, is before I was

19 employed at the company.

20 Q. Do you know whether you've ever

21 seen this document before? Just by looking at

22 it right now, can you tell me one way or the

23 other?

24 A. Just looking at the front page?

25 I can't tell by looking at the front page

Page 113

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 alone.

3 Q. Can you tell me prior to Merck

4 producing this document as part of discovery

5 in this case you've ever seen this document?

6 A. We're talking about the front

7 page. I mean, how much do you -- are you

8 going to let me look through it --

9 Q. Yes.

10 A. -- to figure out what I've seen

11 of it?

12 Q. Yes. And I want to know what

13 you've seen of it other than what you've seen

14 as part of this litigation?

15 A. I have to look at every page

16 then.

17 Q. We'll go off the record and you

18 can look at every page.

19 A. For God's sake. If you want an

20 accurate answer, I've got to look at it.

21 MS. DYKSTRA: Could we go off

22 the record for a moment?

23 VIDEOGRAPHER: The time is

24 11:49. We're going off the video

25 record.

Page 114

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2             - - -

3             THE WITNESS: I want to be back

4             on the record so I can ask -- it's

5             going to be a long day. I've got to

6             look at it. I'm just looking to see if

7             I recognize it. I'm not reading it.

8             It would take two hours.

9             MR. SCHNELL: You can go back

10            on the record and ask your question.

11            - - -

12            VIDEOGRAPHER: The time is

13            11:52. We're back on the video record.

14            THE WITNESS: I'm on page 25

15            and I'm whipping through this, not

16            reading it. I'm just trying to see if

17            I recognize any pages, and I'm pretty

18            sure, based on what I'm looking at,

19            there's a package -- there are sections

20            I have seen before in here, basically

21            the package insert. Other than the

22            package insert, I don't know if I've

23            ever seen this document before.

24 BY MS. DYKSTRA:

25     Q.     This document, do you see it's

Page 115

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     authored by Keith Chirgwin on the second page?

3     A.     I don't -- I mean, I trust that

4     you're saying that this page represents the

5     entire document. If so, then I do see that.

6     Q.     Did you have any discussions

7     with Keith Chirgwin when you were an employee

8     at the company?

9     A.     Not that I'm aware of.

10    Q.     Did you work with Keith

11    Chirgwin -- I don't mean to be this

12    duplicative, I just want it to be clear. Did

13    you work with Keith Chirgwin on any regulatory

14    submissions to the FDA in connection with the

15    mumps vaccine?

16    A.     I can't say I worked with him

17    in person because I don't know who he is. But

18    to say -- I can't exclude that he didn't rely

19    on the data from our lab.

20    Q.     I understand. Do you recall

21    ever working directly with Keith Chirgwin or

22    discussing with Keith Chirgwin any regulatory

23    submissions to the FDA?

24    A.     I don't know who he is. As far

25    as I know I've never talked to him.

Page 116

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q.     So that would be a no?

3     A.     I'm trying to be clear.

4     Q.     You don't know who he is and

5     you've never talked to him?

6     A.     As far as I know. I mean, it's

7     possible I met someone who talked to me and

8     didn't tell me he was Keith Chirgwin. But it

9     seems to me I don't know who the guy is.

10    Q.     I'll pull it out if you want,

11    but we asked you in your request for admission

12    to admit that during your employment with

13    Merck you were never asked to communicate with

14    the FDA directly on behalf of Merck and you

15    admitted that.

16    A.     Can you show me the RFA?

17    Q.     Sure. Yes, I can.

18    A.     Can I put this one away or I

19    need to leave it open?

20    Q.     Leave it open for a second.

21            - - -

22            (Exhibit Krahling-6, Relator

23            Stephen A. Krahling's Responses and

24            Objections to Defendant Merck's

25            Requests for Admission, was marked for

Page 117

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     identification.)

3            - - -

4 BY MS. DYKSTRA:

5     Q.     I'm marking as Exhibit 6

6     Relator Stephen Krahling's Responses and

7     Objections to Defendant Merck's Requests for

8     Admissions.

9            I'm marking as Exhibit 7 the

10    amendments to your responses to Merck's

11    requests for admissions, revised June 21st.

12            - - -

13            (Exhibit Krahling-7, 6/21/16

14            Letter, was marked for identification.)

15            - - -

16 BY MS. DYKSTRA:

17    Q.     I'm giving you 6 and 7 because

18    you changed your answer so I want to make sure

19    I understand.

20            If you look at request for

21    admission 30 in both of them, in both

22    Krahling-6 and Krahling-7. Our question to

23    you was, admit that during your employment at

24    Merck you were never asked to communicate with

25    the FDA directly on behalf of Merck. You

Page 118

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 originally denied it and then you admitted it.

3 Correct?

4     A. I see that, yes.

5     Q. Do you know why you originally

6 denied it?

7     A. You mean beyond what's written

8 here?

9     Q. Well, you changed your answer

10 from deny to admitted, so I want to understand

11 why.

12     A. Well, the definition of Merck

13 includes Relators and other former employees.

14 I was asked to contact the FDA by my co-workers.

15     Q. Who asked you to do that?

16     A. Suzie Maahs, Joan and Jon was

17 shaking his head yes and agreed with it. Jill

18 DeHaven. Frank Kennedy.

19     Q. So other contact -- other than

20 contacting the FDA, which I'm assuming you're

21 talking about 2001 in connection with the FDA

22 inspection. Correct?

23     A. Can you restate that a little

24 slower?

25     Q. Assuming -- other than the

Page 119

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 conversations you may have had with the FDA

3 that led to the inspection that you're

4 referring to here, other than those

5 conversations, were you ever asked to, during

6 your employment with Merck, to communicate

7 with the FDA directly on behalf of the

8 company?

9     A. On behalf of the company, no.

10 I believe that's why it switched over. The

11 loss of ambiguity on that and we can admit

12 that. As part of my job duties, it wasn't my

13 job to communicate with the FDA on behalf of

14 Merck.

15     Q. What about with the CDC, were

16 you ever -- was it ever part of your job

17 duties to communicate with the CDC on behalf

18 of Merck?

19     A. No, it was not.

20     Q. Have you ever communicated with

21 the CDC in connection with this case or your

22 allegations here?

23     A. I can't know -- other than not

24 knowing if I'm talking to someone who is at

25 the CDC, but I don't believe that I have.

Page 120

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q. Putting aside you might have

3 met somebody on the street that happened to

4 work for the CDC and you didn't realize it,

5 have you ever talked to somebody in their

6 capacity as an employee of the CDC about the

7 allegations in this case?

8     A. No.

9     Q. If you also look at your

10 request for admissions numbers 34. I'm sorry,

11 in the first RFA, I think that's number 6,

12 Krahling-6. Number 34. We asked you to admit

13 that you've never attended any meetings

14 between Merck and the FDA and you denied that.

15 Correct?

16     A. Yes, denied the request.

17     Q. And why did you deny it?

18     A. Merck is a company, the FDA is

19 a regulatory agency, so if you're -- if those

20 two things subsume all the people that work

21 there, that can be taken to mean did I attend

22 any meeting by an employee at Merck and

23 employee at the FDA. I did.

24     Q. And which meetings did you

25 attend?

Page 121

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     A. I attended a meeting in person

3 that occurred in Krah's lab.

4     Q. Other than that meeting -- I'm

5 assuming you're talking about August 2001?

6     A. Yes.

7     Q. Other than that August 2001

8 meeting, have you ever attended a meeting

9 between Merck and the FDA?

10     A. I attended a telephone

11 conference meeting.

12     Q. When was that and with whom?

13     A. It was four or five teleconference

14 calls or telephone meetings from the middle of

15 June to the end of July, 2001.

16     Q. They were between you and the

17 FDA. Is that correct?

18     A. Yes.

19     Q. That was in connection with

20 your complaints around 007?

21     A. Yeah, it was in connection with

22 the fraud that I reported, that Joan and I

23 reported and the rest of the lab with the

24 Protocol 007 testing in Krah's lab.

25     Q. Other than those complaints

Page 122

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     about what was happening in Krah's lab in

3     2001, have you ever attended a meeting between

4     Merck and the FDA?

5     A.    In person or on the phone, I

6     don't believe I did.

7     Q.    And I have the same question

8     for number 35. We ask, admit that you've

9     never attended any meeting between Merck and

10    the FDA concerning Merck's mumps vaccine.

11            Aside from the complaints you

12    made to the FDA and the FDA inspection in

13    2001, have you ever attended any meetings

14    between Merck and the FDA concerning its mumps

15    vaccine?

16    A.    So this is the same as 34?

17    Q.    Essentially.

18    A.    Yes. So we denied it because

19    the meeting I attended in their lab, if you

20    exclude the same things that were excluded in

21    request 34, I don't believe that I did attend

22    any other meetings.

23    Q.    You can put those admissions

24    aside for a moment.

25            I'm going to show you what I'm

Page 123

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     going to mark as Krahling-8.

3            - - -

4            (Exhibit Krahling-8, Letter,

5            MRK-KRA00001446 - 00001469, was marked

6            for identification.)

7            - - -

8     BY MS. DYKSTRA:

9     Q.    This is a September 8, 1998,

10    letter from the FDA to Dr. Chirgwin at Merck.

11    Have you ever seen this document before?

12    A.    It's only two pages, can I read

13    it?

14    Q.    You may. My question is just

15    going to be have you seen this before or had

16    any involvement with discussions about it with

17    Dr. Chirgwin or anybody else at Merck?

18    A.    I have not seen it before. But

19    the first page which I'm done with, yes, I've

20    had discussions with Krah about item point

21    number 1. I had discussions with him about

22    3(a) which were related to 3(b). We talked

23    about number 4.

24    Q.    You and Dr. Krah?

25    A.    Yeah. Well, I mean, not just

Page 124

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     me and Dr. Krah, but Dr. Krah, Dave and the

3     lab, Krah and the lab, he talked about it in

4     front of the lab members. So not exclusively

5     to me. Definitely number 5. He alluded to

6     number 8 but tangentially in a way. So I

7     mean, quite a bit was discussed about this,

8     but I haven't seen the document before you

9     giving it to me.

10    Q.    Other than people in -- Dr. Krah

11    or in Dr. Krah's lab, did you ever have any

12    discussions about those -- the topics raised

13    in that letter with anybody else at Merck or

14    the FDA?

15    A.    So broad. These cover everything.

16    Q.    My question is, other than people

17    in the lab that you referred to including

18    Dr. Krah, did you ever talk to anybody else at

19    the company about those issues?

20    A.    These issues are broad. They

21    cover the entire clinical study. Alan Shaw,

22    Emilio Emini certainly. These issues are so

23    broad. This is everything about how the --

24    not everything, but these are quite broad

25    issues.

Page 125

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q.    So is there anybody else

3     besides Dr. Emini, Dr. Shaw, or Dr. Krah and

4     people in his lab that you talked about these

5     issues at the company?

6     A.    A lot of -- this is Protocol

7     007. I talked to the FDA about Protocol 007.

8     Now we're talking outside of the company?

9     Q.    No, I'm talking about the

10    company right now.

11    A.    Okay. Not that I can think of.

12    Q.    Outside the company who did you

13    talk to about 007 other than the FDA and

14    Merck?

15    A.    And outside of my lawyers?

16    Q.    Yes.

17            MR. SCHNELL: I want to

18    instruct you, though, to the extent

19    that counsel was present or that it

20    discloses attorney-client

21    communications, work product, you

22    should not answer.

23            THE WITNESS: No one at this

24    level.

25    BY MS. DYKSTRA:



Page 126

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 Q. I'm sorry, what do you mean "no

3 one at this level"?

4 A. I didn't talk to anyone outside

5 of lawyers or people at Merck to the degree of

6 specificity we're talking about here about

7 that he -- you know, using heat to degrade the

8 virus, things like that. No one.

9 Q. You said, I just want to make

10 sure I'm correct, you did not discuss -- other

11 than your discussions with the FDA in 2001

12 when you complained about what was happening

13 in Dr. Krah's lab, you did not discuss the

14 development of the assay with anyone at the

15 FDA. Correct?

16 A. That's so broad.

17 Q. It's not really broad at all.

18 A. Can you say it slower then?

19 Q. Absolutely. Other than your

20 complaints to the FDA in 2001 about what was

21 occurring in Dr. Krah's lab, have you ever

22 talked to anybody at the FDA about the

23 development of the assay?

24 A. That's a great question. The

25 word "development," what do you mean by that?

Page 127

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 The rest of the question is pretty good. What

3 are we defining as development? From the

4 first time they said we have to do this

5 clinical study or we may lose our license or

6 have to change the label, to them turning it

7 into regulatory agencies, or are we talking

8 about something more narrow?

9 Q. I think you stated already that

10 the only time you talked to the FDA about

11 anything related to 007 were those

12 conversations in 2001 about what happened in

13 Dr. Krah's lab. Is that not accurate?

14 A. That's accurate, but the

15 question is about what you're defining as

16 development so that I can say whether I talked

17 about it or not.

18 Q. Well, if the only conversations

19 you had with the FDA around 007 at all were in

20 2001 and around what happened in his lab, then

21 the answer to my question, I believe, is, no,

22 you never talked to them about anything else

23 other than those few conversations?

24 A. We talked about these specifics

25 of Protocol 007.

Page 128

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 Q. I'm talking about the FDA, to

3 the FDA.

4 A. I know. But you're saying

5 about the specifics of Protocol 007 and now

6 you're talking about the development. I just

7 want you to define development.

8 Q. Let me do it this way: The

9 conversations you had with FDA in 2001, let's

10 put them in two buckets. There were a couple

11 of times you called the FDA. Correct?

12 A. More than a couple.

13 Q. Four times I believe you say in

14 your complaint.

15 A. Four or five.

16 Q. So you called the FDA four or

17 five times, and that was in 2001?

18 A. Yes.

19 Q. And your conversations with the

20 FDA which we'll go through were about what was

21 occurring in Dr. Krah's lab. Correct?

22 A. Yes.

23 Q. And then you also met with the

24 FDA when they inspected the lab on August 6,

25 2001?

Page 129

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 A. I was in the room when the

3 meeting took place, so...

4 Q. You were present when the FDA

5 came?

6 A. Uh-huh.

7 Q. Other than your telephone calls

8 we just talked about and the August 6, 2001,

9 inspection, have you had any conversations at

10 all with the FDA around 007?

11 A. Any conversation with him about

12 Protocol 007 at all around that -- other than

13 the ones where I talked to him.

14 Q. Other than the two situations

15 you just identified, the complaint --

16 A. No.

17 Q. So then I don't understand why

18 you had a problem answering the question did

19 you ever talk about the development other than

20 those times.

21 A. Whether I talked about the

22 development of --

23 Q. Other than those specific

24 instances we just discussed.

25 A. Because we were developing the

Page 130

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     assay as we were running it. You're using a

3     definition of development that you're not

4     giving me.

5     Q. I'm trying to exclude four

6     phone calls you made to the FDA to complain

7     about the assay and the FDA's inspection.

8     A. Okay. You can exclude those

9     things but your definition of development

10    seems to be things that didn't happen in

11    Krah's lab or happened before. Krah was

12    developing, altering, changing the assay as we

13    worked on it.

14    Q. I understand.

15    A. I used that as a definition of

16    development, and I think I said the only

17    problem I had with your question was your

18    definition of development.

19    Q. I understand.

20           MR. SCHNELL: We've been going

21           more than an hour so whenever is a good

22           time to break.

23           MS. DYKSTRA: Yeah, give me one

24           second, let me just --

25    BY MS. DYKSTRA:

Page 131

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q. Let me ask you about one more

3     document and then we'll take a break.

4     - - -

5           (Exhibit Krahling-9, 12/1/99

6           Letter, MRK-KRA00001222 - 00001230, was

7           marked for identification.)

8     - - -

9    BY MS. DYKSTRA:

10    Q. We're going to mark as

11    Krahling-9 a December 1, 1999, letter from

12    Ms. Manal Morsy to Ms. Vujcic at FDA. Here

13    you go, I'll give you that. Before you read

14    it, let me just ask some initial questions.

15           Have you ever worked -- have

16    you ever talked to or do you know Dr. Manal

17    Morsy?

18    A. I know who she is. I think she

19    said something to me, but I didn't say

20    anything back to her.

21    Q. Why do you remember that

22    conversation? Was that in recent times with

23    her deposition?

24    A. Yes.

25    Q. Let's focus on when you were

Page 132

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     working with Merck. At any other time other

3     than your [sic] deposition, have you ever

4     talked to or worked with Manal Morsy?

5     A. I never met her or talked to

6     her in person. I don't know whether my work

7     would consider -- I don't know if she used my

8     work in part of her work or not at the time.

9     Q. You can take a couple minutes

10    to look through this letter. We can go off if

11    you want to review the whole thing, I just

12    want to ask you one specific question before

13    we break.

14    A. Just one question?

15    Q. I'll show you where I'm going

16    to talk and then you can take time to look at

17    this over the break.

18           On page 2 of Merck's letter to

19    the FDA, Merck inserts a table with

20    seroconversion rates using Jeryl Lynn and

21    London-1 strain of the vaccine -- of the

22    virus. Do you see that chart?

23    A. I see the chart.

24    Q. Are you aware that Merck

25    submitted this data to the FDA in 1999?

Page 133

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     A. Krah told me that -- he

3     indicated that the FDA had known something

4     along this line with LO-1 strain.

5     Q. What did he specifically say to

6     you?

7     A. He said that the LO-1 was the

8     best they could get against any wild type

9     strain and that the rest were -- the efficacy,

10    seroconversion against the other strains was

11    worse.

12    Q. So you were aware that Merck

13    submitted to the FDA seroconversion rates with

14    LO-1 that were as low as 54 percent?

15    A. I can't say specifically, but

16    he said that they were sharing their best case

17    scenario of a wild type -- of the test against

18    the wild type with Merck, not with -- you

19    know, Merck was sharing it with the FDA as

20    rationale for a need to change the assay or to

21    do more. He considered it a failure. But,

22    you know, he was clear that the other stuff

23    was worse, that the seroconversion they were

24    seeing against Swiss isolate and some of the

25    other strains was much worse. I haven't even

Page 134

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     read the document, I'm just looking at the

3     table.

4             MS. DYKSTRA: Why don't we take

5     a break and you can -- you want to take

6     a lunch break, I guess?

7             MR. SCHNELL: I think we should

8     go one more hour.

9             MS. DYKSTRA: That's fine. Why

10    don't we take a 15-minute, 10-minute

11    break, whatever, you can read this

12    document during the break before we go

13    back on.

14             VIDEOGRAPHER: The time is

15    12:15. We're going off the video

16    record.

17             - - -

18             (A recess was taken.)

19             - - -

20             VIDEOGRAPHER: The time is

21    12:34. We're back on the video record.

22    BY MS. DYKSTRA:

23             Q.    Mr. Krahlung, do you have the

24    letter from Merck dated December 1, 1999, from

25    Manal Morsy in front of you?

Page 135

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2             A.    Exhibit 9?

3             Q.    Yes.

4             A.    Yes, I have it.

5             Q.    I think you stated you did not

6    work with Manal Morsy directly when you were

7    at Merck. Correct?

8             A.    Yeah, I didn't directly work

9    with her face to face, no.

10            Q.    Are you -- and you said, I

11    think, I don't want to put words in your

12    mouth, that you're aware based on discussions

13    with Dr. Krahl that Merck had disclosed to the

14    FDA that the LO-1 vaccine strain was producing

15    lower seroconversion rates than the Jeryl Lynn

16    strain?

17            A.    He said that they had reported

18    some result of the PRN assay against the LO-1

19    strain because the LO-1 strain was the best

20    case scenario for a wild type strain and that

21    they needed to switch the indicator strain to

22    the vaccine strain.

23            Q.    Are you aware that Merck

24    reported to the FDA the information found at

25    page 2 of Exhibit 8 -- 9. I'm sorry,

Page 136

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2    Exhibit 9. That the LO-1 strain had

3    seroconversion rates as low as 54.5 percent.

4    Are you aware of that fact?

5            A.    Right now?

6            Q.    Were you aware of it before

7    this meeting, this deposition?

8            A.    I can't recall when I saw this.

9    At the time I worked there, I wasn't aware of

10   the exact numbers other than that they were

11   significantly lower against LO-1 than the

12   label claim which is why Krahl gave us the

13   rationale for needing to switch the indicator

14   strain so that we would get results that would

15   match the label.

16            Q.    But you were not aware when you

17   were working in the lab that Merck had

18   disclosed these specific rates to the FDA in

19   December of 1999. Correct? These meaning the

20   rates on page 2 of Exhibit 9.

21            A.    Krahl indicated at the time that

22   they had to disclose the best case scenario

23   for the wild type strain as a rationale to

24   change the indicator strain. And I knew at

25   the time because I -- these things -- my best

Page 137

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2   memory is that these things were done by Krahl

3   in our lab. So, I mean, I saw the original

4   data that LO-1 was London-1. That's what I

5   remember. Does it say London-1? That that

6   was the best case scenario that Merck could

7   get in Krahl's lab for a PRN testing against a

8   wild type.

9            Q.    Were you aware when you worked

10   in Krahl's lab that Merck disclosed to the FDA

11   seroconversion rates with LO-1 that were as

12   low as 54.5 percent?

13            MR. SCHNELL: Object to form.

14            THE WITNESS: I don't know the

15   actual number reported.

16   BY MS. DYKSTRA:

17            Q.    So you don't know whether Merck

18   disclosed that information when you were

19   working there?

20            MR. SCHNELL: Object to form.

21            THE WITNESS: I mean, I

22   answered the question. Krahl --

23   BY MS. DYKSTRA:

24            Q.    Let me ask the question again

25   to make sure I'm clear.

Page 138

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2             Prior to filing the complaint

3 in this case, were you aware that Merck

4 disclosed to the FDA seroconversion rates

5 using the LO-1 virus strain, using a PRN assay

6 that showed seroconversion rates as low as

7 54.5 percent? Were you aware that that was

8 disclosed to the FDA?

9     A.    Everything about your question

10 is fantastic. The number 54.5 percent,

11 replace that with a number against exactly

12 everything you said that is significantly

13 lower than Merck is reporting on their label.

14 And then, yes, I did know that.

15     Q.    Did you -- if you look at page

16 4 of this letter marked Exhibit 9, were you

17 aware that Merck proposed to the FDA based on

18 the PRN assay results, that they should use a

19 Jeryl Lynn virus as the target strain in the

20 PRN assay?

21     A.    Krah indicated to me that the

22 rationale for giving them the best case

23 scenario against LO-1 is that they had to

24 report something as a prelude to requesting

25 permission to test against the vaccine strain

Page 139

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 because they couldn't possibly match the

3 seroconversion on the label without testing

4 against the vaccine strain. In that sense,

5 yes, I was aware.

6     Q.    If you look at page -- actually

7 I think we're good with that document. You

8 can put that one away for now.

9             I'm going to show you a very,

10 very gigantically large document. I'm only

11 going to ask you about one table in the middle

12 of it. I don't want to take it apart to keep

13 the integrity of the document together. But

14 this is a December 30, 1999, IND submission

15 from Merck to the FDA, Bates-labeled 01449.

16 That -- I'm sorry, that's Krahling-10.

17             - - -

18             (Exhibit Krahling-10, 12/30/99

19             IND submission, MRK-KRA00001470 -

20             00001924, was marked for identification.)

21             - - -

22 BY MS. DYKSTRA:

23     Q.    And I just -- I don't want to

24 ask you anything about this document other

25 than one or two specific questions. If you

Page 140

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 turn -- so I'm not asking about the content,

3 I'm not asking if you know anything about it.

4 If you turn to what's Bates-labeled at the

5 bottom KRA 1618, the middle Bates label. Not

6 the one on the right. The middle one.

7 There's a Bates label in the middle and on --

8     A.    Oh.

9     Q.    There's a two-page, or, I

10 guess, four-page double-sided chart called:

11 "Table 1: Summary of published studies on

12 clinical efficacy and field effectiveness of

13 Jeryl Lynn."

14     A.    We're talking two sheets of

15 paper?

16     Q.    Yes. If you look at this

17 table, this "Table 1: Summary of published

18 studies on clinical efficacy and field

19 effectiveness of Jeryl Lynn," you'll see that

20 the sixth column is called: "Efficacy

21 Estimates." You have to kind of hold it

22 right. You'll see the sixth column is called:

23 "Efficacy Estimates"?

24     A.    What page are you on?

25     Q.    The very first page on the top.

Page 141

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     A.    Okay. Got you.

3     Q.    Do you see where it says,

4 "Efficacy Estimates"?

5     A.    Is it above the table or in it?

6 Oh, on number one?

7     Q.    One, two, three, four, five,

8 the heading on the sixth column.

9     A.    "Efficacy Estimate," I see that

10 column.

11     Q.    You see in that column the

12 efficacy estimates reading down 97 percent,

13 88 percent, 96.5 percent, 37 percent,

14 52 percent, 65 percent, 70 percent,

15 74 percent, 85 percent. That's the first

16 page. Do you see that?

17     A.    Yeah. If we're going to -- if

18 the question is going to be about like a

19 column running down, I have to -- I'm going to

20 have to look at --

21     Q.    That's fine. What I want to

22 know, I'll tell you the question, then you can

23 take time to look at this, is whether you were

24 aware -- and I'll just note that there are

25 three other pages of different efficacy rates

Page 142

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     on here, you can look at those as well --

3     whether you were aware that Merck submitted

4     this table to the FDA? That's all I want to

5     know, whether you were aware prior to filing

6     the complaint that Merck submitted this data

7     to the FDA?

8     A.   Those are two different

9     questions. The data or the table?

10    Q.   Either one.

11    A.   Okay.

12    MR. SCHNELL: Counsel could

13    direct the witness if he feels he needs

14    to, the page preceding the table

15    explains the context of the table.

16    MS. DYKSTRA: Bates-labeled 1617?

17    MR. SCHNELL: 1616 and 1617 --

18    MS. DYKSTRA: Sure.

19    MR. SCHNELL: -- is what

20    precedes the table and explains what it

21    is. I don't know if that helps or not.

22    But it might be useful in understanding

23    the table.

24    THE WITNESS: I think I

25    understand the table. I'm good to go.

Page 143

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     BY MS. DYKSTRA:

3     Q.   Were you aware prior to filing

4     this lawsuit that Merck provided this data in

5     this form or any other to the FDA?

6     A.   I was aware that Merck reported

7     data similar to this, if not this exact data,

8     along with reasons why they didn't agree that

9     the lower numbers accurately characterized

10    their vaccine as a prelude to be able to

11    switch the indicator strain to the vaccine

12    strain which would match Hilleman's data.

13    Q.   But this is a just a summary of

14    published clinical efficacy data. So why they

15    submitted it, putting that point aside, you

16    weren't aware that we submitted this -- you

17    were aware that we submitted this type of data

18    to the FDA?

19    MR. SCHNELL: Objection. Asked

20    and answered.

21    THE WITNESS: I was aware --

22    I'll answer it. I mean, Krah made it

23    clear that if -- that they could not

24    get 95 percent efficacy without testing

25    against the vaccine strain and that

Page 144

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     they needed to try to make an argument

3     of why they needed to do that.

4     BY MS. DYKSTRA:

5     Q.   I take it you did not help

6     prepare that table in any way that's in front

7     of you?

8     A.   I don't know. I don't know

9     if -- well, we should be able to figure it

10    out.

11    Q.   Well, do you remember preparing

12    that table or you don't? That's my only

13    question.

14    A.   I was going to say I don't know

15    if work that I did went into this table.

16    Q.   Do you remember preparing that

17    table?

18    A.   No, I do not.

19    Q.   You can put that aside.

20           Have you ever had any -- I

21    don't mean to belabor the point, but have you

22    ever had any discussions at any point in time

23    other than related to the FDA inspection of

24    Merck in 2001 with Dr. Carbone of the FDA, Dr.

25    Kathryn Carbone?

Page 145

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     A.   I don't recall.

3     Q.   What about Dr. Luba Vujcic?

4     A.   I don't recall any conversations.

5     Q.   Are you aware that CBER

6     considered an early passage of the Jeryl Lynn

7     virus -- are you aware that if Merck used an

8     earlier passage of the Jeryl Lynn virus

9     similar to passage 7, that CBER would accept

10    that to be a wild type virus strain?

11    A.   I understood that Krah

12    indicated that we were not going to be

13    permitted to test against the fully passage

14    vaccine strain, so that they were trying to

15    come up with a way to use something that was

16    attenuated, Merck was trying to come up with a

17    way to use a strain that was attenuated so

18    that they could get a better response.

19    Q.   Are you aware that CBER

20    considered passage 7 of the Jeryl Lynn strain

21    to be similar to a wild type?

22    A.   I was aware -- wait, what was

23    the question again?

24    Q.   Are you aware that CBER

25    considered passage 7 of the Jeryl Lynn strain

Page 146

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     to be used in the neutralization assay as a

3     wild type virus strain?

4             MR. SCHNELL: Object to form.

5             THE WITNESS: That sounds like

6     the -- that might have been written

7     into the protocol, the AIGENT assay

8     protocol. And I was aware that CBER

9     would see that protocol.

10  BY MS. DYKSTRA:

11     Q.    So independently of that

12     answer, did you have any independent knowledge

13     prior to filing this lawsuit that CBER

14     confirmed and considered passage 7 of the

15     Jeryl Lynn strain to be a wild type virus

16     strain?

17             MR. SCHNELL: Object to form.

18             THE WITNESS: I can't speak to

19     what the CDC thought of that strain.

20  BY MS. DYKSTRA:

21     Q.    I'm just asking whether you

22     knew, whether you were aware that CBER

23     believed passage 7 of the Jeryl Lynn strain to

24     be considered a wild type strain?

25     A.    I don't know that CBER thought

Page 147

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     that was a wild type strain.

3     Q.    Are you -- were you aware prior

4     to filing this complaint that CBER and Merck

5     discussed the use of antihuman IgG to

6     potentially enhance the PRN assay?

7     A.    Can you read that question

8     again? I'm still on the first one with the

9     wild type.

10     Q.    I'll ask more questions about

11     that later.

12             Are you aware that Merck and

13     CBER discussed the use of using an antihuman

14     IgG to potentially enhance the PRN assay?

15     A.    I'm aware that the anti-IgG was

16     written into the protocol that we used and

17     that CBER okayed it, okayed the protocol.

18     Q.    Okay.

19     A.    I should clarify that.

20     Q.    Let me ask you a question

21     about --

22     A.    Can I clarify that?

23     Q.    Sure.

24     A.    When I said protocol, the

25     protocol was transient and kept changing. So

Page 148

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     the most I can really say is that the FDA,

3     from what I understand from Krah, said that

4     the FDA okayed some version that we started to

5     use of that protocol. But the protocol

6     changed as we were doing that. So I don't

7     think the word "protocol" is clear. I was

8     aware from what -- what Krah said was that the

9     FDA knew that anti-IgG was to be incorporated

10    in some form. And he tied that, that

11    conversation came about when Jenny Kriss asked

12    him why we were changing the pre-positives.

13    And he said that if we didn't change the

14    pre-positive rates and lower them, that would

15    be a red flag that the protocol was a problem,

16    that it was a thing. So we had to lower the

17    pre-positive rate.

18             So in that sense, I don't know

19    that the FDA approved the usage, because I

20    don't know what you mean by usage. I think

21    they were aware that the product was bought

22    and used in some manner, but they certainly

23    didn't know how it was used or how the results

24    were being manipulated so they wouldn't

25    understand how it was being used.

Page 149

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q.    Are you aware that Merck

3     provided data around the use of the anti-IgG,

4     a different dilution, that they provided that

5     data to CBER?

6             MR. SCHNELL: Object to form.

7             THE WITNESS: What do you mean

8     by "data"?

9     BY MS. DYKSTRA:

10     Q.    Are you aware that Merck

11     produced data related to the use of the

12     anti-IgG for dilutions?

13     A.    I'm pretty certain they

14     produced something you could call data. One

15     of the things in that data would be different

16     dilutions of anti-IgG used.

17     Q.    So I understand from your

18     answers that a lot of your information around

19     what Merck communicated with and produced to

20     CBER was through Dr. Krah. Is that correct?

21     A.    A good amount of it originated

22     there.

23     Q.    Did you review documents

24     submitted to CBER and CBER's responses to

25     those documents such as the protocol, before

Page 150

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     you filed this complaint?

3     A.    What are we asking?

4     Q.    Did you review Merck's

5     submissions to the FDA and CBER's questions

6     back to Merck around the development of the

7     essay?

8     A.    So I don't know what you mean

9     by "submissions." And then, again, you're

10    using development. The thing was developed in

11    our lab.

12    Q.    Did you review documents and

13    protocols that Merck submitted to CBER, CBER's

14    questions back and our answers to CBER's

15    questions, the written forms, did you review

16    those?

17    A.    What time period?

18    Q.    Prior to filing the complaint,

19    did you review Merck's written submissions to

20    CBER and CBER's questions back and Merck

21    answers back to CBER around the assay?

22    A.    It's not clear to me what

23    constitutes as submission. But the protocol,

24    I believe, is a submission, and I would have

25    seen that. I did see it. So in that sense I

Page 151

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     knew something of at least some submission if

3     you include the definition that includes

4     protocols.

5     Q.    What's in front of you, the

6     large document, Exhibit 10 right there, did

7     you see that document prior to this litigation?

8     A.    Come on.

9     Q.    It's not a difficult question.

10    A.    Yeah, I have to look at it. I

11    have to go through it.

12    Q.    Sitting here today without

13    going through it, you don't know whether you

14    looked at it or not? You would need to go

15    through it to say whether you looked at it

16    prior to filing this complaint?

17    A.    Looking at this front page, I

18    didn't see the front page that I know of. But

19    I mean, I don't know what is contained in

20    here. You said to look at just the middle

21    part. I can't speak to the rest of the

22    document.

23    Q.    Other than -- when you talk

24    about protocol, what are you characterizing as

25    the protocol?

Page 152

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     A.    That's a good question because

3     they kept changing.

4     Q.    What do you generally mean a

5     protocol to be?

6     A.    The protocol standard operating

7     procedure, how -- what you would be doing as a

8     methodology to run an assay.

9     Q.    Other than the protocol, did

10    you see any submissions, meaning documents

11    that Merck wrote to CBER around 007?

12    A.    Yes.

13    Q.    What did you see?

14    A.    I saw the -- I saw -- what's

15    your time frame?

16    Q.    Before the filing of the

17    complaint.

18    A.    I saw a CBER review of the

19    biological license application for ProQuad.

20    Q.    Anything related to 007 other

21    than the protocol?

22    A.    Ton of things related to

23    Protocol 007.

24    Q.    Are you suggesting that

25    Protocol 007 was used in connection with the

Page 153

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     approval of ProQuad?

3     A.    I'm not just suggesting it, it

4     absolutely was.

5     Q.    Why do you think that?

6     A.    I know that.

7     Q.    Why do you know that, on what

8     basis?

9     A.    Do you have the BLA with you,

10    I'll go through it?

11    Q.    We will later. Just give

12    me your answer.

13    A.    The basis? The immunogenicity

14    testing was validated against the Protocol 007

15    PRN. The immunogenicity data used in there

16    was calibrated against falsified PRN data that

17    Merck knew was unreliable. Not only that, but

18    the ProQuad, because like you said, it's

19    unethical to withhold the mumps vaccine once

20    people have the perception that it works, a

21    lot of the things in the ProQuad BLA

22    bootstrapped to MMR. MMR II.

23    Q.    Other than ProQuad BLA and the

24    007 protocol, did you see any documents

25    submitted by Merck to CBER in connection with

Page 154

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Protocol 007?

3     A.    I mean, I knew of information

4     that was submitted. I knew that Protocol 007

5     was a completed trial.

6     Q.    I'm not talking about information

7     you may have heard. I'm asking whether you

8     actually saw submissions from Merck to CBER or

9     their questions back around 007 other than the

10    protocol itself or the ProQuad BLA?

11   A.    From Merck to CBER?

12   Q.    Yes.

13   A.    Submissions, you're talking

14   about the final form, like the day it went out

15   or are you talking about content?

16   Q.    I'm talking about actual

17   documents that Merck sent to CBER. Whether

18   you saw those documents. Other than the

19   protocol or the BLA for ProQuad, have you

20   seen, prior to filing this lawsuit, any

21   documents Merck sent to CBER?

22   A.    After the August visit,

23   inspection by the FDA, Krahl was compiling

24   documents to respond to that. So I think that

25   would qualify as I was aware of some of the

Page 155

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     content, but to say like a final form

3     submission, like the day it went out, I'm not

4     recalling anything at the moment that went

5     right from Merck to the FDA in some sort of

6     final form --

7     Q.    Can we look at -- sorry.

8     I'm going to show you --

9     A.    -- prior to filing any lawsuit.

10    Q.    I'm going to mark as

11    Krahl-11 a March 12, 2001, response to the

12    FDA request for information from Merck.

13    - - -

14    (Exhibit Krahl-11, 3/12/11

15    Response to FDA Request for Information,

16    MRK-KRA00018864 - 00018937, was marked

17    for identification.)

18    - - -

19    BY MS. DYKSTRA:

20    Q.    And before we go through the

21    whole document, I just have a couple of

22    initial questions.

23    So to your point earlier, this

24    is the kind of document you would not have

25    seen on March 12, 2001, letter to the FDA --

Page 156

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     MR. SCHNELL: Object to form.

3   BY MS. DYKSTRA:

4     Q.    -- from Merck?

5     MR. SCHNELL: Object to form.

6     THE WITNESS: First of all, I

7     would have to --

8   BY MS. DYKSTRA:

9     Q.    Let's just start with the

10   initial letter itself.

11   A.    How long is that?

12   Q.    Two pages. One and a half.

13   That letter. Just that letter, the front

14   letter, March 12, 2001. This is the type of

15   communication I was referring to as submission

16   from Merck to the FDA. This is the kind of

17   document you said you would not have seen

18   prior to filing this lawsuit?

19   A.    I don't know that I said that.

20   I would not have seen this cover page in its

21   final form. I would have seen content that

22   was in these documents because documents

23   generally that went to regulatory contained

24   data and content from our labs. Krahl was

25   pretty clear that we worked closely with

Page 157

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     regulatory, which meant regulatory and Merck,

3     the people that would send things to

4     regulatory. So I know that our information

5     was used in submissions. I haven't looked at

6     this one to know if anything from our lab was

7     used -- cited in any way.

8     Q.    Again, I want to show you,

9     without taking the document apart, a chart,

10    let me find it -- may have given you the wrong

11    document. Hold on. There is a chart in this

12    document at Bates label 18872. Table 1 which

13    is the "M-M-R@II Protocol 007: Mumps End

14    Expiry Preliminary Summary of the Percent of

15    Subjects Who Develop Neutralizing Antibodies

16    to Mumps."

17    Do you see that?

18    A.    I see the table on that page,

19    yes.

20    Q.    Do you recall if you had any

21    input into developing this table?

22    A.    I can't read the rest of the

23    document?

24    Q.    Well, if you think you need to

25    to talk about this table, that's okay. We can



Page 158

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 go off the record and look at it.

3 A. Well, tables are usually

4 supplemental to information contained in the

5 document. I don't want to read the whole

6 thing. Are you okay if I read up to the table

7 and see if that's good enough? It's only a

8 couple of pages. Otherwise, I have to pick

9 apart this table.

10 Q. It's only three pages. Read

11 that if you need to. I have two questions

12 while you read that so you can think about

13 them when you're reading it to answer them.

14 Number one, whether you had any assistance in

15 developing this particular table itself,

16 preparing this table for submission to CBER,

17 and whether you knew prior to filing this

18 complaint that this table was presented to

19 CBER?

20 A. Can you restate the question?

21 Q. Yes. First, did you have any

22 assistance in developing this table itself,

23 preparing it for CBER?

24 A. Did I have assistance?

25 Q. Yes.

Page 159

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 MR. SCHNELL: Object to form.

3 BY MS. DYKSTRA:

4 Q. Did you help prepare this table

5 that was submitted to CBER?

6 A. Absolutely.

7 Q. What did you do?

8 A. The experiments that it cites.

9 Q. Did you prepare the table

10 itself, though, the document?

11 A. I define prepare to mean I

12 provided the labor that went into the

13 experiments. The numbers wouldn't be what

14 they were without me working there.

15 Q. Do you see in the seroconversion

16 rates identified in this table the 4.0 log10

17 TCID50 mumps potency had an observed response

18 rate of 93.3?

19 A. Yes.

20 Q. Was that based on the work that

21 you did at Merck?

22 A. That was based on the fraud

23 that was perpetrated at Merck while I was

24 there.

25 Q. So you think it was -- the real

Page 160

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 result was lower than 93.3?

3 A. I mean real result. I mean,

4 the data is gone. I mean, that's based on

5 fraudulent data.

6 Q. This 93.3 percent you're saying

7 is based on fraudulent data?

8 A. Absolutely.

9 Q. Did you review this table

10 before it went to CBER?

11 A. In its final form like this?

12 Q. Yes.

13 A. No.

14 Q. So you didn't review this

15 correspondence that went to CBER then, either?

16 A. I don't believe I reviewed that

17 correspondence at all. It wouldn't have been

18 my job to review it.

19 Q. Let me go -- put the documents

20 away for a second and pull out the complaint

21 which is labeled Exhibit 3. If you turn to

22 page 10, paragraph 29 of your complaint, you

23 state in paragraph 29 that Merck "...did not

24 test the vaccine for its ability to protect

25 against a wild-type mumps virus." Correct?

Page 161

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 A. Can I read 29?

3 Q. Of course, yes.

4 A. Got it.

5 Q. So you asserted in your

6 complaint that Merck did not test the vaccine

7 for its ability to protect against a wild type

8 mumps virus. Correct?

9 A. As we defined wild type virus.

10 Q. We who?

11 A. Well, it's right here. Wild

12 type virus is a disease-causing virus. Your

13 statement is correct as wild type virus is

14 defined in this paragraph in this complaint.

15 Q. Do you disagree that CBER

16 defined a wild type virus as a Jeryl Lynn

17 passage 7 virus?

18 A. I don't know what CBER defined

19 as a wild type virus.

20 Q. If you go to paragraph 30 --

21 I'm sorry, 35.

22 A. Did you say paragraph or page?

23 Q. Paragraph 35. You can read

24 that paragraph.

25 A. Okay.

Page 162

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q.    You state that "Merck added

3 animal antibodies to both the pre and

4 post-vaccination blood samples." And "The use

5 of animal antibodies in laboratory testing is

6 not uncommon."

7     A.    Uh-huh.

8     Q.    Are you aware that CBER approved

9 the use of animal antibodies, generally

10 speaking?

11    A.    I don't know what you mean by

12 "approved."

13    Q.    Are you aware that CBER knew

14 that Merck was using animal antibodies in the

15 running of PRN?

16    A.    CBER didn't know how Merck was

17 using them.

18    Q.    What did CBER believe Merck was

19 doing?

20    A.    I don't know what CBER

21 believed. I can't speak to that as much as I

22 knew what Krah was hiding from CBER.

23    Q.    If you don't know what CBER

24 knew or didn't know, I'm not sure how you know

25 whether they knew what Merck was doing, but

Page 163

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 tell me what --

3     MR. SCHNELL: Object to form.

4     THE WITNESS: How do you know?

5 BY MS. DYKSTRA:

6     Q.    How do you know CBER did not

7 know Merck -- how Merck was using the anti-IgG

8 in connection with the PRN assay?

9     A.    Because Krah told us that they

10 were hiding it from the FDA. That they

11 weren't to know that the data was being

12 changed.

13    Q.    Is that what he said?

14    A.    Yes.

15    Q.    Tell me what you mean when you

16 say Merck added animal -- I'm sorry, tell me

17 what you mean when you say, "The use of animal

18 antibodies in laboratory testing is not

19 uncommon."

20    A.    That means when you're doing an

21 enzyme immunoassay, secondary antibodies are

22 used to identify and quantify primary

23 antibodies.

24    Q.    And that's an appropriate

25 methodology?

Page 164

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     A.    As long as you're aware of what

3 you're measuring. Secondary antibodies can be

4 a tool to measure primary antibodies. You're

5 doing a binding assay. You're just trying to

6 see if the antibodies are there. But as Krah

7 pointed out, it's no longer a functional

8 assay. The point of the PRN, according to

9 Krah and according to what -- I mean, it's

10 textbook, is that you're simply mixing the

11 child's serum with a virus and then seeing if

12 that child's serum can neutralize, kill the

13 virus. Once you add -- these are rabbit

14 antihuman antibodies. Human bodies don't make

15 those normally. They're not in the real

16 world. When you add something exogenous like

17 that, it's not a functional assay anymore. So

18 if you're willing to say this is a binding

19 assay, which is what an enzyme immunoassay is,

20 then, yes, secondary antibodies can be an

21 appropriate tool for saying is there an

22 antibody there or not. But it doesn't tell

23 you in the real world whether that antibody

24 can neutralize the virus because it's not a

25 functional assay.

Page 165

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q.    So it's your position that

3 animal antibodies can be appropriately used in

4 an ELISA assay but not in a PRN assay?

5     A.    That's not what I said. I'm

6 just saying it changes what the assay is. And

7 that was Merck's representation to me also.

8     Q.    Is it appropriate ever to use

9 an anti-IgG antibody in a PRN assay?

10    A.    I can't speak to that. I mean,

11 you're talking -- under what conditions would

12 it be appropriate, I don't know. But you have

13 to be clear about what you're measuring. It's

14 not a functional -- rabbit antihuman, goat

15 antihuman, sheep antihuman, the reason it's

16 some other animal is because humans don't make

17 those antibodies. It's not going to be in the

18 kid's blood when the kid is out there and

19 contracting the mumps virus. It's not a

20 functional assay of whether the child's blood

21 alone can neutralize that disease virus.

22 That's all I'm saying.

23    Q.    But you concede that CBER knew

24 that Merck was using anti-IgG in its PRN

25 assay?

Page 166

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2             MR. SCHNELL: Object to form.

3             THE WITNESS: You keep going to

4     the word use. They don't know how

5     Merck was using it. Krah represented

6     that if they knew how we were using it,

7     they wouldn't let us do it.

8 BY MS. DYKSTRA:

9     Q. Did you ever have discussions

10 with CBER about how Merck was using the

11 anti-IgG in the PRN assay?

12     A. Can you repeat that?

13     Q. Did you ever have any

14 discussions with CBER about how Merck was

15 using the anti-IgG in the PRN assay?

16     A. That's a little bit open ended.

17 I remember that I called the FDA to report

18 fraud in our lab, hoping they would come in

19 and investigate it and find everything out.

20     Q. Other than those phone calls to

21 the FDA, did you ever have discussions with

22 CBER about how Merck was using the anti-IgG in

23 its PRN assay?

24     MR. SCHNELL: Object to form.

25     THE WITNESS: No.

Page 167

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 BY MS. DYKSTRA:

3     Q. Can you look at your RFAs that

4 we marked in front of you? It's 6 and 7.

5 Exhibits 6 and 7.

6     A. Exhibit 6 and 7.

7     Q. Can you look at RFA number 6,

8 request for admission number 6. Yeah, the

9 number 6. They're both denied in both

10 answers.

11     A. I didn't know if you meant

12 Exhibit 6.

13     Q. I'm sorry, request number 6.

14 You have to go past the objection. The actual

15 question. It's denied in both, you just need

16 it in one. You don't need to look at both.

17     So the question is: Admit that

18 prior to filing this lawsuit, you had no

19 knowledge of the seroconversion rates Merck

20 reported to the FDA for the mumps component of

21 M-M-R@II in connection with Merck's

22 development of the PRN assay.

23     So tell me what knowledge you

24 did have since you denied that request?

25     A. I had some knowledge of the

Page 168

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 seroconversion rates that -- the ProQuad BLA.

3     Q. Other than the development of

4 the PRN assay in Protocol 007.

5     A. You're going by development of

6 PRN assay. The development and the running

7 are run simultaneously. The knowledge I have

8 of that is that the testing that came

9 afterward was based on the development of the

10 PRN. If you're looking for knowledge of the

11 seroconversion rates reported to the FDA,

12 yeah, I mean, I knew that the seroconversion

13 rates based on the ProQuad BLA, for one, were

14 at or above 90 percent.

15     Q. Let's -- you can put those

16 exhibits away for the moment. We'll come back

17 to them.

18     I want to talk about when you

19 first joined Dr. Krah's lab.

20     A. Can we just like take a short

21 two-minute bathroom break?

22     Q. Absolutely.

23     MR. SCHNELL: It's 1:15, what

24 do you want to do for --

25     MR. KELLER: Let's break for

Page 169

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 lunch.

3     THE WITNESS: My stomach is

4 growling, so I wouldn't mind that.

5     MS. DYKSTRA: That's fine. We

6 can do that.

7     VIDEOGRAPHER: The time is

8 1:17. We're going off the video

9 record.

10     - - -

11     (A recess was taken.)

12     - - -

13     VIDEOGRAPHER: The time is

14 2:09. This begins disc three in the

15 videotape deposition of Stephen

16 Krahling.

17 BY MS. DYKSTRA:

18     Q. Mr. Krahling, before you worked

19 at Merck in March 1999 had you ever ran a PRN

20 assay previously?

21     A. A plaque reduction neutralization

22 assay where you measure the ability of serum

23 to neutralize virus in a cell-based assay, no.

24     Q. And since your work at Merck,

25 have you ever had an opportunity to run a

Page 170

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 plaque reduction neutralization assay since

3 November 2001?

4 A. By the same definition, no.

5 Q. And the same question for an

6 ELISA assay, have you ever run -- prior to

7 your work at Merck, did you ever run an ELISA

8 assay?

9 A. Yes.

10 Q. And after your work at Merck,

11 did you ever run an ELISA assay?

12 A. Yes.

13 Q. In what context after Merck did

14 you run an ELISA assay?

15 A. Penn State. At Penn State the

16 department of molecular and cell biology that

17 I worked at.

18 Q. What time frame was that again?

19 A. 2002 to 2004.

20 Q. Since 2004, have you ever run

21 an ELISA assay?

22 A. No.

23 Q. I'm going to show you what's

24 marked as Exhibit 12.

25 - - -

Page 171

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 (Exhibit Krahlung-12, 8/1/00

3 Letter, MRK-KRA00048418, was marked for

4 identification.)

5 - - -

6 BY MS. DYKSTRA:

7 Q. This is August 1, 2000, letter

8 from you to Dr. Krahl.

9 A. Got it.

10 Q. So you -- did you leave Merck

11 in mid-August 2000 to head to Penn State?

12 A. I did.

13 Q. Did you participate in a

14 graduate school program at Penn State?

15 A. If I recall correctly, I was

16 going to enroll in taking some classes and

17 continue working in Dr. Schlegel's lab with

18 the possibility that I might pursue a PhD.

19 Q. And did you do that work in

20 Dr. Schlegel's lab at Penn State and work

21 towards a PhD?

22 A. I did work in Dr. Schlegel's

23 lab, but I ended up coming back to Merck just

24 a few months later.

25 Q. Why did you not stay at Penn

Page 172

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 State and participate in the graduate program?

3 A. Met Dr. Krahl. Dave and I --

4 Colleen got married, Colleen Milliken got

5 married, became Colleen Barr with two Rs. And

6 at her wedding, I think it was in October of

7 2000, Dave and I spent a lot of time talking,

8 we were seated at the same table and he said

9 that he wanted me to come back, he said things

10 weren't the same since I left. And he asked

11 me -- you know, he asked why I left, we left

12 on such good terms.

13 I told him that, I said, Well,

14 you never had offered me that permanent

15 position. There wasn't much keeping me there.

16 He said, What if I offered you

17 that, would you come back and say yes and work

18 there.

19 I said, You got to offer it and

20 see. You got to take a chance.

21 But he and I got along well

22 enough that, I believe it was the next week or

23 two, the letter was sent, and I thought we

24 were on good enough terms, you know, he

25 basically made the offer sound really good to

Page 173

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 come back and work at Merck. He wanted me

3 back, so I came back.

4 Q. So you left Merck in -- I guess

5 was, in fact, your last day at Merck

6 August 17th as this letter indicates --

7 A. I have no idea.

8 Q. -- or sometime mid-August of

9 2000?

10 A. I really don't know.

11 Q. So you left Merck sometime in

12 the summer of 2000, let's say. Is that fair?

13 A. I mean, this letter would say

14 the second half of August.

15 Q. And between that point and when

16 you saw Dr. Krahl at Colleen Barr's wedding in

17 October of 2000, had you already enrolled and

18 started in the graduate program at Penn State?

19 A. I'm not sure what the criteria

20 are for what enrollment would be.

21 Q. Had you taken any classes or

22 participated in any studies at Penn State?

23 A. Well, I was doing research and

24 I believe I may have enrolled for some

25 classes.

Page 174

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 Q. What kind of research were you

3 doing?

4 A. It's outlined on my resume, if

5 you want to go over it again.

6 Q. I'll go back to that in a

7 second.

8 So you thoroughly enjoyed

9 working with Dr. Krah in his lab during your

10 first period at Merck from March 1999 to

11 August 2000?

12 A. Absolutely. That's why I came

13 back. That's why his offer sounded good.

14 Q. Do you remember how much you

15 made at Merck in your position as a full-time

16 employee?

17 A. I don't remember.

18 Q. Was it above or below \$50,000?

19 A. I don't remember. You can try

20 over and under some other -- I don't know. I

21 can't narrow it down.

22 - - -

23 (Exhibit Krahling-13, Employee

24 Initialization, MRK-KRA00582401, was

25 marked for identification.)

Page 175

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 - - -

3 BY MS. DYKSTRA:

4 Q. I'm going to mark as Krahling-13

5 your employee initialization and has in here

6 compensation. This is dated 12/27/00 as your

7 hire date.

8 A. Can I look over it?

9 Q. Sure.

10 A. Okay.

11 Q. Does this refresh your

12 recollection that your base rate was a rate of

13 \$3,670 per month for an equal -- for a yearly

14 equivalent of \$44,000?

15 A. It doesn't refresh my memory.

16 I don't remember what I made, but...

17 Q. Does that sound about right?

18 A. It does. I mean, I -- it could

19 be right.

20 Q. Do you have any reason to

21 believe that it's not right?

22 A. Base for benefits. I don't

23 know what base for benefits means. Base rate.

24 I don't really know how to read this chart.

25 So I mean, I really just don't know.

Page 176

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 Q. I'm going to show you one more

3 exhibit on this issue.

4 - - -

5 (Exhibit Krahling-14, 10/24/00

6 Letter, RELATOR\_00001058 - 00001060,

7 was marked for identification.)

8 - - -

9 BY MS. DYKSTRA:

10 Q. Krahling-14. Take a look at

11 that just to refresh your memory and your

12 salary. This is an October 24, 2000, offer

13 letter from MRL human resources, and it states

14 your yearly salary is \$44,004. Does that

15 refresh your recollection as to your yearly

16 salary?

17 A. It doesn't refresh my

18 recollection, but I mean, I --

19 Q. But you believe that to be

20 accurate?

21 A. If it's off, it doesn't seem

22 like it would be far off. Can I read the

23 thing if you want me to confirm that?

24 Q. No, that's fine.

25 So tell me what training you

Page 177

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 did receive, since you had not run a plaque

3 neutralization assay prior to joining Merck,

4 when did you first receive training on a

5 plaque neutralization assay at Merck?

6 A. What do you mean by "training"?

7 Q. Instruction on how to develop

8 and run a plaque neutralization assay.

9 A. 1999.

10 Q. How did you -- what kind of

11 training did you receive?

12 A. It's hard to remember what kind

13 of training. Whatever training Krah was

14 showing me back then and the lab members at

15 the time. I was trained in Krah's lab on how

16 to do the assays.

17 Q. Who trained you?

18 A. I don't recall specifics.

19 Whoever would have been working at the time

20 and Krah himself.

21 Q. Can you give me a little bit

22 more detail about what your training involved,

23 what did they teach you to do?

24 A. You want me to run through the

25 protocol of the assay?

Page 178

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q.    If that's how you learned how

3     to work on the assay, sure.

4     A.    I don't think that's how I

5     learned, but that's how I would describe how

6     you run the assay. I'm not quite sure what

7     you're asking. There's a difference between

8     like how I trained and the methodology and

9     like -- I don't understand quite what you're

10    asking.

11    Q.    You got to Dr. Krah's lab and

12    you had never run a plaque neutralization

13    assay. How did you learn how to work on the

14    assay? Who taught you and what did you do?

15    A.    First of all, a plaque

16    reduction neutralization is dependent on

17    methods that you don't learn from scratch

18    there. So understanding how to culture cells

19    is a critical part of running the assay. I

20    didn't learn that in Krah's lab. I had

21    already known how to do that. So that element

22    of it, they just -- they could give you a

23    protocol, say here's how you culture these

24    cells. I already knew how to do that, easy to

25    adapt to it. So I'm not sure what you're

Page 179

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     looking, like is there a certain element how I

3     was trained? The thing as a whole, I'm not

4     sure I can describe how I was trained.

5     There's different -- you learn them as you do

6     them. They show you how to do them. When

7     they feel comfortable that you're doing them

8     however the protocol is set up, you run the

9     assays.

10    Q.    So what were your

11    responsibilities in the lab?

12    A.    As given to me by Krah?

13    Q.    Well, did somebody else give

14    you job responsibilities in the lab other than

15    Dr. Krah?

16    A.    In the beginning you could get,

17    I could get instructions through, say, Mary

18    Yagodich who would be speaking for Krah. So I

19    could get them indirectly.

20    Q.    So what did -- instruction did

21    you get from Dr. Krah or Mary Yagodich about

22    what you were to do?

23    A.    Generally or any one time?

24    Q.    You were in the lab for a year

25    and a half?

Page 180

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     A.    Yeah.

3     Q.    Well, you were in -- well, you

4     actually joined Dr. Krah's lab again, and what

5     was your hire date, the second hire date?

6     A.    December 2000.

7     Q.    December. So from

8     December 2000 until we'll just say

9     November 2001, although I know you left

10    physically being in the lab before then, what

11    were your job responsibilities in the lab?

12    What did you do day to day?

13    A.    Before we were talking about

14    1999.

15    Q.    Okay. Well, what did you --

16    well, I was talking about when you came back.

17    Okay. But the first time you ever did a

18    plaque neutralization assay in Dr. Krah's lab

19    was when you were there as a contractor then.

20    Correct?

21    A.    I believe so, yes.

22    Q.    What did you do day to day as a

23    contractor in Dr. Krah's lab?

24    A.    It depends on the day.

25    Sometimes we did VZV assays, potency assays.

Page 181

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Sometimes you assisted with -- Krah and Mary

3     were doing plaque reduction neutralization

4     assays against wild type mumps. They were

5     doing things that they considered validation

6     of the mumps neuts that were possibly coming.

7     Stuff like that. I mean, do you want every

8     single thing I did in his lab?

9     Q.    What was the majority of your

10    time spent on?

11    A.    Cell-based assays and support

12    for cell-based assays that would characterize

13    Merck's live virus vaccines.

14    Q.    What was your job in cell-based

15    assay? What did --

16    A.    To do that.

17    Q.    -- you actually do?

18    A.    To do that.

19    Q.    Explain to me what that means,

20    "to do that."

21    A.    That's a lot of work to explain

22    that. Well, I mean for varicella, you had to

23    know how to culture MRC-5 cells because the

24    human diploid cells and varicella grows in

25    that so those assays were based on doing that

Page 182

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 cell line. You had to know how to run Vero

3 cell lines which is a different cell line, had

4 some different requirements, and you have to

5 know how to do all the things in support of

6 growing those cells to run assays. You have

7 to know how to use the gelatin which overlays

8 mumps virus assays because they act as a solid

9 barrier to keep the plaques in place. VZV you

10 could use a liquid medium because varicella is

11 cell-associated infectivity. So it doesn't

12 need the gelatin to spread. It's already

13 constricted so you didn't have to have that

14 type of thing. All of those intricacies were

15 learned in the first few months over time of

16 how to do the things. And by the time Krah

17 hired me, he knew I could do those things. So

18 I'm not sure what else instead of -- that can

19 answer your question.

20     Q. What portion of your time was

21 spent actually counting plaques with respect

22 to the mumps virus and the neutralization

23 assay?

24     A. I couldn't guess at a percentage.

25     Q. A lot, a little? One day a

Page 183

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 week, most of the time?

3     A. I don't even know how to even

4 guess at that. I can tell you that to

5 count one assay, to count all the plaques for

6 one assay would take in the ballpark of half a

7 day.

8     Q. Do you know how many assays you

9 counted at the time you were at Dr. Krah's

10 lab?

11     A. I don't know.

12     Q. Did you ever work in Bill

13 Long's lab?

14     A. Bill Long? I don't know that

15 I -- I don't recognize the name.

16     Q. Do you know Pam Burke?

17     A. I don't recognize the name.

18     Q. How about Beverly Rich?

19     A. I do not recognize the names

20 you're saying.

21     Q. Do you know Rocio Marchese?

22     A. That name sounds familiar.

23     Q. But you don't recall working

24 with her?

25     A. I think I recall her being

Page 184

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 discussed.

3     Q. What about do you recall

4 working with Laura Millett?

5     A. I don't recognize that name.

6 The name before, I think Krah worked with that

7 woman. What was her name again?

8     Q. Rocio Marchese.

9     A. That's a woman, right?

10     Q. Yes.

11     A. I think Krah worked with her.

12     Q. You don't recall directly

13 working with her?

14     A. I think she worked with Krah on

15 the stuff that we were doing.

16     Q. But you don't recall working

17 directly with her yourself?

18     A. What do you mean by "directly"?

19     Q. Did you have discussions with

20 her? Do you recall talking to her, you

21 talking to her?

22     A. Not on that level. But I think

23 she worked with our -- I think she worked in

24 our lab. Not in our lab. I think Krah worked

25 with her. I think he discussed her, that he

Page 185

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 had -- I'm not sure what capacity. That name

3 is familiar.

4     Q. Now, you mentioned -- strike

5 that.

6             Explain to me the configuration

7 of the lab. Who was in the lab day to day

8 with you and where -- who was in the lab with

9 you day to day?

10     A. The physical configuration?

11     Q. Yes, who was there and who were

12 you working with?

13     A. I think I can answer that, but

14 it changed over time because there was what I

15 would consider protocol and other people say

16 the employee high turnover rate. So if I say

17 where somebody's desk was at, I mean, at what

18 point in time are we talking about?

19     Q. Tell me the first period you

20 were there as a contractor, who did you work

21 with in Dr. Krah's lab besides Dr. Krah?

22     A. Kevin Szczypiorski, Kristin

23 Tirpak. Her married name was Kristin Haas.

24 DeeMarie, I mentioned before. Colleen Barr.

25 She was Milliken at the time. Mary, Dave, Sam

Page 186

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Calarco, Larry Doolittle. I'm probably

3     missing somebody. When I showed up and worked

4     there, those people were all there.

5             I've got more. The

6     configuration of the lab, the building,

7     there's a hallway that runs the outside.

8     There's a middle hallway that runs through the

9     lab that connects all the labs, it's like a

10    common area. Dave's office was on the front

11    end of that. Mary's office was on the back

12    end of that. Everybody else's desks were

13    scattered in between.

14    Q.    When you came back for your

15    full-time employment in December 2000, was it

16    the same list of people or different people?

17    A.    Different people.

18    Q.    Who was in the lab then?

19    A.    Some of them are different.

20    Dave and Mary were still there. Colleen was

21    still there. Jill DeHaven would have been a

22    full-time employee, or she was an employee, I

23    believe, back when I worked there the first

24    time but she was on leave. So when I came

25    back, she was there. A new hire Frank Kennedy

Page 187

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     was there.

3             Can you go through who I

4     mentioned? I missed one, on the second one,

5     just on the second part.

6             - - -

7             (The court reporter read the

8     pertinent part of the record.)

9             - - -

10    THE WITNESS: Jenny Kriss was

11    either there at the time or showed up

12    shortly after. Joan showed up shortly

13    after. And there were -- there may

14    have been contract employees. I'm sure

15    I'm not getting everyone.

16    BY MS. DYKSTRA:

17    Q.    Did you have a romantic

18    relationship with anybody in the lab?

19    A.    No.

20    Q.    At any point in time?

21    A.    No.

22    Q.    Did Dr. Krah have a romantic

23    relationship with anybody in the lab?

24    A.    I was told -- what do you mean

25    by with anyone in the lab?

Page 188

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q.    The people that you just went

3     through.

4     A.    I don't know that he had --

5     okay. Can you just restate the question?

6     Q.    Was it your understanding that

7     Dr. Krah had a romantic relationship with

8     anybody in the lab?

9     A.    No.

10    Q.    Why did you hesitate before?

11    A.    Because the sister of someone

12    in the lab.

13    Q.    Who was that?

14    A.    Colleen and Mary said that Dave

15    dated Mary's older sister.

16    Q.    And you said Dr. Krah reported

17    to Dr. Alan Shaw. Is that correct?

18    A.    My understanding at the time

19    was that Alan had authority over Dave.

20    Q.    Did you work with Dr. Shaw,

21    have direct contact with Dr. Shaw?

22    A.    I did have direct contact with

23    Dr. Shaw.

24    Q.    What was your relationship with

25    Dr. Shaw?

Page 189

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     A.    Pretty amicable to start with.

3     I mean, how much do you want me to go into

4     detail there?

5     Q.    Well, tell me why it was

6     amicable and if when it changed, if it did?

7     A.    I don't know why it was

8     amicable. He liked me, I thought he was okay.

9     I know why it changed, because I pointed out

10    the fraud that Krah was committing in the lab.

11    That soured my relationship with Krah, too.

12    Q.    When did you first point out

13    the fraud in Dr. Krah's lab to anyone, and to

14    whom did you do that?

15    A.    I pointed it out to Krah

16    sometime in the first half of January of 2001.

17    Maybe toward the middle front of January 2001.

18    Q.    What did you tell him at that

19    time?

20    A.    Well, there was a prelude to

21    that. I mean, if you understand that

22    conversation, you have to go back to the

23    conversation before where he instructed me to

24    commit fraud. Do you just want the second

25    part of that?



Page 190

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q.   Why don't you tell me when he

3     allegedly instructed you to commit fraud?

4     A.   That was December 2000.

5     Q.   What did he say?

6     A.   Said quite a bit. That was my

7     first week back and he was running -- he was

8     counting plates in the front lab. And he was

9     excited because he was explaining to me that

10    the mumps neutralization assay, that Protocol

11    007 was going forward in his lab and that they

12    got an indicator strain and a methodology that

13    they knew could give them 95 percent efficacy

14    which is what they needed. He was counting

15    plates at the time and he said that in order

16    to meet the 95 percent efficacy FDA mandate,

17    that we needed to cross out pre-positives when

18    we found them and change them to

19    pre-negatives. He said that we had to target

20    a 10 percent pre-positive rate. And that the

21    reason we needed to do that is because the FDA

22    might not allow them to use that protocol or

23    method including the rabbit antihuman IgG

24    unless they change those results.

25           He then showed me an example of

Page 191

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     what I was supposed to do. He took a plate

3     that had four pre-positives on it. He had

4     counted it. There were four pre-positives.

5     He took and wiped the numbers off the plates

6     with an alcohol wipe. I'm sorry, he -- that

7     time he wiped with alcohol the plate

8     identification number and switched it with the

9     plate identification number for the next

10    plate, because all of the ones on the next one

11    were positive -- or they were negative. So he

12    had a plate that he counted that was

13    pre-vaccine, they were all positive. The

14    sample after it was the post for that same

15    kid, and those were all negative. And so he

16    crossed out the identification, switched the

17    plates. He kept -- he had to switch those

18    numbers on his counting sheet so he crossed

19    them all out. And then he wrote in the next

20    numbers fresh for the next plate. When he did

21    that, he took a second look at the dilution

22    above that plate and he noticed that it was

23    also pre-positive. And he was like, damn.

24    Because the whole thing was still pre-positive

25    because of that one dilution. So he crossed

Page 192

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     it out.

3           He said, This is what you have

4     to do. You have to cross out these results

5     and write in a pre-negative.

6           I just repeated, We're supposed

7     to just cross out the results.

8           And he said, If you need to,

9     you can recount the plaques, but if you

10    recount the plaques, you have to count very

11    liberally and make sure that you count more

12    plaques so that the result would switch from

13    pre-positive to pre-negative.

14           And then he wrote down on the

15    sheet, rechecked plaques. But he was pretty

16    clear that the directive was to change the

17    results. He didn't order me to have to

18    recount the plaques. He just said change the

19    results.

20    Q.   Let me break that down a little

21    bit. So this is in December of 2000 when you

22    first started?

23    A.   It was the week between

24    Christmas and New Year's.

25    Q.   And how did he -- you're saying

Page 193

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     he changed the plates themselves and then

3     crossed out the numbers on the counting sheet?

4     A.   Start with the plate

5     identification number. The plate identification

6     number would have identified the first plate

7     he was counting, the pre-vaccination sera as a

8     pre-vaccination sample. All of those were

9     positive. All the dilutions were positive.

10    He counted that and wrote them on the counting

11    sheet. He noticed that the next plate were

12    all negative in the post. There was a

13    comment, I said, oh, that's -- I mean, that's

14    a seroconversion in reverse. Basically the

15    kid had immunity, got Merck's vaccine and lost

16    his immunity. I asked, that's a weird result.

17    He said it was due to the artificial nature of

18    the anti-IgG. That whenever he sees that, he

19    just switches the plates.

20           So he crossed out the

21    identification number that would identify it

22    as a pre-vaccine versus a post-vaccine and

23    switched them so that all the positives went

24    to the post. Now, because he did that, he had

25    to cross out all the results he had just

Page 194

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     written down. But because he was doing it in

3     realtime with a calculator next to him, the

4     next plate which is the other one that he had

5     switched, he could write the numbers fresh

6     onto the counting sheet.

7             Now, after he did that, there

8     was still one pre-positive dilution in a

9     different plate above the first one he had

10    switched. That pre-positive would have made

11   the whole sample pre-positive. All that work

12   switching the plates would have been for

13   nothing. They still couldn't have used it.

14   So he crossed out the numbers and said,

15   "Change the results."

16             I said, You just cross out the

17   numbers.

18             And that's when he said, You

19   can recount these if you need to, but you have

20   to change the results.

21             He told me specifically that we

22   were targeting pre-positives. If you recount

23   them, you need to count very liberally and

24   find as many plaques as you can in order to

25   switch the result from pre-positive to

Page 195

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     pre-negative.

3     Q.    And when he told you all of

4     this, who did you report it to?

5     A.    Right back to him.

6     Q.    What does that mean?

7     A.    What does that mean? That was

8     in December of 2000. Like the last week of

9     December. A few weeks later Mary had

10    challenged me because I wasn't doing that.

11    And when I refused to do that, she took the

12    counting sheet to Dave and Dave confronted me

13    over it. And I told him I couldn't do that.

14    Q.    And did you report this fraud,

15    this alleged fraud or recounting to Dr. Shaw

16    in December of 2000?

17    A.    I reported it to him in July of

18    2001.

19    Q.    Did you report this fraud to

20    anybody else between -- well, did you report

21    this fraud to anybody else other than Dr. Krah

22    in December of 2000?

23    A.    In December of 2000 it was one

24    week, the week between Christmas and New

25    Year's. I think only Krah and I were working

Page 196

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     there. Maybe Joe had come in once. Most

3     everybody was taking vacation. So I didn't

4     have the opportunity to say much during that

5     week.

6     Q.    Did you report this alleged

7     fraud to anybody in January of 2001 other than

8     Dr. Krah?

9     A.    When you mean report, you mean

10    talk about in any way?

11    Q.    Let's go there first. Did you

12    talk about this what you viewed as fraud to

13    anybody else in -- anybody else other than

14    Dr. Krah in January of 2001?

15    A.    Let's start with, and you may

16    have to come back to more, but Mary, I told

17    her -- I reported to her and she was

18    considered my superior. So I talked to her

19    about it.

20    Q.    What did she say to you in

21    response?

22    A.    She came to me with an

23    accounting sheet for an assay that I had

24    counted. I was gloved up in the front lab.

25    So I'm in the fume hood doing work with gloves

Page 197

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     on and everything. And she walked into the

3     lab with a counting sheet and said, Steve, you

4     have a pre-positive in this assay, can you

5     change the count?

6             I said -- you know, I said

7     something to the effect, wait, let me -- I

8     said, What do you mean I have a pre-positive?

9             She said, Well, you have a

10    pre-positive and you've -- you know, you have

11    to change this. If you try to look, you can

12    find more plaques.

13             I said, How do you know that?

14             She said, Well, I recounted it

15    and if I look at it, I can find more plaques

16    if I try.

17             I said, Did you recount all of

18    my results or just that one?

19             And she said, I just counted

20    that one.

21             I said to her, How do you know

22    that you wouldn't find more plaques in any of

23    the other results in the rest of that assay?

24             And she said, We're not trying

25    to change the results of anything other than

Page 198

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     the pre-positives.

3             I told her that I didn't think

4     I could do that. I told her I wouldn't do

5     that based on her telling me to.

6             She seemed to think that I

7     thought that was coming from her, so she said,

8     I'm not telling you to do it. This is Dave.

9     Dave said we need to change these.

10            I told her that I wasn't

11    comfortable with changing results just because

12    Dave wasn't -- didn't like the result. At one

13    point she said she would leave it on my desk

14    for me to change, and I said I wouldn't change

15    it.

16            I found out later she had gone

17    to Krah and told -- and reported to him what

18    transpired there, that I refused to change the

19    result she had identified. Krah called me in

20    to -- up to his front office to talk about it,

21    which brings us back to your original question

22    way back when of when I first officially

23    reported, complained about the fraud to my

24    superior Dave Krah.

25    Q.    Did you ever complain to Dr. Shaw

Page 199

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     about the alleged fraud before July 2001?

3     A.    I'm not sure what you mean by

4     "complain," but...

5     Q.    About the recounting and the

6     fraud you just described, did you ever

7     complain about those activities to Dr. Shaw

8     prior to July 2001, which is the date you gave

9     me just a second ago?

10    A.    I'm not sure if you're using it

11    in a legal sense. What I did is, I wasn't

12    sure if the things I was saying to Shaw had

13    impacted, that he fully understood the

14    complaint I was making. So I made it very,

15    very clear, I don't remember the exact day, at

16    some point in July that the entire -- not the

17    entire lab. There were several of us in the

18    lab had accused Krah of committing fraud at a

19    lab meeting. That was my complaint where I --

20    unequivocally he knew I was saying there was

21    fraud being committed.

22    Q.    That was in July of 2001?

23    A.    Yeah. I was reporting to him

24    about a lab meeting where Joan had stood up

25    and called Krah a fraud right in the middle of

Page 200

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     the lab meeting.

3     Q.    So would it surprise you if

4     some of your colleagues had said you actually

5     aren't competent at counting plaques?

6            MR. SCHNELL: Object to form.

7            THE WITNESS: I don't know what

8     you're getting at. Like, are you

9     talking about what they would have said

10    back then when we were co-workers or --

11    BY MS. DYKSTRA:

12    Q.    Yes.

13    A.    -- what they're saying now?

14    Q.    What they were saying back

15    then.

16    A.    Back then before August 2001?

17    Here's what I know: Emimi had an internal

18    audit to investigate our allegations that Krah

19    was committing fraud. Merck had a lawyer

20    there that was threatening the workers. And

21    Suzie, Jill, both came and talked about how

22    afraid they were of that, afraid they were of

23    retaliation. So in light of that kind of

24    context, I wouldn't be surprised by too much

25    of anything.

Page 201

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q.    Did you think Dr. Shaw was

3     trustworthy?

4     A.    That would be situational.

5     Q.    Well, you must have thought he

6     was trustworthy if you took your complaints to

7     him in July of 2001.

8     A.    That's not necessarily true.

9     Q.    Did you think he was trustworthy

10    in July of 2001 when you took your complaints

11    to him?

12    A.    I don't know what to think of

13    him and his trustworthiness. Bob Suter, human

14    resources, said if I wanted to get anywhere up

15    the chain of command, I had to go through the

16    chain of command. There's no way I would get,

17    ever get a face to face with Emilio if I

18    didn't talk to Shaw first.

19    Q.    So you complained to Dr. Shaw

20    in 2001, and what did Dr. Shaw say in response?

21    A.    He started talking about these

22    big bonuses we were supposed to receive. He

23    said, You already earned the money to get it,

24    you're going to get a lot of money, just

25    basically do as you're told. He didn't want

Page 202

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     to engage in the conversation.

3     Q.    So after July 2001 when you

4     complained to Dr. Shaw about this alleged

5     fraud, what did you do then?

6     A.    A lot of things.

7     Q.    Tell me what you did.

8     A.    If you can be more specific.

9     Q.    Well, what did you do in

10    connection with your concerns about lab

11    misconduct?

12    A.    There was so much going on

13    between January and October that it's -- for

14    me to sit here and lay out the story, I mean,

15    we can go through it piece by piece with the

16    interrogatories, but that's such a broad

17    question. I couldn't recite it from memory.

18    I mean, I had -- there were so many

19    conversations with Krah alone about Protocol

20    007.

21    Q.    Other than complaints to

22    Dr. Krah and your complaint to Dr. Shaw in

23    2001, did you complain to Dr. Emini about the

24    fraud?

25    A.    Can you read that back? Can I

Page 203

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     ask her to read it back?

3     Q.    Sure.

4     - - -

5     (The court reporter read the

6     pertinent part of the record.)

7     - - -

8     THE WITNESS: I wasn't sure if

9     you said complaints plural to Krah

10    because we -- I was trying all the

11    time. There were many complaints to

12    him. There were complaints to my

13    co-workers. See, I don't know if you

14    count those as complaints since some of

15    them are equal to me. But Mary was

16    above me. So there were complaints

17    there. But in addition to the

18    complaints to Krah and how my

19    co-workers and I, some of us were

20    working together to try and stop the

21    fraud, I complained to Mary, Alan and

22    Emini and Bob Suter. Several

23    complaints to -- well, at least two

24    complaints to Bob Suter because he

25    refused to talk about it.

Page 204

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     BY MS. DYKSTRA:

3     Q.    So other than Dr. Krah and your

4     colleagues in the lab, you complained about

5     this alleged fraud to Bob Suter, Alan Shaw,

6     Emilio Emini and Mary Yagodich. Correct?

7     A.    Does complain -- are we defining

8     that to include discussed and notified?

9     Q.    Yes.

10    A.    Former members of the lab also.

11    Kevin Szczypiorski who had left. DeeMarie who

12    was out. Kristin Haas who is no longer there.

13    Those people also.

14    Q.    What was the atmosphere in the

15    lab between January and July 2001?

16    A.    Such a -- atmosphere, variable.

17    Q.    I mean, you thought there was

18    this ongoing fraud. Is that correct?

19    A.    There was an ongoing fraud.

20    Q.    But you continued to work there

21    from January to July 2001?

22    A.    I was trying to stop it.

23    Q.    But you didn't go to Alan Shaw

24    until July 2001?

25    A.    I was told by Bob Suter not to

Page 205

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     even e-mail him.

3     Q.    When did you first raise

4     concerns to Bob Suter about the fraud?

5     A.    My best guess is in the area of

6     February 2001.

7     Q.    And Bob Suter told you -- I'm

8     sorry, what did he say in response to you

9     raising concerns?

10    A.    That was a whole conversation.

11    Q.    What was that conversation?

12    A.    The conversation was that he's

13    not a scientific guy, that I need to go

14    through the chain of command. And I said, I

15    had already gone to Krah to discuss it and I

16    felt that there was some tension there.

17    He told me -- and if you'll

18    remember what e-mail was like back then, it

19    was -- an e-mail was treated as a more formal

20    medium. He told me that I should never, under

21    any circumstances, e-mail Emilio or Alan about

22    this and I shouldn't talk to them about it.

23    He said he would serve as a conduit of

24    information of things, that if he felt they

25    were necessary, could make it in front of

Page 206

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Emilio.

3             So he said I could only e-mail

4     Krah about this, and that I had to keep my

5     e-mails to Krah about administrative personnel

6     issues. And that if there were waves in areas

7     like that where it could affect, you know, the

8     company getting the things done they needed to

9     do, maybe Emilio could hear my other concerns.

10    But he would not let me talk to Emilio or run

11    through there unless I had gone to Dave first

12    and up through the chain of command.

13    Q.    Why did it take you from

14    January to July 2001 to talk to Dr. Shaw about

15    these concerns?

16            MR. SCHNELL: Object to form.

17            THE WITNESS: I just told you

18    that the route that -- I was going

19    through Dave Krah and when I went to

20    Bob Suter to say I think I should go to

21    Alan with this and up the chain of

22    command from there, he said, don't

23    e-mail them, you have to go exhaust

24    your things through Dave before you do

25    things like that.

Page 207

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     BY MS. DYKSTRA:

3         Q.    So you're saying it took you

4     six months to exhaust your things through Dave

5     before you could talk to Alan Shaw about this

6     alleged fraud?

7         A.    Six months.

8         Q.    January to July you said?

9         A.    No. Absolutely not. I wrote a

10    letter to Emilio before that.

11        Q.    And did that letter to Emilio

12    discuss count changes and pre-positive and

13    fraud?

14        A.    Suter directed me to write the

15    letter and give it to him. He said I had

16    better not make any allegations against people

17    above me or it could ruin my career. He said

18    stick to anything administrative because he's

19    a human resources guy. If I want to get a

20    face to face with Emilio, there had to be

21    human resources reasons why he would go to

22    Emilio with it.

23            He said, Anything you can think

24    of. Anything to you complain about,

25    administrative related, human resources, put

Page 208

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     it in the letter and maybe it will be enough

3     that Emilio would want to talk to you.

4             He said, Keep the science out

5     of it.

6             He directed me to write the

7     letter, give it to him anonymously.

8         Q.    So what you're telling me is

9     that Bob Suter told you that if you wrote HR

10    administrative concerns to Emini you might get

11    an audience, but if you wrote fraud

12    allegations you would not?

13        A.    That's not what he said. He

14    told me not to write to Emini. He told me to

15    write up this letter, which would basically be

16    a human resources tool. And that if there

17    were problems in the lab that impacted the

18    ability to get this Protocol 007 done, maybe

19    it would rise to the level of where Emini

20    would see it. He told cross -- Suter

21    specifically said that it would be career

22    suicide to make an allegation of fraud up the

23    chain of command.

24        Q.    But your testimony is that you

25    did tell Suter, Bob Suter in February of 2001

Page 209

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     that there was fraud in the lab?

3         A.    I told him that there was data

4     manipulation going on in the lab. I'm not

5     sure what terms I used. But I described it in

6     the terms of it's creating friction in the

7     lab.

8         Q.    And in -- and I'm sorry, when

9     was that discussion about data manipulation

10    with Mr. Suter?

11        A.    It's hard to peg it. I believe

12    it was around February of 2001. I know that

13    it was before I wrote the letter to Emilio

14    because that letter was written at the

15    direction of Suter, told what I was supposed

16    to put in it and told I was supposed to give

17    it to Bob, but that it wouldn't be going to

18    Emilio. I decided to not listen to Bob's

19    advice as far as I pegged -- I didn't like the

20    idea of complaining about administrative

21    issues, so I pegged everything to getting

22    Protocol 007 done. So there were several

23    places in the letter where I said this impacts

24    our ability to get the results he said we

25    wanted to get. I signed it so that Emilio

Page 210

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     knew it was me, and I was hoping to get a face

3     to face so that I could report the fraud to

4     his face.

5     Q.    But you stated you did report

6     the fraud to Dr. Shaw's face in July of 2001

7     first?

8     A.    That was the first time I told

9     Shaw about it, in July.

10    Q.    When was the first time you

11    told Emilio Emini about the fraud in the lab?

12    A.    To his face?

13    Q.    Yes.

14    A.    The end of July.

15    Q.    Do you know how much time is

16    between those two discussions, the one with

17    Shaw and the one with Emini?

18    A.    They both occurred in July.

19    Q.    July 2001?

20    A.    Uh-huh. And the one with Shaw

21    was first.

22    Q.    Why did you stay in the lab

23    between January 2000 and July -- January 2001

24    and July of 2001 if you thought there was data

25    manipulation going on?

Page 211

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     A.    To stop it.

3     MR. SCHNELL: Objection.

4     THE WITNESS: Sorry. First of

5     all, I had agreed to go back there

6     because I wanted a career at Merck. I

7     was excited to go there. The reason I

8     didn't just quit like Shaw told me to

9     was because I thought I could stop the

10    fraud in the lab. I thought we could.

11    I mean, it wasn't just me. There

12    were -- the people I named before, we

13    would meet and talk about it, like this

14    has to stop. We were the ones doing

15    the assays, we thought we could stop

16    it.

17    So it's tough to give you a

18    reason I didn't quit. The reason I

19    continued to work there and the reason

20    I continued to not commit fraud, they

21    are what they are. I wasn't going to

22    commit fraud and we tried to stop it.

23    BY MS. DYKSTRA:

24    Q.    Which other lab members that

25    you worked with also agreed with you, to the

Page 212

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     best of your knowledge, that there was data

3     manipulation in that lab?

4     A.    Jill DeHaven, Suzie Maahs, Jon

5     Gombola, Frank Kennedy, Joan Wlochowski and

6     myself used to meet and talk about it. Some

7     of them were under a lot of pressure. They

8     didn't like -- Suzie did not like Krah coming

9     up and telling her what data to change and

10    telling her how many plaques to find. So they

11    discussed it a lot as in what do we do, what

12    do we do.

13    In a discussion with all of

14    them, Suzie and Joan were talking about

15    somebody has to tell the FDA. Suzie said I

16    should do it. And everybody agreed that if

17    the FDA knew, they would stop it.

18    Q.    So you discussed talking to the

19    FDA with these colleagues?

20    A.    We discussed the potential of

21    going the FDA, that we should go to the FDA

22    because everyone thought it was fraud.

23    Q.    The people that you mentioned

24    just thought it was fraud. Correct? You

25    mentioned --

Page 213

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     A.    During the discussions there --

3     I mean, Suzie said cheating a lot. This is

4     cheating. He can't tell you to change the

5     data.

6     Q.    You said Jill DeHaven, Suzie

7     Maahs, Frank Kennedy and Joan Wlochowski and

8     you. Correct?

9     A.    Can you read those again?

10    Q.    Sure. Jill DeHaven, Suzie

11    Maahs, Frank Kennedy, Joan and you.

12    A.    Jon Gombola --

13    Q.    And Jon Gombola.

14    A.    -- was he in there? To the

15    best of my knowledge, yeah, that was the

16    group.

17    MR. SCHNELL: I think you

18    interrupted him in the middle of an

19    answer. Did you finish the answer

20    before --

21    THE WITNESS: I wanted to go

22    back.

23    MR. SCHNELL: Read back where

24    he was before the interjection.

25    - - -

Page 214

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL  
 2 (The court reporter read the  
 3 pertinent part of the record.)  
 4 - - -  
 5 THE WITNESS: I'm using fraud  
 6 to cover their use of the word cheating  
 7 and not liking Krah to tell them to  
 8 change data, that they didn't like, you  
 9 know, having to throw away their  
 10 counting sheets after they counted an  
 11 assay just because he didn't like the  
 12 results. Retesting results they didn't  
 13 like. There was so much about it. A  
 14 lot of it is in the allegation or the  
 15 complaint. A lot of the allegations  
 16 are in the complaint.  
 17 So I mean, I can't give you an  
 18 enumerative list on what they said was  
 19 fraud or what they thought was fraud.  
 20 BY MS. DYKSTRA:  
 21 Q. Other than witnessing Dr. Krah  
 22 wipe those numbers off the plate, did you  
 23 witness other employees in the lab wipe  
 24 numbers off the plates?  
 25 A. All the time. All the time.

Page 215

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL  
 2 We can go through example by example.  
 3 Q. Who else in the lab did you  
 4 identify wiping numbers off the plates?  
 5 A. Jenny Kriss, Mary Yagodich,  
 6 Colleen. Some of the other people that I  
 7 mentioned were told to do things like that.  
 8 They were told to throw away counting sheets.  
 9 Mary, Colleen and Jenny followed Krah's  
 10 instructions to do that. The other people did  
 11 it when Krah stood over them and told them. I  
 12 witnessed that.  
 13 Q. I want to show you what I'm  
 14 going to mark as Exhibit 15.  
 15 - - -  
 16 (Exhibit Krahling-15, E-mails,  
 17 MRK-KRA00048342, was marked for  
 18 identification.)  
 19 - - -  
 20 BY MS. DYKSTRA:  
 21 Q. This is an e-mail between you  
 22 and Dr. Krah and others, a couple of e-mails  
 23 in March of 2001. So in the bottom e-mail, if  
 24 we start there first, read the bottom e-mail.  
 25 A. And not the top one or just do

Page 216

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL  
 2 it all at once?  
 3 Q. The bottom one is shorter, just  
 4 talks about needing to hold up on vacation.  
 5 Correct?  
 6 A. Okay.  
 7 Q. Do you recall -- you can read  
 8 the top two as your responses back and forth  
 9 with Dr. Krah. Do you recall these discussions?  
 10 A. Hold on. Now you want me to  
 11 read the top one?  
 12 Q. Yes, please.  
 13 A. Okay.  
 14 Q. What do you recall about this  
 15 issue? Do you recall these e-mails?  
 16 A. When I look at this, what I see  
 17 is doing what Suter told me to do. He said I  
 18 have to go to Dave first. I had to stick to a  
 19 personnel issue. I need to -- that I need to  
 20 go through him, keep any other accusation  
 21 about -- except for administration of this  
 22 thing through Dave.  
 23 It looks like it's kind of  
 24 cordial. I know that deteriorates as it goes  
 25 on, but this is me trying to do as Suter

Page 217

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL  
 2 directed me to do, which was jump through some  
 3 hoops. He described it, he gave me a big  
 4 World War I analogy. He said, You know when  
 5 Germany invaded France in World War I and then  
 6 they set up a line of trenches for four years?  
 7 It was a stalemate. He said that there is  
 8 trench warfare. And he said, You know what  
 9 happened when people stuck their head up? He  
 10 said, They got killed.  
 11 I said, I hope you're talking  
 12 metaphorically. But he called it a trench  
 13 policy. And he said, You need to keep your  
 14 head down. Don't accuse anything of fraud.  
 15 Make sure you're talking about administrative  
 16 things, challenge Krah on any administrative  
 17 policy that might make its way through Suter  
 18 to Emimi, and I should be nice about it. This  
 19 was me following Suter's orders.  
 20 Q. Mr. Suter is in Merck -- was in  
 21 Merck HR at the time?  
 22 A. That was my understanding.  
 23 When I went to the human resources, that's --  
 24 he was there.  
 25 Q. Did you talk to anybody else in

Page 218

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Merck's HR department about your concerns?

3     A.    I don't recall.

4     Q.    So your testimony is that you

5     went to Merck HR about concerns around data

6     manipulation and Mr. Suter in Merck's HR told

7     you not to complain to Dr. Krah about data

8     manipulation but rather to complain only about

9     administrative issues?

10    A.    That's not -- no. He said to

11    make sure I don't archive any allegations that

12    could hurt Dave's career in an e-mail. He

13    didn't say I couldn't complain to his face.

14    He's saying e-mails were much more formal.

15    And you did not write an e-mail to your boss

16    saying anything that could look like you're --

17    that could -- well, Bob called it career

18    suicide for me to even say anything like that.

19    In addition to that, he said I should never

20    e-mail Shaw or Emini.

21           - - -

22           (Exhibit Krahling-16,

23           Compilation of e-mails, RELATOR\_00000731 -

24           00000735, was marked for identification.)

25           - - -

Page 219

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     BY MS. DYKSTRA:

3     Q.    I'm going to show you what's

4     marked as Krahling-16. This is a compilation

5     of e-mails, so it looks like March 22nd,

6     March 26th -- a couple of March 26th e-mails

7     and then it looks like, and I need you to

8     explain to me what this is, a list of HR-type

9     complaints. I think maybe you wrote this to

10    Bob Suter, but I'm not clear.

11    A.    This is March 26th, right? The

12    previous exhibit is March 26th, and we have

13    March 26th here.

14    Q.    Yeah, the first e-mail on

15    Krahling-15 is the same e-mail on Krahling-16,

16    but the rest of it is all different.

17    A.    Where are those ones the same?

18    Q.    This bottom e-mail here --

19    A.    Yes.

20    Q.    -- is the same as the first

21    e-mail here.

22    A.    Got it.

23    Q.    And then there's an additional

24    e-mail that follow.

25           So can you tell me when you

Page 220

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     look through this, after you've had a chance,

3     who you prepared this for, what was the

4     purpose or who you gave it to or sent it to?

5     A.    Okay. What's your question?

6     Q.    Did you put these e-mails

7     together and write this section following

8     e-mails that's a list of grievances?

9     A.    I'm not sure putting the

10    e-mails together, but this look like Suter's

11    assignment that he gave me. Told me to just

12    compile as many human resource things that I

13    could, give it to him, that maybe he could

14    discuss some of the points anonymously -- that

15    I would be anonymous. To give it to Suter and

16    that maybe he could pick one or two points out

17    to talk to Emini and then maybe Emini would

18    meet me face to face. This looks like Suter's

19    assignment that he gave me.

20    Q.    So you prepared this and you

21    provided it to Mr. Suter. Is that correct?

22    A.    Yeah, I don't recall with that

23    detail. I'm just saying what it looks like.

24    It likes like -- based on the fact that it

25    says please allow me to maintain my anonymity,

Page 221

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     wherever that is. I know that when I wrote

3     the letter to Emilio I signed it. That would

4     make it an earlier draft. But this looks like

5     Suter's assignment he gave me. He asked

6     for me to do this.

7           Suter also told me that if I

8     were going to say something that could reflect

9     negatively on Dave in this, that I should go

10    out of my way to say something positive about

11    Shaw who is one up from us so it didn't look

12    bad. He said, if you're going to say

13    something negative become Krah, try and say

14    something positive about Shaw.

15           So this looks like my

16    assignment for Suter that he asked for. I

17    don't remember -- I don't think I would have

18    given it to Suter because I decided to do a

19    little bit of what he told me about put those

20    HR complaints in, but I wrote a letter to

21    Emilio where I linked this to the Protocol 007

22    testing. And I brought up Protocol 007

23    testing right away in that letter, if I

24    recall. I haven't looked at it.

25    Q.    I'm going to show it to you.



Page 222

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     A.    The point was so that I could

3    get a face to face with Emini so that I could

4    tell him about the fraud going on in the lab.

5     Q.    So you did -- when you wrote --

6    so what you're saying is you sent these

7    complaints to Emini but you did list the fraud

8    in addition to these HR complaints?

9     A.    That's not what I said.

10    Q.    I'm sorry, I thought that's

11   what you just said?

12    A.    That's not what I said at all.

13   I said this is like a rough draft that Suter

14   asked me for. Suter wanted only human

15   resource type complaints against Dave. He

16   said I had to come out with as many as I could

17   possibly think from, give the list anonymously

18   to Bob Suter. And he might pick out a few,

19   discuss them with Emini and if Emini had

20   concerns, that Emini might want to interview

21   me and I could get that face-to-face meeting.

22   I don't believe I gave this to Bob Suter

23   because I know that at some point I said I

24   wasn't comfortable with just HR complaints, I

25   wanted to talk about Protocol 007 testing.

Page 223

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     So I did a little bit of what

3    Bob wanted because he said that if I were

4    going to make a complaint, I needed to show

5    that I would listen and obey the rules he was

6    giving me. That was part of his trench

7    policy. So I had to do as I was told. So I

8    tried -- I didn't e-mail Shaw right away. I

9    didn't e-mail Emini, you know. So what I did

10   was I said I'm going to link this to Protocol

11   007 because that's what I want to talk about.

12   And I believe I talked about Protocol 007

13   testing generally in there, that this could

14   impact the company. And then I signed the

15   letter and I put it in Emilio's mailbox.

16   - - -

17   (Exhibit Krahling-17, 4/8/01

18   Letter, RELATOR\_00000328 - 00000331,

19   was marked for identification.)

20   - - -

21   BY MS. DYKSTRA:

22   Q.    I'm going to mark Krahling-17

23   which I believe is the letter you're referring

24   to that you gave to Emini in his mailbox. Can

25   you just confirm that that is your letter to

Page 224

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2   Mr. -- Dr. Emini?

3     A.    If we're going to talk about

4   it, I'd like to read it.

5     Q.    That's fine.

6     A.    So what's the question?

7     Q.    Is Krahling-17 a letter that

8   you wrote to Emilio Emini complaining about

9   issues you had in the lab?

10    A.    This looks like it. Yeah.

11   That's my signature.

12    Q.    So in this letter, in the first

13   paragraph, last sentence you complain about

14   procedural inequalities.

15    A.    Where are we at?

16    Q.    The last line of the first

17   paragraph.

18    A.    Okay.

19    Q.    The first line of the second

20   you say, "Dave has developed highly personal

21   relationships with a few of his female

22   employees. This often manifests itself in the

23   form of personal gifts that he unashamedly

24   delivers in the presence of those employees

25   who are to receive nothing. I have personally

Page 225

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2   witnessed several of these events which

3   include but are not limited to: holiday gifts,

4   work anniversary gifts and gifts for no

5   occasion. Last Easter Dave prepared and

6   handed out four baskets of candy to four

7   female employees while four contract

8   employees, one permanent male employee and one

9   permanent female employee received nothing."

10   So is this all accurate of what

11   you observed in the lab?

12    A.    I don't remember. The

13   paragraph didn't even exist for any of that.

14   The paragraph existed because my departure

15   will likely affect the timely completion of

16   the mumps testing. That was the point of the

17   first paragraph.

18    Q.    I'm sorry, where does that say

19   that?

20    A.    Second sentence.

21    Q.    The second sentence of the

22   first paragraph?

23    A.    Yeah. The other -- all those

24   other things are just what Suter told me to

25   do.

Page 226

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 Q. So did these other things

3 happen or did you make them up?

4 A. I don't remember. You know

5 what, I don't think I lied at the time. I'm

6 sure they happened, I just don't really

7 remember a whole lot of these little things

8 that happened. They were -- the point of the

9 first paragraph was to say to, you know --

10 Suter pointed out that my only value to the

11 company was in getting this testing done. He

12 pointed out that I wasn't pregnant because

13 that was valuable to the company because I

14 could work with live virus whereas pregnant

15 women could not. He said if you demonstrate

16 your value, maybe these human resource

17 quibbles will rise to the level of getting a

18 face to face with Emini.

19 So this was part of Suter's

20 assignment of list every human resources thing

21 you could list. The point of this was to say

22 if I leave, this could affect the company's

23 mumps testing.

24 Q. Do you --

25 A. The other little things --

Page 227

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 Q. Go ahead.

3 A. -- I'm sure they were true, but

4 I don't remember them.

5 Q. Do you think that your

6 departure from the lab would have actually

7 impacted the timing of the completion of the

8 mumps testing given that you are only one of

9 many employees in that lab?

10 A. One of many employees, Krah

11 told me that the reason he wanted me to come

12 back -- when we were at Colleen's wedding, one

13 of the reasons he wanted me to come back was

14 he wasn't sure he could get it done without

15 me. That's what he said. So, yeah, I

16 believed him.

17 Q. Were you a faster worker than

18 other people? Did you complete more assays

19 than other people in the lab?

20 A. Two of the women in the lab

21 were pregnant. They couldn't do the assays.

22 Jill worked part time. Colleen worked part

23 time. He -- Dave wanted to fire Frank and

24 Joan and didn't want them running any assays.

25 So they weren't even allowed to do it. At the

Page 228

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 time we didn't even have the interns yet. I'm

3 trying to think of another full-time employee

4 besides me that was working in the test.

5 Maybe there is -- I think I was the only one.

6 Was there another one?

7 Q. So you believed your departure

8 would impact the timing of the mumps?

9 A. Krah told me if I didn't come

10 back, it could impact it.

11 Q. It could. And you believe that

12 these personal gifts and holiday gifts and the

13 work anniversary gifts and the baskets of

14 candy and these procedural inequalities, they

15 all occurred. Correct? You didn't make them

16 up, they actually occurred?

17 A. I wouldn't have lied in here

18 but I don't remember any of that stuff too

19 well. I mean, it's --

20 Q. A little further down in the

21 second paragraph you say that Dave -- it's

22 like the fifth line from the bottom. "Dave's

23 discrimination functions as a constant source

24 of strain and tension between lab members...."

25 Can you explain that to me, how that came out

Page 229

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 in the lab?

3 A. It's just part of Bob Suter

4 saying you're never going to be heard by upper

5 management if you don't make a complaint. So

6 I don't know. If you keep putting down, what

7 you see is mumps testing, mumps testing; the

8 last two paragraphs you see mumps testing;

9 over here, mumps neutralization assays.

10 Q. I'd like to focus on my

11 questions first.

12 In the second paragraph, can

13 you describe the strain and tension that

14 occurred in the lab?

15 A. As a result of the fraud or as

16 a result of this, whatever is here?

17 Q. Well, the only thing mentioned

18 in this paragraph is these gifts and

19 inequalities. So explain to me whatever

20 strain and tension was in the lab at the time.

21 A. The strain and tension in the

22 lab had to do with the fraud being committed.

23 This was just part of Suter saying make an HR

24 complaint or you can't write to Dave. Or

25 actually this was to Emini. But make an HR

Page 230

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     complaint to Bob anonymously. And I decided

3     to sign it. I was following Bob's advice.

4     Q. And then the third paragraph

5     you talk about problems with Dave keeps many

6     of us unintentionally [sic] uninformed about

7     work schedules and policy changes. Is that

8     accurate?

9     A. Yeah, I think that's true.

10    Q. And then a couple of lines down

11    you say, "He has no schedule for when he

12    arrives in the morning." And "This is very

13    upsetting, to me at least..." Is that true?

14    A. I know that he came in to work

15    late. Well, you see the whole point of this

16    is about work schedules, mumps neutralization

17    assay. The point of the paragraph is to get a

18    meeting with Emini so that we can discuss the

19    mumps neutralization assays, getting it done

20    and I can tell him what's going on in the lab.

21    Q. So the purpose of this letter

22    was to get -- tell him enough HR complaints to

23    get a meeting with him so you could then

24    report fraud?

25    A. No. I was following Bob's

Page 231

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     order to compile a list. I wanted to get a

3     face to face so that I could report the fraud

4     to Emini, that he would hear it and I could

5     see his reaction. I didn't want to write some

6     e-mail and even at Suter's -- Suter said you

7     can't put an allegation against fraud in

8     there. You have to talk to people's face.

9     You don't memorialize it in an e-mail.

10    So I was following Suter's

11    orders. Where I disobeyed Suter was signing

12    my name to it, giving it to Emini instead of

13    Suter and linking everything and talking about

14    the mumps neutralization assays, Protocol 007

15    testing in here.

16    Q. My question was, you wrote this

17    letter and put as many HR complaints as you

18    could reasonably identify into a letter to

19    Emini, Dr. Emini so that you could then get a

20    face-to-face meeting with Dr. Emini to report

21    fraud?

22    A. That's not quite right. I

23    followed Bob Suter's order about making

24    certain HR complaints, but the letter was to

25    talk about the impact of the testing getting

Page 232

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     done and to get -- the underlying goal was to

3     get a face to face with Emini so that I could

4     report the fraud.

5     Q. Did you ever consider filing a

6     Title VII complaint against the company for

7     discriminatory practices?

8     A. What's a -- is that what a

9     Title VII complaint is?

10    Q. Yes.

11    A. I remember that Shaw came up to

12    the lab and he pointed at me and waived me

13    over and we walked down to his office. And he

14    said, you have two options. You can maintain

15    the status quo in which case Dave is going

16    to -- things are going to keep getting worse,

17    Dave is going to give you a poor review and

18    life is going to be hell for you. He said,

19    or and -- he said, and you're never going to

20    get that bonus.

21            He said option -- and option

22    two is you voluntarily resign, you can get the

23    bonus. He said, you're just not going to be

24    able to maintain the status quo.

25            In response to that I said, it

Page 233

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     sounds like, you know, you're telling me Dave

3     is going to retaliate against me because I'm

4     not following his orders, because Bob Suter is

5     big on following orders. They're, like, you

6     follow the orders. And Shaw said no, no, no,

7     I'm just telling you what I think Dave is

8     going to do.

9            And then I said, well, that --

10    because you're aware of it, isn't that

11    harassment, wouldn't I be able to file

12    something like that? And he warned me be

13    very, very careful, don't threaten -- you

14    know, don't threaten a lawsuit. He said I --

15    you know, don't threaten a lawsuit, think

16    about resigning. I said, I don't even want to

17    think about resigning. I don't want to do

18    that. There's got to be other ways. And I

19    said, why can't I transfer out of Krah's lab

20    but still stay at Merck.

21            He -- at the time he didn't see

22    it as a viable option. He said, your best bet

23    is to voluntarily resign.

24    Q. Did you or did you not consider

25    filing a Title VII Discrimination complaint

Page 234

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL  
2     against the company?  
3     A.    I don't think I seriously  
4     considered it at all. I used it in defense of  
5     his seeming support of Dave Krah's treatment  
6     of me. And he demanded that I take it back.  
7     So I think later on I may have -- I'm not  
8     sure. I mean, I may have said something  
9     about, you know, not doing that.  
10    Q.    On the top of the page  
11    RELATOR\_330 --  
12    A.    Yeah.  
13    Q.    -- you state, Our lab has been  
14    assigned a critical project which does not  
15    allow me to remain silent about what is  
16    happening, or to leave without adversely  
17    affecting people I respect. I had all  
18    intentions of going to HR and then leaving  
19    when the mumps test was finished. I planned  
20    to stay because of the inordinate amount of  
21    respect Dr. Shaw showed to our entire lab,  
22    visiting with us and talking to us almost  
23    every day on the project. His actions boosted  
24    lab morale whereas Dave's silence on the same  
25    issues only served to isolated us. Mary has

Page 235

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL  
2     also been a mitigating factor.  
3     Is that all accurate?  
4     A.    Yes. As part of Bob's  
5     assignment, he said, if you do anything that  
6     sounds like a complaint against Krah, you  
7     better say something positive about Shaw. And  
8     so that -- I mean, that's me trying to say  
9     something positive about Alan Shaw. But the  
10    very first line, our lab has been assigned a  
11    critical project. Protocol 007 does not allow  
12    me to remain silent about what is happening.  
13    That's an allusion to the fraud. If I leave,  
14    it will adversely affect the people I respect.  
15    They'll have to carry more of the weight. But  
16    the -- as I said throughout this, maybe the  
17    project doesn't get done. The point was  
18    Emini -- according to Bob, Emini might care  
19    enough to talk to me face to face. So at  
20    Bob's suggestion, I tried to say some positive  
21    things about Dave and Mary.  
22    Q.    I want to show you back to the  
23    complaint which we've marked Exhibit 3. Can  
24    you go back to that for a moment?  
25    A.    Am I leaving this open?

Page 236

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL  
2     Q.    You can leave that open, sure.  
3     If you look on paragraphs 54  
4     and 55 which are on page 19, please.  
5     A.    54 and 55?  
6     Q.    Yes. Look at those and then  
7     let me know when you're done.  
8     A.    All right, I'm good.  
9     Q.    So in your complaint you state  
10    that, in paragraph 54, In July 2001, after  
11    completing a secret audit, you and Joan  
12    Wlochowski openly accused -- well, Joan  
13    Wlochowski openly accused Krah during a lab  
14    meeting of committing fraud in the mumps  
15    testing.  
16    Paragraph 55 says, "Relator  
17    Krahling then met with Bob Suter."  
18    So this complaint makes it  
19    sound as if you met with Mr. Suter following  
20    that July 2001 meeting. Is that accurate or  
21    inaccurate?  
22    A.    They're in different  
23    paragraphs.  
24    MR. SCHNELL: Object to form.  
25    THE WITNESS: You're cherry

Page 237

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL  
2     picking the first -- there's a  
3     different paragraph.  
4    BY MS. DYKSTRA:  
5    Q.    The whole first paragraph says,  
6    "In July 2001, ...Joan Wlochowski openly  
7    accused Krah during a lab meeting of  
8    committing fraud in the mumps testing." You  
9    then met with Shaw and confronted him. Is  
10   that accurate, that you met with Shaw after  
11   that July meeting?  
12   A.    These paragraphs don't  
13   necessarily --  
14   Q.    I'm reading the first two lines  
15   of the paragraph 54.  
16   A.    Can I finish?  
17   Q.    Sure.  
18   A.    These paragraphs don't  
19   necessarily occur in chronological order  
20   throughout this complaint. 54 is a  
21   self-contained paragraph. You're taking the  
22   front part of 54 and trying to go, ah, you  
23   went to Suter first. That's not what this  
24   says.  
25   Q.    Let's just look at paragraph

Page 238

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 54, then, in its entirety. How about that?

3 A. I'm good with that.

4 Q. Okay. Paragraph 54 says, In

5 July 2001, after completing the secret audit,

6 Relator Wlochowski openly accused Krah during

7 a lab meeting of committing fraud. Relator

8 Krahling then met with Shaw, the Executive

9 Director of Vaccine Research and confronted

10 him about the fraudulent testing.

11 Do you see those two lines?

12 A. Yes, I do.

13 Q. Are those accurate?

14 A. They are accurate.

15 Q. So you met with Dr. Shaw

16 sometime in July 2001 as you testified

17 previously?

18 A. You're talking softly. What is

19 that?

20 Q. I'm sorry. You met with

21 Dr. Shaw and confronted him about the

22 fraudulent testing in July 2001?

23 A. When Joan accused Krah of fraud

24 at that lab meeting, he was quiet. And then

25 he said, I can't be committing fraud. I don't

Page 239

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 know -- I'm blinded as to the -- as to the --

3 he said he was blinded. I shot back, You're

4 not blinded as to what's the pre and post and

5 you're changing pre-positives.

6 He was just dead silent. He

7 was very uncomfortable. And it was long and

8 there was pizza sitting in the middle of the

9 table. I got up and walked to Alan Shaw's

10 office and said, We just accused Krah of

11 committing fraud in that lab meeting. That's

12 paragraph 54.

13 Q. Was that the first time you

14 directly discussed fraud in the lab with

15 Dr. Shaw?

16 A. That was the first time I

17 unequivocally said it so that I knew 100

18 percent he knew what I was saying.

19 Q. Paragraph 54 goes on to say

20 that you told Shaw the falsification of the

21 pre-positive data. You also confronted Shaw

22 about improper use of animal antibodies to

23 inflate post-vaccination neutralization

24 counts.

25 "Shaw responded that the FDA

Page 240

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 permitted the use of the animal

3 antibodies...that should be good enough for

4 Krahling." And "Shaw refused to discuss

5 anything further about the matter. Instead,

6 Shaw talked about the significant bonuses that

7 Emini had promised to pay the staff...."

8 Is that all accurate?

9 A. That's very accurate.

10 Q. In next paragraph says,

11 "Relator Krahling then met with Bob Suter,

12 Krahling's HR representative at Merck.

13 Krahling told Suter about the falsification of

14 data..." [As read.] Is that accurate?

15 A. "Krahling told Suter about the

16 falsification....," I told him again about

17 that. That's not the first time I had

18 mentioned it. I told him again about the

19 falsification of data. Remember Suter had

20 said don't talk to me about that. I went back

21 to him again.

22 Q. So the first time you went to

23 Mr. Suter about falsification of data was when

24 again?

25 A. February 2001. In or about

Page 241

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 there. It was definitely before I wrote that

3 letter. I think it was February.

4 Q. In paragraph 55 you say that

5 Mr. Suter told you you would go to jail if you

6 contacted the FDA. Is that true?

7 A. He said that more than once.

8 Q. Who would put you in jail if

9 you contacted the FDA?

10 A. He didn't say who would put me

11 in jail. I assume he meant the police. He

12 just said you'd go to jail.

13 Q. Did he say why you would go to

14 jail if you contacted the FDA?

15 A. No. He just said you'll go to

16 jail.

17 Q. Did you ask him why would I go

18 to jail if I contacted the FDA?

19 A. I responded bullshit.

20 Q. Did you believe it was bullshit?

21 A. I had hoped it was bullshit.

22 Q. Did you think you would be

23 arrested if you contacted the FDA?

24 A. I wasn't certain, but I had --

25 was trying to call his bluff, if indeed it was

Page 242

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 a bluff. I didn't know for sure.

3     Q.   When you said "bullshit," what

4 did he say in response?

5     A.   I think he basically reiterated

6 it, but that was the end of the conversation.

7 I was walking away at that point, if I recall

8 correctly. Tell you what sticks out in my

9 mind is him saying you'll go to jail and me

10 saying bullshit. And then -- I don't know

11 that there was much conversation after that.

12 That was the first time that he said that. He

13 mentioned that I would go to jail when -- the

14 time that I was also -- when I went in to have

15 a meeting where he actually said I would get

16 to meet with Emini.

17     Q.   So at some point you clearly

18 made the decision that you were going to

19 contact the FDA. Correct?

20     A.   Yes. Because I did contact

21 them, I must have made a decision to do it,

22 sure.

23     Q.   Tell me about your discussions

24 with the FDA. When was the first time you

25 contacted the FDA about the fraud in

Page 243

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 connection with 007?

3     A.   The middle of June 2001 was the

4 first time I called.

5     Q.   Middle of June?

6     A.   Middle of June, right around

7 June 19.

8     Q.   What did you tell -- who did

9 you talk to, do you know?

10    A.   Whoever answered the phone.

11    Q.   What did you tell them in that

12 conversation?

13    A.   I said that I worked at a lab

14 at Merck and that the lab was committing

15 fraud.

16    Q.   Did you give them detail around

17 the -- your allegation of fraud?

18    A.   I remember she sounded stunned.

19 And she wanted information on who I was, how

20 she could contact me, you know, affirming

21 that, you know, this is a real thing. And I

22 told her where I worked. So basically where

23 is the company, things like that. It only

24 lasted -- I mean, it didn't -- it wasn't a

25 very long call. She basically ended up with

Page 244

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 setting up, okay, we're going to have to talk

3 again.

4     Q.   So she could get more

5 information about your allegations?

6     A.   I don't recall. She was just,

7 we're going to have to talk again.

8     Q.   How long before your second

9 call with the FDA? When was your second call

10 with the FDA?

11    A.   So four or five phone calls

12 that all occurred between -- around June 19,

13 2001 and August 1st, 2001. I can't give you

14 exact dates, but there's about four or five

15 calls in there during that time period.

16    Q.   So the first call was about how

17 long?

18    A.   I can't -- I mean, isn't

19 this -- isn't this in the interrogatories if

20 you want an exact time? It was short.

21    Q.   Who did you talk to on the

22 second call?

23    A.   I think it was the same woman.

24    Q.   You think it was the same

25 woman?

Page 245

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     A.   I think it was. I don't know.

3     Q.   How did you -- did she arrange

4 the call or did she get ahold of you, what did

5 she do?

6     A.   I don't remember. We

7 exchanged -- I'm sure we must have exchanged

8 contact information. It was a series of

9 calls, the second one I remember was

10 predicated on the first one. They weren't

11 independent things, now who am I going to talk

12 to this time. There were a series of phone

13 calls.

14    Q.   How long was the second call?

15    A.   Short.

16    Q.   What did you say during the

17 second call to the FDA?

18    A.   The totality of the phone calls

19 went -- I was getting to the person I believe

20 she needed to put -- the person who answered

21 the phone obviously isn't -- probably not that

22 high up. But she was trying to get me in

23 front of someone who could hear it. And so

24 the series of four phone calls I didn't get to

25 tell them too much. I told them that fraud

Page 246

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     was occurring, they should come in.

3             So I'm not sure of the content

4     so much as there was fraud happening. And the

5     last phone call I said they needed to come in,

6     that data was being destroyed.

7     Q.   How much detail did you give

8     the FDA about what kind of fraud was

9     occurring? Or did you just say fraud and they

10    said, Well, okay, we'll come. Or did you say,

11    Let me explain to you plaque neutralization

12    assay, for example, and what was actually

13    occurring?

14    A.   Isn't this in the interrogatories?

15    Q.   I'm just asking what you

16    remember.

17    A.   I wasn't able to tell them too

18    much. The point was to get them in there so

19    they could investigate it and see it. I told

20    them that there was fraud occurring. My last

21    call was they needed to come in, that Krah was

22    destroying plates. He was destroying

23    evidence.

24    Q.   So you recall telling them that

25    he was destroying evidence and destroying

Page 247

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     plates. Do you recall telling them that data

3     was being falsified in connection with the PRN

4     assay?

5     A.   I think that the -- well, come

6     on, now, you had to go and add that last part.

7     What are -- you know, the very first phone

8     call I reported that fraud was occurring. The

9     last phone call I said they needed to come in

10    quickly. The details that I remembered, I

11    believe we put in interrogatories, but sitting

12    here today to say -- I mean, I know that I --

13    there was so much going on, there's no

14    possible way I could have detailed everything

15    to them over a phone call. But I gave them

16    details and I believe that the details that I

17    could remember were in the interrogatories and

18    there wasn't much outside of that. There

19    wasn't a lot of time to talk.

20    Q.   Were you honest with the FDA,

21    and truthful?

22    A.   Of course I was.

23    Q.   Did you leave anything out of

24    your allegations --

25    A.   It's not --

Page 248

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q.   -- in reporting to the FDA?

3     MR. SCHNELL: Object to form.

4     THE WITNESS: Yeah. Look, it's

5     not that I left it out. I didn't have

6     time to tell them everything. I

7     couldn't put together some big

8     presentation. We were over the phone

9     and they needed to come in and

10    investigate it. That's a big project,

11    Protocol 007 testing. They needed to

12    come in and investigate. I couldn't

13    lay out point for point everything of

14    misconduct I saw. I tried to get the

15    point across that fraud was happening

16    in this lab, the FDA did not know about

17    it, it was -- and they should come and

18    investigate it.

19    BY MS. DYKSTRA:

20    Q.   So you understood that in order

21    for them -- strike that.

22             It was your belief that for

23    them to fully investigate the fraud, they

24    needed to come in and do an investigation of

25    Dr. Krah's lab?

Page 249

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     A.   What I know is that I wanted

3     them to come in and investigate it because

4     fraud was happening and we were not able to

5     stop it in the lab.

6             MS. DYKSTRA: Why don't we take

7     a break.

8             VIDEOGRAPHER: The time is

9     3:40. We're going off the video

10    record.

11             - - -

12             (A recess was taken.)

13             - - -

14             VIDEOGRAPHER: The time is

15    4:05. This begins disc four in the

16    videotape deposition of Stephen

17    Krahling.

18    BY MS. DYKSTRA:

19    Q.   Mr. Krahling, I just want to

20    make sure I understood one of the things you

21    said previously correctly. You stated that

22    you met with Mr. Suter and originally

23    complained of fraud in February of 2001.

24    Correct?

25    A.   I said that I believe it was

Page 250

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     probably February 2001, based on the fact that

3     that letter to Emilio was whenever it was and

4     I had already talked to Bob before that a few

5     times.

6     Q.    The letter to Emilio is dated

7     April 8, 2001?

8     A.    Uh-huh.

9     Q.    You believe you talked to

10    Mr. Suter two months before you wrote the

11    letter to Dr. Emini?

12           MR. SCHNELL: Object to form.

13           THE WITNESS: What I remember

14    is that I originally went to Bob based

15    on the fact that there was fraud

16    happening in the lab. He didn't want

17    to listen to it. He didn't want me to

18    document it in e-mails. That I had

19    some number of meetings with him that

20    started to involve more of the fraud

21    and people in the lab that were trying

22    to resist the fraud also.

23           So in March there was this --

24    Krah instituted error reports. He said

25    he was instituting error reports so

Page 251

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     that he could fire Frank and Joan.

3     Frank and Joan were two people who

4     weren't -- wanted to resist the fraud,

5     and I didn't want those two getting

6     fired, number one, because they were

7     resisting the fraud; but number two, it

8     just seemed the right thing to do. So

9     my conversations with Bob at some point

10    included those. That happened in

11    March. I know Krah instituted those

12    error reports in early March. That's

13    why I'm saying I was most likely

14    talking to Bob in February because I

15    had already talked to him once at

16    least.

17           - - -

18           (Exhibit Krahling-18, 7/17/01

19    E-mail, MRK-KRA00002243, was marked for

20    identification.)

21           - - -

22    BY MS. DYKSTRA:

23    Q.    I'm going to show you what I'm

24    marking as Krahling-18. Take a look at that.

25    It's a July 17, 2001, e-mail from you to

Page 252

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Dr. Shaw.

3     A.    All right.

4     Q.    Can you explain to me, was this

5     e-mail written by you following your

6     discussion with Dr. Shaw where you allege that

7     there was lab misconduct in Dr. Krah's lab?

8     A.    If you'll recall back when I

9     said that Alan came up and pointed at me, told

10    me to follow him and took me to his office,

11    that conversation where he gave me two

12    options, option one and option two, and said I

13    couldn't have option one. Option one he

14    called status quo. Option two is he said you

15    should voluntarily resign. That idea that he

16    said that Dave was going to continue to

17    retaliate against me and I brought up the idea

18    that couldn't I sue for that. And he said,

19    you don't even say that, you need to take that

20    back.

21           He said, I want you to consider

22    voluntarily resigning. That's the only way

23    you'll get this bonus.

24           I rejected that out of hand.

25           He said, I want you to come

Page 253

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     back to me and tell me you'll consider this as

3     an option. I don't want to hear any more talk

4     that you'll sue.

5           That meeting there, this

6     appears to be an e-mail that was a follow up

7     to that, as far as I can tell.

8     Q.    And you say in this e-mail that

9     you want to let him know that if a severance

10    package is put together including a bonus for

11    completion of the mumps project, my July

12    salary and severance pay for lost wages and

13    benefits, I will resign -- I will voluntarily

14    resign from Merck even though I don't have

15    another job lined up. I would have approached

16    HR but you said to come to you if I wanted to

17    get things done. This is my idea of a peace

18    offering.

19           So this is -- was this your

20    proposal of how to reach a resolution with the

21    company so that you could leave with a

22    package?

23    A.    No.

24    Q.    It was not your proposal?

25    A.    No. This was in response to



Page 254

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     him telling me that I need you to admit

3     that -- or I need you to consider and tell me

4     you're going to consider voluntarily quitting.

5     This was a change in nomenclature. I was

6     giving him what he wanted. Listen, we can

7     have that as an option on the table but don't

8     use the nomenclature giving me this double

9     bonus and options. It says options. Not like

10    this is the only option. He wanted me to not

11    talk about suing the company, and at least put

12    that option on the table, because he did not

13    want me to keep the status quo. This is a

14    follow-up e-mail. So I -- I mean, I don't

15    think it's a follow up to another e-mail. I

16    believe it's a follow up to the meeting where

17    he said those things.

18    Q.    I think you lost me there. I

19    understand he gave you two options; one,

20    status quo, meaning you would continue to work

21    in Dr. Krah's lab?

22    A.    But that life would continue to

23    get worse. That Krah would give me a poor

24    performance review. And that I would not get

25    the bonus that he said Emini had promised us,

Page 255

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     we had already earned.

3     Q.    The another option was to work

4     out a severance deal?

5     A.    No. The other option was a

6     voluntary resignation where they paid the

7     double bonus. And he wanted me to just say

8     that I would accept it as an option or

9     consider it as an option. I didn't give him

10    that when I left that meeting. He was very

11    concerned with the fact that I said, you know,

12    if Krah is going to retaliate and you don't

13    step in to do it and you know he's going to do

14    it, then don't I have a right to sue over

15    that.

16        He said, I want you to

17    basically take that back and just say you'll

18    consider this.

19        My peace offering was that I'm

20    saying, look, I'll say I'll consider this as

21    -- if you change the nomenclature as one of

22    the options. But at this time in the middle

23    of July, I was still holding out hope, naively

24    albeit in retrospect, that I could move out of

25    Krah's lab and remaining at Merck after I had

Page 256

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     stopped the fraud. Or we, we had stopped the

3     fraud, because there were active efforts by

4     people in the lab to stop this fraud.

5     Q.    What were those efforts?

6     A.    I believe some of them or many

7     of them are detailed in either the

8     interrogatories, the complaint or both.

9     Q.    What were the steps people took

10    to stop the fraud as you say?

11    A.    You want to item -- you want me

12    to itemize things that happened on a daily

13    basis --

14    Q.    You said there were active --

15    A.    -- over half a year?

16    Q.    You said there were active

17    efforts by people in the lab to stop this

18    fraud, and I'd like to know what you mean by

19    that?

20    A.    What I mean by that is

21    everything we were doing every day to stop it

22    as outlined partially in the complaint, in the

23    interrogatories. I can't recite for you the

24    things we did every day.

25    Q.    Why don't you recite for me

Page 257

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     what you can remember you did -- or not you,

3     what people were doing to stop the fraud, the

4     active efforts people were taking in the lab

5     to stop the fraud?

6     A.    Well, it was Suzie and Jon's

7     idea that they should be photocopying counting

8     sheets and giving them to me or someone should

9     be preserving them so that they didn't get

10    destroyed. They also wanted the counting

11    sheets preserved in case changes were made on

12    them. They started the idea of

13    countersigning, having people countersign

14    their own counting sheets. So if Suzie did a

15    count, she would have Jon Gombola countersign

16    it so that there would be two signature saying

17    when it did. So if Krah came in and changed

18    data, there would be two signatures and you'd

19    know -- you would have a solid time point from

20    which Krah's change happened after. Those

21    were their -- one of their ideas to archive

22    and preserve the fraud. That's one.

23    Obviously one of the other ones is that they

24    said that the FDA needed to be notified what

25    was going on because they could come in and

Page 258

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL  
2 stop it.  
3             Another effort was Joan and I's  
4 decision to audit the data to make sure that  
5 there was statistical proof of fraud in the  
6 data because then we knew for certain that our  
7 allegations that the pre-positives at least  
8 were being changed, could survive independently  
9 of us saying, well, we saw it here on this  
10 one, we saw it here on that one. There's  
11 another one. We were fighting all the time  
12 not to have the controls manipulated and  
13 changed. I had one disagreement with Krah in  
14 front of the lab members about what he called  
15 spots in the cell control. If there were  
16 plaques in the cell control, the entire assay  
17 had to be redone. Krah said that when we had  
18 favorable results, you simply never see  
19 plaques in the cell control. You should --  
20 don't even count it. And I said there are  
21 plaques in this one.  
22             He said, doesn't matter. He  
23 goes, you know what, those are spots.  
24             I said, what's the difference  
25 between a spot and a plaque?

Page 259

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL  
2             He said, well, I can tell.  
3             I said to him, how come there  
4 aren't spots in the rest of the assay? How --  
5 if we can't tell a spot from a plaque, we had  
6 a bit of a debate about spots versus plaques,  
7 but he wanted to salvage favorable data when  
8 controls indicated a retest. And he also  
9 wanted to dump undesirable data when several  
10 data points in one assay proved to be  
11 undesirable. It was easier for him to just --  
12 for him to manipulate a control and say it  
13 needs a retest.  
14             Now, a lot of the times he did  
15 that right on the plates. But sometimes the  
16 first count that would happen on the tissue  
17 culture plate would get archived on the sheet  
18 and he had to make the cross out on the sheet.  
19 So Joan and I looked at the fraud which made  
20 it to the counting sheets and said was there  
21 enough there to indicate statistical evidence  
22 of fraud.  
23             Those are just a few of the  
24 ways that we were doing this on a daily basis.  
25 There were more. I can't sit here off the top

Page 260

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL  
2 of my head and just recite them verbatim when  
3 we detailed quite a few of them, I believe, in  
4 both the interrogatories and the complaint.  
5             Q. Do you believe that you were as  
6 good as or better a plaque counter than  
7 Dr. Krah?  
8             A. The implication of your  
9 question is that he was rechecking and  
10 recounting plaques. He wasn't. He told us --  
11 the directive from him was to change the  
12 results. He didn't say we had to recount the  
13 plaques.  
14             Q. That wasn't my question.  
15             A. I know. I identified the  
16 implication of your question.  
17             Q. Can you answer my question? Do  
18 you believe you were as good at or a better  
19 plaque counter than Dr. Krah?  
20             A. I don't even know what that  
21 means.  
22             Q. Do you think that experience  
23 helps you more accurately recognize a plaque  
24 from some other rip or degradation in the cell  
25 culture?

Page 261

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL  
2             A. The question makes no sense to  
3 me. Krah was recounting his own assays later  
4 in the day. That would be like me asking,  
5 Krah, what was it about the lunch you had  
6 today that made you better able to count  
7 plaques in the afternoon than the morning when  
8 you changed your own counts, when you change  
9 six pre-positives in a row. That questions  
10 doesn't make sense to me. He had lunch. He  
11 had coffee. Did he not use his glasses? I  
12 don't know what Krah did in the afternoon that  
13 made him better at counting his own plaques  
14 than when he first counted them during the  
15 day.  
16             Q. Do you think that counting  
17 plaque is subjective in nature?  
18             A. There's an element of  
19 subjectivity to counting plaques.  
20             Q. Do you think that experience in  
21 counting plaques make -- can make you a more  
22 accurate plaque counter in the PRN context?  
23             A. I have no idea.  
24             Q. Can you look at Exhibit 3, the  
25 complaint again. Paragraph 33 on page 11,

Page 262

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     we'll start there.

3     A.    Just that paragraph?

4     Q.    Yes.

5     A.    Okay.

6     Q.    In the last paragraph you state

7     that you and Joan were -- well, it says, "In

8     fact, each was significantly pressured by Krah

9     and other senior Merck personnel to participate

10    in the fraud."

11           I understand you already

12    described Dr. Krah's instructions to you. Did

13    anybody else above Dr. Krah or senior to you,

14    other than Mary and Dr. Krah, instruct you to

15    change plaque counts?

16    A.    Emini met with our entire lab

17    and instructed us to follow Krah's orders. He

18    said that the only way we would get Protocol

19    007 testing done is if we followed Krah's

20    orders. And he said if we did that, he would

21    double the amount of a bonus that we had

22    already earned. So Emini for sure.

23    Q.    Did Emini say something

24    specific to counting plaques or did he just

25    use the words follow Krah's orders?

Page 263

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     A.    When he said follow the --

3     follow Krah's orders, I was pretty clear that

4     meant do what Krah said needed to be done to

5     get that assay done by the fall. And Krah

6     many times told us that one of the reasons we

7     had to change the pre-positives was because it

8     was reducing the sample size, that we might

9     not -- that we would not get the results we

10    needed and that in order to avoid retest and

11    stretch the testing out -- or to avoid

12    retesting which would stretch the testing out,

13    he had to manipulate controls to save assays

14    that were invalid when the assays -- when the

15    rest of the assay had data that he liked and

16    was favorable and wanted to keep. So I

17    thought it was very clear that Emini was

18    telling us to follow Krah's orders no matter

19    what those orders were.

20    Q.    How is it that Dr. Krah knew

21    which pre-vaccination samples were

22    pre-positive?

23    A.    Because he did the results and

24    calculated the results on a calculator as he

25    counted them.

Page 264

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q.    What exactly did he calculate?

3     A.    The results of the assay. He

4     would start by calculating -- he would count

5     the mock control and calculate the value of

6     the mock control because that's the standard

7     for what is seroconversion. Then he counted

8     the rest of the plates, write down numbers and

9     he would know the results before he even moved

10    on to count the next result. That way,

11    according to him, he could change the numbers

12    or change the data on the plate without

13    leaving a residue on the counting sheet. So

14    he had the capacity to know the results. And

15    he did that. The pre-vaccine and the

16    post-vaccine sera for each kid was ran right

17    next to each other. He even at one point was

18    excited about an Excel sheet that they have

19    developed so that people could just plug in

20    numbers and the undesirable results, and he

21    called them undesirable results, would light

22    up and you could identify them.

23    Q.    Can you go to paragraph 49,

24    please, in the complaint. In this paragraph

25    you state that, ".. none of the 'recounting'

Page 265

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     or 'retesting' that Krah and his staff

3     performed as part of the 'enhanced' testing

4     was performed on any post-vaccination samples

5     or...any pre-vaccination samples that were

6     pre-negative."

7           Do you see that?

8     A.    Yes.

9     Q.    So are you saying that no

10    recounting was done at all on pre-vaccination

11    negatives or post-vaccination positives?

12    A.    Let me clarify that for you.

13    This refers to the audit that Joan and I had

14    done because at the time we filed that

15    lawsuit, that's all we had access to to know

16    that this would be like this. So what Joan

17    and I found when we audited sheets that

18    represented something like 30,000 plaque

19    counts, was that all of that -- and you see

20    the recounting and retesting are in quotes,

21    the recounting and retesting wasn't the

22    directive. The directive was to change the

23    results. So the recounting and retesting that

24    changed results, that changed the serostatus

25    of what you could see in the original number

Page 266

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     on the counting sheet -- when I say

3     "original," I mean the first time it was

4     recorded on the counting sheet, ultimately

5     it's not the original number that's on the

6     plate. But when a serostatus change occurred,

7     what we found is every single one was a

8     pre-positive changed to a pre-negative. There

9     were no pre-negatives changed to -- there were

10    no pre-negative change, there were no

11    post-negative change, no post-positive change.

12    All the changes were pre-positive. Now, your

13    question, though, says -- can you read her

14    question back because there was another part

15    to it?

16             - - -

17             (The court reporter read the

18             pertinent part of the record.)

19             - - -

20             THE WITNESS: She said, am I --

21             your question is basically, am I saying

22             that no recounts were done at all on

23             these things -- on the post-sera. And

24             when you say "at all," one time at

25             least to Mary and a couple of times to

Page 267

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Dave, I pointed out that you are only

3     recounting the pre-positives. And that

4     if -- even if you were going to claim

5     that we were bad counters, you're only

6     recounting the data you don't want to

7     keep.

8     Krah adapted the fraud

9     according to our complaints. So by the

10    end of this, he adapted and said you

11    should write check marks by -- he was

12    telling the auditors to write check

13    marks by things they weren't going to

14    change to make it look like they had

15    checked them. The instruction was

16    still change the pre-positives, but he

17    would pepper in the checkmarks and

18    backdate them sometimes to make it look

19    like he had checked some results.

20    Those only happened later. I mean, I

21    don't know if he's going in and

22    peppered more in, but in the beginning,

23    yeah, the serostatus changes were only

24    pre-positive to pre-negative that Joan

25    and I found. But I can't say if he

Page 268

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     ever went back and claimed to have

3     looked at -- checked post-sera because

4     he started to direct the auditors that

5     they should put an indication that

6     maybe they looked at it.

7     BY MS. DYKSTRA:

8     Q. When you say "auditors," who

9     are you referring to?

10    A. That's a good question. We

11    should define that. Krah assigned Colleen,

12    Mary and Jenny and himself. He defined them.

13    He had a meeting with us to say that these

14    people are going to be auditors now and they

15    have the right to look at your counting sheet

16    and make changes to them.

17    Q. Did you see them make changes

18    to counting sheets, the auditors?

19    A. All the time.

20    Q. And did they -- and what you're

21    saying is they changed -- originally they only

22    changed the pre-positives and later on they

23    went back and changed the post?

24    A. I'm saying I don't know what

25    they went back and did. But originally Krah

Page 269

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     directed them and us that if you get a

3     pre-positive result, you go back and you

4     change it.

5             One time Jenny counted, she

6     counted a pre-positive and it was still a

7     pre-positive. She took an alcohol wipe,

8     destroyed her data. Counted it again. Still

9     got a pre-positive. Destroyed her data. She

10    did it like five times. And she actually said

11    can anybody else count this, I can't find

12    enough plaques to switch this to a

13    pre-negative. And I said, look at -- I said,

14    why are we even trying to change

15    pre-positives.

16             She went and asked Krah the

17    question, Why are we even trying to change the

18    pre-positive anyway.

19             Krah said, Because kids aren't

20    normally immune to mumps before they've had a

21    vaccine or before they've been exposed to a

22    disease. And this would be a big red flag

23    that the use of antibodies with an improper

24    control, that this isn't a methodology that is

25    providing reliable data.

Page 270

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2             The point was to hide those

3 pre-positive -- that high pre-positive rate

4 from the FDA so that the Protocol 007 could be

5 a success. And -- yeah.

6     Q. Did you ever challenge them,

7 meaning these auditors, on what they were

8 doing?

9     A. Yes.

10    Q. What did you say?

11    A. Well, I just told you what I

12 said to Jenny. I tried to -- I said, Why are

13 you trying to just change the result? And she

14 seemed to think that was a good question which

15 is why she redirected it to Krah. So there's

16 your one time. But I was friends with these

17 people.

18             I didn't go out and say, Jenny,

19 you're a horrible person. I was like, what

20 are you doing, why aren't you recounting this?

21             I pointed out to her that when

22 she used an alcohol wipe to erase all the

23 markers on there, that she's destroying the

24 first count. That the second, third, fourth

25 count that she destroyed, those are all -- I

Page 271

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 mean, she's -- the fifth count goes to the

3 counting sheet or, you know, the data is being

4 changed. The counting sheets aren't archiving

5 the information, you know. The same with

6 Colleen. I was like should you be ripping up

7 your counting sheet and getting a new counting

8 sheet when you have to make 10 or 20 changes

9 in one counting sheet. She said it looks ugly

10 to have that many changes on a counting sheet,

11 you know. And then Mary, I challenged the

12 very first time she brought me an assay and

13 said change the result. The rest of the lab

14 was against it and didn't want to do it. But

15 they -- a lot of them -- I mean, they

16 submitted to the pressure. Dave stood over

17 them and said change the plaque count, sign

18 your initials to it. He wouldn't even let

19 them sign it. Dave had told them to make the

20 change. He told Suzie, change the plaque

21 count. He stood over her until she pretended

22 to see more plaques and change it. When he

23 left the room, she said that, you know, I had

24 the feeling he wasn't going to leave until I

25 changed it. Things like that. I mean,

Page 272

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 that's -- those are some ostensive examples.

3 It's not enumerative. I think we pointed out

4 examples in -- right here, so...

5             - - -

6             (Exhibit Krahling-19,

7 Handwritten notes, RELATOR\_00001068 -

8 00001070, was marked for identification.)

9             - - -

10 BY MS. DYKSTRA:

11    Q. I'm going show you what's been

12 marked Krahling-19. You can take a look at

13 that.

14    A. Are we done with this one for

15 now?

16    Q. Yes, we are.

17    A. Okay.

18    Q. Can you tell me what this is?

19    A. I think the first page might

20 just be something I wrote out to figure some

21 things out. The second page is a list of

22 things I wanted to have in front of me when I

23 met with Bob Suter to push for a meeting with

24 Emini. I mean, it's a photocopy of it.

25    Q. But you prepared this in

Page 273

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 preparation of your meeting with Mr. Suter.

3 Correct?

4    A. The second -- oh, I didn't see

5 the back of this one. It looks to be the same

6 thing. Yeah. I'm not sure that the front --

7 I mean, that's basically scratch paper. It's

8 calculations.

9    Q. So you're saying pages

10 Bates-labeled 1069 and 1070 were your notes in

11 preparation for your meeting with Mr. Suter?

12    A. Were these originally on the

13 same sheet? Weren't these different pages?

14    Q. Well, they were produced to us

15 in this order, so...

16    A. Yeah, for sure this and this

17 are part of the same list.

18    Q. 69 and 70?

19    A. Yeah. And I would have had

20 this or -- I would have had this with me when

21 I met with Suter in late July when I was

22 pushing for a face to face with Emini.

23    Q. So in late July 2001, in

24 preparation for your meeting for Suter, did

25 you walk through each of these issues with

Page 274

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Mr. Suter when you met with him?

3     A.    No.

4     Q.    Did you -- the options that you

5     listed, status quo, voluntary resignation,

6     expose David to liability. Did you walk

7     through those with Mr. Suter?

8     A.    What I remember is that I

9     started with the options Alan had given. See,

10    it's right there. Status quo, voluntary

11    resignation. Alan contacted me. So, yes, I

12    remember talking about the options Alan had

13    handed me. And then I remember having first

14    on my list something that would indicate it

15    was an example of fraud but it was this error

16    report fraud where he was trying to fire Joan

17    and Frank. But he was backdating, he was

18    not -- Krah wasn't filing error reports. And

19    then when I called him on it, he was

20    backdating them to make them look like they

21    were filed in time. So I wanted to start off

22    with that.

23            The middle things I had because

24    Suter said I was not allowed to bring this --

25    complaints of scientific misconduct to him.

Page 275

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     So I had to have examples in there, otherwise

3     he's -- he questions why I'm there. But I

4     wanted to use the very first thing on that

5     list there to get that face to face with

6     Emini.

7     Q.    The error report?

8     A.    Yeah.

9     Q.    What did you say the error

10    report was? What is this error report,

11    March 7, 2001, referring to?

12    A.    That's a whole digression. You

13    want to go into that now?

14    Q.    Sure.

15    A.    Okay. In March Dave met with

16    Colleen, myself, I don't know if Mary was

17    there at the time. But he said that he wanted

18    to institute a policy of error reports so that

19    he could compile evidence to fire Frank and

20    Joan, that he'd have a reason to do it. He

21    said since they weren't contract employees, he

22    can't fire them. So in March he instituted

23    error reports.

24            Later down the road -- it's not

25    even down the road, what is it, in April?

Page 276

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Colleen -- at some point Dave informed us that

3     those error reports were only for Frank and

4     Joan. If something happened, he said we

5     didn't even have to file an error report. We

6     didn't have to do that. It was only for Frank

7     and Joan.

8            After I sent the letter to

9     Emilio, shortly after that, Colleen informed

10    me that Dave had made an error in an assay

11    that they were doing and that it was a

12    significant error. And I said, What happened

13    to the assay? She said, ah, we just incubated

14    it.

15            So I waited a week because the

16    error reports had to be filed within one week.

17    On the seventh day, I went to Dave and I asked

18    him for the error report. And Colleen had

19    told me it hadn't been written.

20            I went to Colleen first and

21    said, Did you write an error report?

22            She said, No, why would we?

23    Those are only for Frank and Joan.

24            When I knew for sure that she

25    hadn't written one, I went to Dave and asked

Page 277

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     if he had written an error report for the

3     error he had made because Colleen said it was

4     his. He directed -- he said no, and then went

5     and directed Colleen to write one and backdate

6     it. And that's what they did.

7     Q.    And then these complaints,

8     Working weekends in June, Colleen's Memorial

9     Day week, candy in mailboxes, Jenny's B-day

10    lunch, discussing my behavior with co-workers

11    but not me, yells at me in front of my

12    co-workers - reviewing data, made me remove a

13    project from my objectives that I had already

14    completed, new project on MRC-5 cells -

15    amended to include rubella. Did you review

16    these issues with Mr. Suter?

17    A.    I don't recall. I did not go

18    through the whole list. When I started on the

19    first one, he said he didn't want to hear it.

20    And then I had to go to the last one and say,

21    listen, he's committing fraud and I have to

22    make that complaint official to you because he

23    said he didn't want to hear it. Then

24    immediately he said you can meet with Emini.

25    Q.    So this time when you

Page 278

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 officially made a complaint, he immediately

3 let you meet with Emini?

4 A. I made complaints before. He

5 said he wouldn't listen to it. But I had to

6 say it so unequivocally. I said, oh, I -- I

7 mean, I told him I was going to call the FDA

8 if I couldn't see Emini about it. So I mean,

9 I made it so unequivocal that I -- that we

10 were going to stop this fraud. And if we had

11 to go to the FDA to get the fraud stopped, we

12 would do that.

13 Q. Then you got a meeting -- he

14 arranged a meeting with Emini?

15 A. Yes. That's beyond the scope

16 of this letter, or whatever this is, this

17 list.

18 Q. Yes. If you look at again the

19 complaint, paragraph 56.

20 A. Can you put it in the right

21 order?

22 I'm good with this paragraph.

23 Q. So in early August 2001 you met

24 with Dr. Emini. Correct?

25 A. It seemed like early August.

Page 279

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 It turns out it was the very end of July.

3 Q. How do you know that?

4 A. I've since seen documents that

5 said it was the end of July.

6 Q. What documents did you see?

7 A. I can't recall. I mean it

8 was -- I don't know. Maybe I didn't see the

9 documents. I mean, somebody pointed out to me

10 that that meeting would have been -- that I

11 was very, very close with my time, that it was

12 actually -- there's 31 days in July. It was

13 the very end of July. The reason I was --

14 when we wrote this complaint that I'm putting

15 early August is because the FDA came in on

16 August 6th, and I knew it was about a week or

17 within a week of that meeting with Emini.

18 Q. It says here that you

19 "...brought actual testing samples and plaque

20 counting sheets to demonstrate to Emini the

21 fraudulent testing that Krah was directing."

22 And "Emini agreed that Krah had falsified the

23 data."

24 Can you describe in more detail

25 what happened at that meeting with Dr. Emini?

Page 280

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 A. I took in a control plate in

3 which I had originally counted it. Krah had

4 changed the data by saying there was a tore

5 monolayer. I had had some fellow lab members

6 recount it without saying what they were

7 counting. So they count this and then could

8 you just tell me what it is and sign it.

9 So I walked in with my original

10 count, possibly what I had in my count. I

11 walked in for sure with my co-workers'

12 recounts, with Krah's counting of my sheet and

13 the plate itself, among a few other things.

14 Okay. And then the first thing Emini tried to

15 say, he tried to say something cordial and I

16 walked up to him, I said, I need you to look

17 at this plate.

18 He tried to say, well, I wanted

19 to -- I said, no, we got to start -- you have

20 to look at this plate. I pointed to the one

21 well. I said, could you count -- I said just

22 count how many plaques are in that, that well.

23 And he looked at it. He could see there were

24 four plaques there. He said four. I said,

25 That's what I saw, too. And then I showed him

Page 281

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 the sheet and said that's what my co-worker

3 saw.

4 I said, Krah says those four

5 plaques aren't there, that they're a torn

6 monolayer. And because this was the mock

7 control, his elimination of that four lowered

8 the standard for seroconversion for that

9 assay. That was one of the assays which Krah

10 had said he was recounting which prompted me

11 to call the FDA.

12 So I wanted to show Emini an

13 example of the fraud. He agreed that Krah

14 misrepresented that data, that there were not

15 four -- I mean, there were four plaques there

16 because the cell monolayer was there. Krah

17 was saying no cell monolayer, torn cell

18 monolayer. You couldn't accept four plaques,

19 that the cells were missing.

20 Q. What else did you discuss with

21 Emini after that?

22 A. I think we answered this pretty

23 detailed in an interrogatory. I can go

24 through that and confirm that everything we

25 said there was true.

Page 282

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q.    Just what you remember.

3     A.    I remember that we put the

4 answer pretty well in an interrogatory, but

5 here you go.

6            So Emini said, yeah, he

7 misrepresented the data. And I explained that

8 Krah was committing fraud. That amongst other

9 things, he was falsifying the pre-positive

10 rate. I can't get the exact order probably

11 correct on this, but Emini's response was to

12 order me not to call the FDA because he knew

13 my solution was to have the FDA come in and

14 set this straight. He ordered me not to call

15 the FDA. He said instead he would put

16 together an independent investigation. I

17 objected that he couldn't possibly put

18 together an independent investigation because

19 if people were receiving their paychecks from

20 Merck, that biased it. And besides, the FDA

21 was the best to do an independent

22 investigation. He told me that under no

23 circumstances should I call the FDA.

24            I tried to explain to him that

25 Krah was under a lot of pressure; that the

Page 283

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 reason he had to falsify the data, that he was

3 supposed to get this done, he had to get the

4 right answer, and that they were using a

5 control that counted a lot of nonspecific

6 effects. So they were counting false

7 positives. I said Krah would not have to

8 falsify the data perhaps if they used a

9 non-immune serum control. He pointed out to

10 me something to the effect that, look, the FDA

11 is aware of the protocol. You don't need to

12 tell them about it. And my rebuttal was they

13 certainly don't know that Krah is committing

14 fraud in the lab so that they could use that

15 protocol.

16            He said, You will not call the

17 FDA.

18            I just said, you know, if you

19 can give me a scientific reason why we're

20 using the rabbit antibodies without a

21 non-immune serum control such to cause Krah to

22 falsify that data, I said I won't call them.

23            He said it's a business

24 decision. And then I was moving towards the

25 door. He said, You will not call the FDA.

Page 284

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2            I'm sure I left a few nuggets

3 out of that, but it was that type of meeting.

4 As soon as I walked out the door, Suter was

5 there saying, You'll go to jail if you call

6 the FDA.

7            I mean, that's just off the top

8 of my head. If you want to give me the

9 interrogatory, maybe -- I don't know.

10    Q.    In what situation would the use

11 of anti-IgG be appropriate, you said if we had

12 used a non-immune serum control?

13    A.    What I said was if Krah, if the

14 assay had involved a non-immune serum control

15 instead of a mock control, it would not have

16 counted such a high amount of nonspecific

17 interactions. It wouldn't have been so

18 nonspecific. Nonspecific interactions are

19 when virus neutralization occurs by

20 anti-bodies which are not mumps antibodies,

21 are not specific mumps antibodies. Krah was

22 very aware that the assay had a very low

23 specificity. I mean, the -- that the low

24 specificity was required to get a high amount

25 of virus neutralization. And as Krah said,

Page 285

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 we, meaning Merck, want that in the

3 post-vaccine results. So they took that

4 nonspecific bump in the post-vaccine results.

5 But when it also occurred in the pre-vaccine

6 results, it looked incredibly artificial, very

7 artificial. He said that it's a red flag to

8 the FDA that we're counting non-specific

9 effects, that we're counting false positives.

10 That's one of the reasons we have to cross out

11 the false positive, we meaning Merck, cross

12 out the false positives, put pre-negatives in

13 where the pre-positives were. The other

14 reason was to save sample size. That if the

15 sample size wasn't large enough, they might

16 fail the criteria for success for Protocol 007

17 for the PRN test. And that was absolutely

18 critical to get this stuff successful so that

19 they could, what did I say, correlate ELISA to

20 it so that they wouldn't have to do this PRN

21 anymore.

22    Q.    Are you aware of whether or not

23 Dr. Emini did put together an independent

24 investigation at the company into your

25 allegations?



Page 286

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     A.    Yes, I had to testify before

3    it. And I'm not using the legal term testify,

4    because we weren't under oath, but that's what

5    it seemed like.

6     Q.    So you were interviewed by the

7    individuals involved or running the

8    investigation?

9     A.    Yeah. Yeah. There was -- do

10   you want me to tell you who was there at it?

11    Q.    Uh-huh.

12    A.    I mean, do you want me to tell

13    you who was at the internal audit?

14    Q.    I want to know if you were

15    interviewed by --

16    A.    I was interviewed.

17    Q.    Did you provide truthful

18    information in that interview?

19    A.    Oh, my God, yes.

20    Q.    You said you had conversations

21    with your other lab colleagues following the

22    interviews?

23    A.    And before it. They were very

24    nervous. Suzie said that she was just a

25    contract employee. If she went in there and

Page 287

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2    told the truth, she'd be fired. Everybody was

3    nervous about it. Frank was like, I can't

4    afford to lose my job. Jill was nervous.

5    Jill had some sort of -- she had some sort of

6    injury and she said that Alan was giving her a

7    tough time about how she would get paid,

8    things like that. She felt that her -- it

9    might get denied if she said anything. And

10   so, you know, it was like everybody do what

11   you want. We're like, we understand whether

12   you're going to tell the truth or not.

13            After the meeting, Suzie came

14   out and said I told the truth, I told them the

15   truth about it and they threatened to fire me.

16   And then we had a meeting with that. That's

17   the most adamant thing I remember because she

18   was so upset that they threatened to fire her.

19   But she stuck to her guns and told the truth.

20            - - -

21            (Exhibit Krahlung-20, Resume,

22            RELATOR\_00002770 & 00002771, was marked

23            for identification.)

24            - - -

25   BY MS. DYKSTRA:

Page 288

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q.    I'm going to show you what I'm

3    going to mark as Krahlung-20.

4     A.    Can I review it?

5     Q.    Yes, you can.

6     A.    Okay.

7     Q.    Can you tell me what this is

8    and whether you created it?

9     A.    I definitely created this.

10   This is me updating my resume, I think you

11   referred to it as a CV, after my employment at

12   Merck concluded.

13    Q.    And what did you use this for?

14    A.    Didn't use it for anything. I

15    never sent it to anyone, never gave it to

16    anyone.

17    Q.    So why did you create it?

18    A.    I was updating it. I have more

19    publications on the back.

20    Q.    I'm sorry?

21    A.    I mean, there's a lot more

22    publications on the back than the one you

23    showed me earlier.

24    Q.    You updated your work at Merck

25    I see. Correct?

Page 289

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     A.    Yes.

3     Q.    And you described your work as

4    manufactured data to protect Merck's exclusive

5    license rights and you have extensive lab

6    experience and experience identifying

7    eliminating bias including methodology

8    designed specifically to produce a

9    pre-determined result, ad hoc manipulation,

10   and confirming bias.

11            What was the purpose of putting

12   this resume together with that information?

13    A.    To update my resume.

14    Q.    But you never did anything with

15   it?

16    A.    No. I didn't use it to apply

17   for a job. I just updated it. The statements

18   are true.

19    Q.    That wasn't really a question,

20   but I understand that you think that they are

21   true.

22            I want to go to your revised

23   interrogatories where you do delineate your

24   descriptions -- I mean, your telephone calls

25   with the FDA. I'll mark these as Krahlung-21.

Page 290

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL  
2             - - -  
3             (Exhibit Krahling-21, Relator  
4     Stephen A. Krahling's Responses and  
5     Objections to Merck's Revised First Set  
6     of Interrogatories, was marked for  
7     identification.)  
8             - - -  
9     BY MS. DYKSTRA:  
10    Q.    So it looks like interrogatory  
11    14 which appears on page 44, begins on  
12    page 39. But I want to focus on your  
13    discussions with the FDA. I believe those  
14    begin at the bottom -- actually the top of 44.  
15    A.    So what interrogatory number is  
16    it?  
17    Q.    14.  
18    A.    So I'd like to read it.  
19    Q.    Sure. Take your time. I'm  
20    going to ask you about your discussions with  
21    the FDA.  
22    A.    You mean I can skip the I spoke  
23    with -- that stuff?  
24    Q.    Yeah, you can skip it the other  
25    people. I just want to focus on your

Page 291

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL  
2     conversations with the FDA at the moment.  
3     A.    Okay.  
4     Q.    I'm going to mark one  
5     additional document we're going to look at  
6     the same time as that, which is Krahling-25,  
7     which also discusses your conversations with  
8     FDA.  
9     A.    I read it.  
10    - - -  
11    (Exhibit Krahling-25,  
12    Handwritten notes, RELATOR\_00001044 -  
13    00001047, was marked for identification.)  
14    - - -  
15    BY MS. DYKSTRA:  
16    Q.    So in your -- in the document  
17    that we labeled 25, you note in the second  
18    paragraph that "In July 2001 I notified Bob  
19    Suter, Human Resources, and Emilio Emini,  
20    vice-president of Vaccine Research, that I  
21    intended to call the FDA to report Merck for  
22    falsifying data. At the time, I had already  
23    contacted the FDA twice and reported Merck for  
24    instituting a policy to fraudulently lower the  
25    pre-positive rate in the mumps anti-IgG

Page 292

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL  
2     neutralization assay."  
3             Is that accurate?  
4     A.    I think it's accurate.  
5     Q.    And in your response to the  
6     revised interrogatories on page 44, in answer  
7     -- in describing your discussions with the  
8     FDA, you say you spoke to two unidentified  
9     employees at the Philadelphia branch of FDA  
10    about topics related to the allegations in the  
11    amended complaint regarding the mumps vaccine.  
12    A.    Where are you at on this?  
13    Q.    In the middle of the page on  
14    page 44.  
15    A.    What does it start with?  
16    Q.    "Relator spoke..."  
17    A.    Okay. Can you go again?  
18    Q.    I just read the first line, you  
19    spoke to two people at the FDA. You say the  
20    first contact was with the Philadelphia branch  
21    of the FDA on June 19, 2001?  
22    A.    Yeah. Yes.  
23    Q.    And remind me what you conveyed  
24    to the FDA during that first phone call. And  
25    I'm giving you this in case this refreshes

Page 293

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL  
2     your recollection.  
3     A.    That Krah's lab was committing  
4     fraud, Merck was committing fraud.  
5     Q.    Did you identify any other  
6     individuals other than Dr. Krah in that phone  
7     call?  
8     A.    I don't remember. It was such  
9     a short call.  
10    Q.    You say it was 15 to 20 minutes.  
11    A.    Yeah, but a lot of that was who  
12    is calling, what's your contact information,  
13    where do you work, the address of the place.  
14    Things like that. A lot of it was setting up  
15    a way that we would be able to contact again  
16    when she had a more appropriate person for me  
17    to talk to.  
18    Q.    So she, the FDA employee,  
19    contacted you or you contacted her a second  
20    time about a month later?  
21    A.    Probably within the next month.  
22    I'm not sure. What I can say is there were at  
23    least another phone call to set up -- she was  
24    setting me -- trying to set up a conference  
25    call where I'd be talking to her and someone

Page 294

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 she said would be more appropriate to talk to

3 than someone who answered the phones there.

4     Q. Do you know who you talked to

5 in that second call or who the person that

6 was --

7     A. I have no idea.

8     Q. -- more experienced?

9     A. I don't recall.

10    Q. You didn't take any notes of

11 those phone calls?

12    A. I was holding the phone and

13 talking.

14    Q. Where did the phone call --

15 where were you at the time you made these

16 calls?

17    A. In the parking lot, Merck's

18 parking lot in my car.

19    Q. You don't have any notes of the

20 phone calls?

21    A. Well, the first couple of phone

22 calls there wouldn't have been any notes. But

23 I was reporting to them what I knew to try and

24 get them to come in and do an investigation.

25 I wasn't detailing for them every step of

Page 295

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 scientific misconduct or fraud I saw. The

3 point was to say fraud is occurring, this is

4 where it's at, come in and investigate it.

5     Q. And then at the top of page 45,

6 your answer, you state that "Relator urged her

7 to get the FDA to conduct an on-site

8 inspection and interview him and his

9 co-workers in Krah's lab. She told him...,"

10 you, "...that putting together an FDA

11 inspection...to visit Merck would take a few

12 days." Is that accurate?

13    A. Yes.

14    Q. Any other conversations with

15 the FDA prior to the inspection?

16    A. No.

17    Q. At the bottom of page 44 in one

18 of your phone calls it says that you called

19 the Philadelphia branch and reported that Krah

20 was destroying garbage bags full of

21 experimental plates from the mumps 007 testing

22 project. Is that accurate?

23    A. Where are you at on this?

24    Q. It's the bottom. It says,

25 "Several weeks later, after Relator...,"

Page 296

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 bottom of page 44.

3     A. Okay, I'm there.

4     Q. You "...witnessed Krah

5 destroying garbage bags full of experimental

6 plates..."

7     A. Uh-huh.

8     Q. You again called the

9 Philadelphia branch office of the FDA and

10 spoke the woman who you spoke with on previous

11 occasions and reported what was happening?

12    A. Yes.

13    Q. Is that accurate?

14    A. Well, I reported that the --

15 that evidence was being destroyed. So the FDA

16 needs to come in and review it so that he

17 couldn't destroy all the evidence. Krah was

18 destroying the evidence the morning after I

19 met with Emini. So things went fast there. I

20 met with Emini, Krah shows up early, is

21 destroying stuff. I called the FDA and said

22 you need to come in, evidence is being

23 destroyed. She said it took a few days and

24 then they showed up August 6th.

25    Q. So Krah didn't -- Krah didn't --

Page 297

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 according to you, Krah did not start

3 destroying evidence until after you meet with

4 Emilio Emini?

5           MR. SCHNELL: Object to form.

6           THE WITNESS: The first time I

7 ever saw him show up early to work that

8 early, the first time I saw him

9 autoclave, destroyed plates for a study

10 that was ongoing, was the day after I

11 met with Emini. And Krah had

12 previously told me that there was a

13 need or an obligation to preserve the

14 Protocol 007 study results and

15 materials that we were generating. So

16 I knew that that was irregular for a

17 few different reasons. At the very

18 least I wanted to call the FDA because

19 the very obvious thing was that the

20 plates were destroyed after he ran the

21 autoclave.

22 BY MS. DYKSTRA:

23    Q. If you go back to the

24 complaint. If you can go back to the

25 complaint, we can go -- we're done with that

Page 298

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     document.

3     A.    Isn't this the complaint?

4     Q.    Those are your interrogatory

5     answers.

6           MR. SCHNELL: Lisa, we've been

7     going an hour, so whenever a good time

8     for a break.

9     BY MS. DYKSTRA:

10    Q.    When you -- you document in

11    your complaint the FDA's inspection on

12    August 6th. Correct?

13    A.    Where is that at?

14    Q.    That's on page 20, paragraph 59.

15    A.    20, paragraph 59. Okay.

16    Q.    Describe to me what happened

17    when the FDA came to Merck.

18    A.    Do you want me to read

19    paragraph 60?

20    Q.    If you think it would help you

21    refresh your recollection, you can.

22    Otherwise, you can just describe it as you

23    recall it.

24    A.    60 describes it.

25    Q.    Okay.

Page 299

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     A.    You want, like, where I was at?

3     Q.    Yes, where were you standing,

4     where was Dr. Krah. Explain in your own words

5     what happened when the FDA arrived.

6     A.    Suzie came back, I was in the

7     back lab and Suzie came back and said the FDA

8     was here, I had to come up to the front lab.

9     And I was kind of shocked, and she grabbed me

10    by the arm and drug me and said I had to go to

11    the front lab which is where my desk was. So

12    I went to my desk which was right where the

13    meeting was happening. It was right -- my

14    desk was, desk/office computer, was right

15    where Krah and Shaw were being questioned by a

16    woman from the FDA. So I sat down and just

17    started taking notes.

18    Q.    Was it one woman or more than

19    one person?

20    A.    I know one woman was talking.

21    I think a second woman was there. But I

22    didn't -- I hadn't recognized the woman, so I

23    don't know if she's from the CDC or Merck at

24    the time. CDC -- whether she was from FDA or

25    Merck at the time. There was one woman from

Page 300

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     the FDA that did the talking.

3     Q.    How long was the conversation

4     between the FDA -- how long -- what happened,

5     you witnessed the FDA interviewing Dr. Shaw

6     and Dr. Krah?

7     A.    They were questioning Krah, and

8     Shaw was standing there. And I was writing

9     notes as fast as I could on what the FDA

10    person was saying and what Krah was answering.

11    And then when Krah ran out of the room, Shaw

12    tried to cover an answer and I just kept

13    writing what I had. I mean, the fact that I

14    was taking contemporaneous notes of exactly

15    what I heard, we should go to those. I mean,

16    can't -- that would be a pretty good record of

17    what happened.

18    Q.    How long was that conversation

19    about, approximately?

20    A.    I couldn't guess. My

21    adrenaline was rushing. Is that written

22    somewhere?

23    Q.    Well, in paragraph 62 of your

24    complaint you say that "The entire interview

25    with Krah and Shaw was short, probably less

Page 301

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     than half an hour."

3     A.    I was going to say I thought it

4     was less than half an hour. It wasn't -- I

5     mean, I didn't sit there for an hour.

6     Q.    So less than a half an hour?

7     A.    Yeah.

8     Q.    The FDA interviewed Dr. Krah

9     and Dr. Shaw for less than half an hour?

10    A.    Yeah. 20 minutes, half an

11    hour. Maybe 20 minutes-ish. Less than half

12    an hour.

13    Q.    And the FDA did not talk to you

14    or Joan Wlochowski or other members of the

15    staff at that time. Is that correct?

16    A.    No, they didn't talk to us at

17    that time.

18    Q.    Following the interview -- so

19    you were there for the entire interview.

20    Correct?

21    A.    I don't know. But they were

22    already talking when I went there, so I would

23    say I wasn't there for the whole interview

24    since --

25    Q.    So you missed the beginning of

Page 302

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     the interview?

3     A.    I don't know how much I missed,

4     but I must have missed at least however it

5     started. I don't know when I picked it up.

6     Q.    What happened after you

7     witnessed that interview?

8     A.    What do you mean after?

9     Q.    You took notes of the FDA's

10    interview, you said Dr. Krah left the room?

11    A.    He left the room and at some

12    point he came back. And toward the end of

13    that interview, they were still walking

14    around. They walked through the lab somewhere

15    and left. They at least left where the lab

16    was.

17    Q.    The FDA left the lab?

18    A.    Yeah. I don't know if they

19    left the premises. They may have been

20    inspecting some other area. They left where I

21    was, and they weren't in the back lab either.

22    So I don't know where they went. But they

23    walked away. The FDA with Krah and Shaw,

24    those people moved out.

25    Q.    Are you aware of any other

Page 303

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     portion of the FDA inspection that they did on

3     August 6th, or did you witness any other

4     portion of an inspection on August 6th?

5     A.    I didn't witness any other part

6     of the inspection.

7     Q.    Did you witness any other

8     inspections on any other days by the FDA in

9     connection with your allegations?

10    A.    I didn't witness any other

11    inspections.

12    MR. KELLER: Lisa, it's been

13    over an hour, can we take a break?

14    MS. DYKSTRA: Let me ask one

15    more.

16    THE WITNESS: She can get done

17    with this.

18    BY MS. DYKSTRA:

19    Q.    Did you compile any data -- did

20    the FDA request any data from Merck in

21    connection with your allegations?

22    A.    I wouldn't know that. Wait.

23    No, I mean, Krah indicated that they had to

24    respond to it. So I mean, I would know that

25    they had to do something in response to it.

Page 304

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     But, I mean, I was cut off from seeing data at

3     that point.

4     MS. DYKSTRA: Okay. We can

5     take a break.

6     VIDEOGRAPHER: The time is

7     5:10. We're going off the video

8     record.

9     - - -

10    (A recess was taken.)

11    - - -

12    VIDEOGRAPHER: The time is

13    5:27. We're back on the video record.

14    - - -

15    (Exhibit Krahling-22,

16    Handwritten notes, RELATOR\_00001072 -

17    00001080, was marked for identification.)

18    - - -

19    BY MS. DYKSTRA:

20    Q.    Mr. Krahling, I'm marking as

21    Exhibit 22 what I believe might be your notes

22    of the conversations you overheard with

23    Dr. Krah, Dr. Shaw and the FDA. Can you just

24    take a look and confirm that that's what that

25    is? Can I see that for one second? Is that

Page 305

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     the highlighted version? Let me give you a

3     cleaner version. Put a clean version there.

4     There you go. Thanks.

5     A.    All right.

6     Q.    Are these your notes?

7     A.    They're all my notes, yes.

8     Q.    Are these the notes you took

9     during the FDA inspection on August 6, 2001?

10    A.    The first five pages are.

11    Q.    What are the other pages, 1077,

12    78, 79 and 80?

13    A.    I could guess. Do you want me

14    to guess what they are?

15    Q.    Well, are these your notes?

16    A.    They're notes, but they're not

17    from when the FDA people were standing right

18    there.

19    Q.    Okay. Do you recall what these

20    are from, these notes?

21    A.    No. The second ones?

22    Q.    Yes, the second 1077 to 1078.

23    A.    Yeah, the neater ones. No, I

24    don't recall what those were.

25    Q.    It look like it says FDA and

Page 306

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Dave, FDA and Dave. Is this not a recitation

3     of what occurred between the FDA and David

4     Krah and Alan Shaw?

5     A.    They're not the contemporaneous

6     notes I took at the time. The first five

7     pages are.

8     Q.    You can put that aside. If you

9     go back to --

10    A.    The whole document aside?

11    Q.    Yes, the whole document.

12        If you could go back to

13    Exhibit 6 and 7 which are your responses and

14    objections to Merck's requests for admissions

15    and your supplemental -- or amendments to

16    those?

17    A.    6 and 7?

18    Q.    Yes.

19    A.    I have 6 and 7.

20    Q.    In response to request number

21    41 which is on page 18 of your original

22    answers, request 41 states, "Admit that you

23    were not involved with responding to the FDA

24    on behalf of Merck following the FDA's

25    inspection of Merck's facilities in August

Page 307

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     and/or September 2001." And you deny that

3     request.

4        Can you tell me the basis for

5     your denial? There's no -- nothing in the

6     supplemental response that I saw?

7     A.    Okay. I'm going to read that.

8     Q.    Sure.

9     A.    Okay. Now, what's the question

10    again?

11    Q.    We asked you to admit that you

12    were not involved with responding to the FDA

13    on behalf of Merck following the FDA's

14    inspection of the Merck facilities in August

15    or September of 2001, and you denied that.

16    Can you tell me the basis of why you denied

17    that?

18    A.    I can tell you one of the

19    bases. Krah's lab was expected to do some

20    work in response to the FDA inspection. I'm

21    not sure what that was because he wasn't

22    talking to me too much, but I still had to do

23    work around providing him data or things to

24    that to -- for him to submit or talk to his

25    superiors. Also -- you want as many as I can

Page 308

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     think of or just --

3     Q.    Let's go one by one so I can

4     follow up on what you just noted and then you

5     can think of another, we can talk about that

6     too.

7        You said that Krah was going to

8     provide some work in response to the FDA

9     inspection. You're not sure what that was

10    because you were working around providing him

11    data. So is it you're not sure of anything

12    that you did may have been given to FDA or you

13    don't know what he gave to the FDA so you

14    can't answer?

15    A.    He told us that in response to

16    the FDA coming in, they may have to do some

17    things like you're talking about gathering

18    counting sheets or doing things like that. I

19    would have been involved in gathering the

20    data. I don't know how he used it.

21    Q.    Do you recall gathering data

22    for Dr. Krah following the inspections?

23    A.    I don't specifically recall

24    what I would have done in support of doing

25    that, no.

Page 309

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q.    Do you remember, is there

3     anything else that you think you may have done

4     to respond to the FDA's questions following

5     their inspections in August or September 2001?

6     A.    Yeah.

7     Q.    What else did you do?

8     A.    There were meetings held

9     throughout Merck that we were informed that we

10    had to attend one of the meetings. The

11    meetings were to tell us what and how to

12    respond the FDA if they talked to us. So they

13    were impromptu assemblies and we were being, I

14    wouldn't say lectured, but we were being told

15    what we need to do, what we're allowed to not

16    do. We were being coached on how to talk to

17    the FDA or deal with the FDA in the event that

18    they came and talked to us and wanted data.

19    Q.    Who held that meeting? Who

20    held that meeting and who spoke at the meeting?

21    A.    What I remember about the

22    meeting is that we were told we had to go to

23    it. Wherever we went, we ended up walking to

24    it. And I ended up -- we ran into DeeMarie

25    who was in a different lab. So her lab, she

Page 310

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     was attending the same meeting we did. So it

3     was -- I can't say it was company wide, but it

4     wasn't restricted to Krah's lab. So I believe

5     Joan might have been at that one, too. And we

6     sat with a group of, you know, more than just

7     Krah's lab. I mean, there was a larger group

8     of people. I don't know who the person was

9     talking, but he was trying to -- he was giving

10    a discussion of how to talk to the FDA if they

11    come in and ask for data. And I remember

12    someone approached him, took over the thing,

13    took over speaking and said the FDA has no

14    right to look at my notes. And he was saying

15    my meaning his notes. He was lecturing on

16    they don't have the right, what gives them the

17    right. They can't look at this data.

18    Q.    You don't remember who that

19    was?

20    A.    No.

21    Q.    But somebody from Dr. Krah's

22    lab?

23    A.    No, no, someone I didn't know.

24    I don't think he was a designated speaker.

25    They were just -- it wasn't very organized.

Page 311

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     People started talking about what rights do we

3     have, do we have to show the FDA stuff, things

4     like that. How to respond to it.

5     Q.    Was there anything that you did

6     that you actually prepared documentation wise

7     to submit to the FDA in response to their

8     inspections in August and September of 2001

9     other than pull together counting sheets?

10    A.    Can you repeat that?

11    Q.    Yes. Was there anything that

12    you did, that you actually prepared,

13    documentation -- any -- I'm sorry, I'll strike

14    that.

15            Was there any documentation

16    that you prepared to be provided to the FDA in

17    response to their questions raised in the FDA

18    inspection in August and September of 2001?

19    A.    So I didn't start gathering --

20    I gathered information like photocopying

21    counting sheets and preserving them. When

22    Krah was destroying plates, I tried to salvage

23    some and hide them so they wouldn't be

24    destroyed. So those things I did before the

25    FDA came in, trying to preserve them.

Page 312

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q.    And after the FDA came in?

3     A.    I put the plates back because

4     it wasn't my place to have them out of where

5     they were designated. I still saved

6     photocopies of the counting sheets and

7     protocols that I had to preserve them. And

8     some of the question is broad to the fact that

9     I did a lot after I left Merck to try and

10    preserve -- lot, that's vague, too. I tried

11    to preserve the information I had in case I

12    would be able at some point in the future to

13    show the FDA or CDC.

14    Q.    What information are you

15    talking about you preserved after you left

16    Merck?

17    A.    The hard copies of documents,

18    photocopies of documents.

19    Q.    Did you ever provide those to

20    the FDA or the CDC, those hard copies of

21    documents you took or photocopied from Merck?

22    A.    After I left Merck?

23    Q.    Yes.

24    A.    No.

25    Q.    Did you ever provide those

Page 313

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     photocopies of Merck -- were they photocopies

3     of Merck counting sheets?

4     A.    A lot of it was the produced

5     documents that you've seen.

6     Q.    But did you ever provide it --

7     other than providing it to us in litigation,

8     did you provide that to FDA or CDC at any

9     point in time?

10    A.    Well, when I worked there,

11    those things would have been available to the

12    FDA if we looked at them. So I was preserving

13    them then. But I didn't independently go and

14    show those documents to anyone outside of

15    counsel.

16    Q.    You can put these aside for the

17    moment.

18            Following the FDA inspection on

19    August 6th, were you still discussing with

20    Dr. Shaw or Dr. -- or Mr. Suter leaving the

21    lab and negotiating some kind of severance

22    agreement?

23    A.    I'm not sure what you're

24    talking about by severance agreement. I think

25    I know what you're talking about. After the

Page 314

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     August inspection by the FDA, I still had

3     communications with Bob Suter and Alan Shaw

4     about how I could get out of Dave's lab.

5     Q.   And did you look for other

6     opportunities at Merck?

7     A.   What to you mean by "opportunities"?

8     Q.   Other places within the company

9     to work other than Dave's lab.

10    A.   I did look to try to move to a

11    lab outside of Dave's lab and outside -- I

12    believe it was outside of Alan's jurisdiction.

13    I'm not sure that's the right word, but to

14    move out of there but still stay at Merck.

15    There was a period of time were I sought that

16    as a solution to be able to stay there.

17    Q.   Did you interview in other labs

18    at Merck? Did you interview for other lab

19    positions at Merck other than Dr. Krah's lab?

20    A.   Can you define interview? You

21    mean like a formal where I applied for it or

22    how do you mean that?

23    Q.   I think you said you were

24    looking for work within Merck but outside of

25    Dr. Krah's lab. Is that correct?

Page 315

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     A.   Yes.

3     Q.   What did you do to that end?

4     A.   Well, let me give you an

5     example. Shaw forced me to take an interview

6     with some guy, I think his name is Conley.

7     So -- I mean, I don't know if I count that as

8     an interview because Conley in the interview

9     said he had no option but to interview me and

10    I was told that I had to go for the interview.

11    It wasn't really an interview because he just

12    said, If you want to work here, you're hired.

13       And I asked him, I said, Why

14    would you hire me? I don't have the kind of

15    background that's real specific to what he's

16    doing.

17       He said, you know, when the

18    executive director, vice president calls you

19    up and tells you to hire somebody or they'll

20    come to your lab, you do it. And I said -- I

21    really appreciated his honesty. I said, I

22    can't take a position in your lab.

23    Q.   So you were offered a position

24    in Dr. Conley's lab but you decided not to

25    take that position?

Page 316

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     A.   I would not characterize that

3     as offered. He was forced to try and take me

4     there. And Shaw was forcing me to go there.

5     Q.   What do you mean forcing you to

6     go there?

7     A.   Shaw said I had to go and take

8     that interview. And Conley said that he was

9     forced to have me work there.

10    Q.   What did Dr. Conley's lab do?

11    A.   I don't remember.

12    Q.   Did you interview or talk to

13    any other employees at Merck about working in

14    another lab other than Dr. Conley?

15    A.   Wait, what was that again?

16    Q.   Did you interview with somebody

17    called Dr. Sepp-Lorenzion or talk to

18    Dr. Sepp-Lorenzion about working in his lab?

19    A.   That name sounds familiar.

20    Yeah. I found my own interview or I found a

21    place that I wanted to go. At one point Shaw

22    was for it. At another point he informed me

23    that that would never happen. So I don't know

24    the chronology of that. But at some point he

25    said I'm never going there.

Page 317

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q.   What lab was that? What

3     position was that?

4     A.   It may have been -- it was a

5     place that I had found the interview for. I

6     can't really say. It may have been that or it

7     may not have been that. I shouldn't guess at

8     that point.

9     Q.   But you found another position

10    at Merck that you wanted to take?

11    A.   I don't recall the exact

12    details, but when Alan said that I can remain

13    in the lab and have Dave continue to retaliate

14    or I can quit and take the money, I said that

15    there was -- you know, in addition to trying

16    to defend myself by saying that he shouldn't

17    support Krah's retaliating against me, I said

18    that there should be an option for me to move

19    outside of Krah's lab but stay at Merck. He

20    said I had one of the two options he named,

21    and I couldn't take the first one. And he

22    wanted me to come back and at least

23    acknowledge as an option that taking money and

24    leaving was an option that I should pursue.

25    But for a while in there, I thought naively



Page 318

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     that maybe I could move out of Krah's lab into

3     another lab and still remain at Merck after

4     the rest of us in Krah's lab had been able to

5     stop the fraud. Beyond that with -- the name

6     you said, I'm not -- I mean, I don't remember

7     all the details.

8     Q.    So you were offered a job with

9     Dr. Conley but you did not take that offer?

10    A.    I'm pretty sure that I said I

11    would not characterize it as being offered a

12    job.

13            Can you read back my response

14    to the first time she asked that? I thought I

15    did. I want to be correct.

16            - - -

17            (A discussion off the record

18    occurred.)

19            - - -

20            (Exhibit Krahling-23, 9/25/01

21    E-mail, RELATOR\_00000745, was marked

22    for identification.)

23            - - -

24    BY MS. DYKSTRA:

25    Q.    I'm going to mark as what I

Page 319

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     think is Exhibit 23 is a September 25, 2001,

3     e-mail from you to Dr. Shaw. Take a look at

4     that.

5     A.    Okay.

6     Q.    So in this e-mail you state in

7     the middle of the paragraph, The company is

8     not in a position to fire me and I am not in a

9     position to be unemployed. However, if you

10    put together a package that includes a fair

11    severance and also the 'bonus' that I'm sure

12    everyone will get after I'm gone, I will in

13    turn -- I will in return give you a letter of

14    resignation and a signature stating I will

15    never pursue litigation against the company.

16            Do you recall writing that?

17    A.    I don't recall writing this

18    exact thing, but this looks right.

19    Q.    Did you discuss this with Shaw,

20    Dr. Shaw at this time as well or just e-mail

21    him this information?

22    A.    We discussed this in person

23    beforehand when he said that I had to -- that

24    my only solution was to voluntarily resign and

25    take the double bonus.

Page 320

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q.    Did you discuss something --

3     after you sent this e-mail, did you discuss it

4     with Dr. Shaw?

5     A.    September 25th, that is late.

6     I don't know. This was after I refused the

7     push to Conley's lab and he was -- he pushed

8     me to at least accept as an option getting

9     paid to leave. And I changed the

10    nomenclature. My proposal was to change the

11    nomenclature and say if that's the way I have

12    to go forward, you can't call it a double

13    bonus, you have to call it a severance.

14            - - -

15            (Exhibit Krahling-24, E-mail

16    string, RELATOR\_00000747, was marked

17    for identification.)

18            - - -

19    BY MS. DYKSTRA:

20    Q.    I'm going to show you what I've

21    marked as Exhibit 24. It is a September 28,

22    2001 -- September 27th and 28th, 2001, e-mail

23    between you and Dr. Shaw. In the first e-mail

24    at the bottom, when you've read that...

25    A.    First e-mail on the bottom?

Page 321

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q.    Uh-huh.

3     A.    What do you got?

4     Q.    So other than these e-mails

5     back and forth, did you discuss with Dr. Shaw

6     in person at this time your proposal for a

7     severance package?

8     A.    I don't recall if I talked to

9     him in person around the end of September.

10    Q.    And then it says at the top of

11    the page, If you are seriously considering my

12    proposal, then I need to know before I meet

13    with my lawyer this afternoon.

14            Do you see that?

15    A.    I see that.

16    Q.    Who was your lawyer that you

17    retained?

18    A.    When I was leaving Merck, I

19    obtained a lawyer, her name is Tonia Torquato,

20    but this -- my proposal was really, it was my

21    acceptance of Alan's push to voluntarily

22    resign. My proposal was to change the

23    nomenclature.

24    Q.    But it says this was your

25    proposal, and I think in the September 25th

Page 322

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 e-mail you stated that if you put together a

3 package that includes a fair severance and

4 also the "bonus" I'm sure everyone else will

5 get, I will in return give you a letter of

6 resignation. Wasn't that your proposal?

7     A.    That's his proposal.

8     Q.    That's his proposal.

9     A.    He said if I stayed in the lab,

10 I wouldn't get the money that Emini promised

11 me we had already earned. Emini had promised

12 us a double bonus when it was finished. Alan

13 was saying if I stayed there, I'd never get

14 that money. And he said if I leave, you can

15 have the -- that I could have the double

16 bonus.

17           My proposal was that it -- you

18 know, he wanted me to accept that just as an

19 option before I left the meeting, and I didn't

20 do that back in July.

21     Q.    Do you know what the value of

22 the double bonus was?

23     A.    Can I finish my answer on that

24 one?

25     Q.    Sure. I thought you were done.

Page 323

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     A.    No. That was -- the proposal

3 to take money to leave Merck was Alan's. My

4 idea was that in order for me to accept this

5 as an option and talk about it, you can't call

6 it a double bonus and leave. You have to --

7 you could say bonus, severance. I didn't like

8 the nomenclature. But I was trying to tell --

9 show him I was playing ball because he said, I

10 want you to come back to me and tell me that

11 you won't sue us, that you take that back, and

12 this was in mid July, and that you'll at least

13 consider taking money to voluntarily resign,

14 to consider it. I said you have to change the

15 nomenclature to severance. And by this time

16 in late September, I was seriously concerned

17 over staying there physically.

18     Q.    Were you threatened physically?

19     A.    Different Merck employees told

20 me that I should be scared for my physical

21 well-being.

22     Q.    Who told you that?

23     A.    Frank Kennedy and Kevin

24 Szczypiorski at two different times. Well,

25 Frank Kennedy numerously. Kevin Szczypiorski

Page 324

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 met with me to tell me I need to be careful,

3 that I should be worried.

4     Q.    Who did they think was going to

5 hurt you physically?

6     A.    They didn't say who. They just

7 said I should be concerned about my physical

8 safety because what had happened was such a

9 big deal and people were very -- Szczypiorski

10 said very pissed off and that I should be very

11 concerned. I was talking to Kevin at the bar

12 right next to the -- right next to Merck.

13 And, you know, that was when I previously told

14 you I had talked to him about the allegations

15 of fraud in the lab. A lot of that happened

16 then. He said, I told you. He said, I told

17 you all along you have to be careful of

18 Colleen and Mary and things like that. He was

19 very concerned about my safety. I thought I

20 was -- you know, he's a good guy to warn me.

21 I'm not saying I agree with him. But that

22 stuff weighs on your mind, you keep hearing

23 it. Frank said that I would be -- he said he

24 would never get in the car with me because he

25 thought it would blow up.

Page 325

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2           So, yeah, by the end of

3 September I was willing to say, Alan, I will

4 listen to -- you say I have to leave and take

5 money. Call it a severance and let's talk. I

6 wanted to go out of there. The FDA had come

7 in.

8     Q.    So you retained -- what was

9 your lawyer's name again, Tonia?

10     A.    I think Tonia -- I don't know

11 how to say her last name.

12     Q.    Tonia Torquato, T-O-R-Q-U-A-T-O --

13     A.    Sounds right.

14     Q.    -- from Donaway Weyandt in

15 State College, Pennsylvania, near where you

16 live?

17     A.    I believe she was in State

18 College. I don't remember all the details.

19     Q.    How many times did you meet

20 with her in connection with your severance

21 agreement or your separation agreement from

22 Merck?

23     A.    Not very often. But I don't

24 recall the exact number of times.

25     Q.    My understanding is Emini --

Page 326

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 Dr. Emini initially proposed a \$15,000

3 severance agreement to you. Do you recall

4 that?

5 A. What are you saying?

6 Q. My understanding is that Merck

7 initially proposed a \$15,000 severance

8 agreement to you through your counsel. Do you

9 recall that?

10 A. I do not recall that.

11 Q. Do you recall that you

12 countered with a \$150,000 severance proposal?

13 A. I do not recall those details.

14 Q. Do you recall that you

15 ultimately agreed on a severance package in

16 the amount of \$22,224?

17 A. I don't remember the details.

18 The one thing I remember is that I was

19 supposed to go back to Merck while it was

20 happening, and I was isolated in a small lab

21 and told not to have a cell phone. I

22 had my -- my co-workers were telling me I

23 needed to be worried about my life and I

24 wanted to get away from -- I wanted to

25 physically be away from Merck.

Page 327

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 Q. I'm going to mark as 26.

3 - - -

4 (Exhibit Krahlung-26, 10/29/01

5 Letter, MRK-KRA00002013 - 00002016, was

6 marked for identification.)

7 - - -

8 BY MS. DYKSTRA:

9 Q. Take a look at that, that's a

10 letter from your counsel to Merck's counsel,

11 October 29, 2001.

12 A. Who did you say it's to or

13 from?

14 Q. From your counsel Tonia

15 Torquato to Alexis Pinto at Merck. On the

16 second page under number 2 in consideration -- it

17 states that "In consideration for your

18 agreement to accept and abide by the terms of

19 this Agreement, Merck agrees to issue a check

20 payable to you in the amount of...\$150,000."

21 Do you recall that you made

22 that proposal to Merck?

23 A. I don't recall seeing this

24 document.

25 Q. You were copied on this

Page 328

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 document. Correct?

3 A. Does that mean cc Stephen

4 Krahlung?

5 Q. That means copied. That means

6 receive a copy.

7 A. Sent as an e-mail.

8 Q. I don't know if it was sent as

9 an e-mail or hard copy.

10 A. Merck had control of my e-mail.

11 I don't recall ever seeing this.

12 Q. So you don't recall ever having

13 conversations with your counsel about these

14 negotiations at all or just this particular one?

15 A. I don't recall my conversations

16 from back then. I remember I wanted to

17 physically be away from Merck. I don't recall

18 seeing this document.

19 Q. You don't recall making a

20 demand of Merck of \$150,000 for a severance

21 agreement --

22 A. I did not make a demand.

23 Q. -- through your counsel?

24 A. I didn't make a demand for

25 \$150,000. What I'm telling you is I don't

Page 329

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 recall seeing this document.

3 Q. Do you recall having discussions

4 with your counsel about making a demand to

5 Merck for a severance agreement and some

6 number of dollars, whether you don't remember

7 150 or not, do you remember that discussion?

8 A. I don't remember a discussion

9 with counsel about any number of 150. I

10 didn't make a demand. What I'm telling you is

11 I don't remember seeing this document. I

12 don't remember ever seeing this document. But

13 I didn't tell my lawyer -- can I say what I

14 didn't tell my lawyer to do?

15 Q. That's up to you.

16 A. I did not make a \$150,000

17 demand of Merck.

18 Q. Are you saying you didn't

19 authorize your attorney or you just don't

20 remember whether you authorized with your

21 attorney to make a demand of \$150,000 to

22 Merck?

23 A. What I know is that I was told

24 I had to go back, that Merck wanted me back in

25 Merck's labs while this negotiation was going

Page 330

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     on and that I was told I couldn't have a cell

3     phone. So I couldn't talk to my lawyer during

4     the day.

5     Q.    I'm going to ask my question

6     again. I need you to answer my question.

7     A.    I thought I just answered it.

8     Q.    No, you didn't.

9             I want to know whether or not

10    you authorized your attorney to make a

11    \$150,000 demand to Merck or you just don't

12    remember authorizing your attorney to do that?

13    A.    I don't recall ever seeing the

14    number \$150,000.

15    Q.    Do you recall having any

16    discussions with your attorney Ms. Torquato

17    about your severance agreement at all?

18    A.    I don't recall a lot of the

19    details back then. But I understand -- I

20    remember saying I would like the money that

21    they're withholding from me, that Emini had

22    said I had already earned. And then this

23    money was -- Shaw said you can be paid that

24    money when you voluntarily resign. That's

25    what I remember about it. And that I had to

Page 331

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     sign -- there was a letter sent that I had to

3     sign in order to physically be away from

4     Merck. I think that does answer your question.

5     Q.    I'm sorry, I don't know about

6     any letter you had to sign. Did you produce

7     that in discovery?

8     A.    I'm sure you have it.

9             MS. DYKSTRA: We don't have a

10    letter so can you produce that?

11            THE WITNESS: You have it.

12            MS. DYKSTRA: That you have to

13    stay away from Merck?

14            THE WITNESS: That's not what I

15    said.

16    BY MS. DYKSTRA:

17    Q.    That you physically be away

18    from Merck?

19    A.    I had to sign a letter in order

20    to be physically away from Merck because I

21    wanted to leave.

22    Q.    So after Ms. Torquato sends

23    this letter, Merck responds. I'm going to

24    show you the response. Actually I'm going to

25    show you a letter in between.

Page 332

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2             - - -

3             (Exhibit Krahling-27, Letters,

4     RELATOR\_00001086 - 00001090, was marked

5     for identification.)

6             - - -

7    BY MS. DYKSTRA:

8    Q.    So in November 26, 2001, your

9    counsel -- Axel Johnson, counsel for Merck,

10   writes to your counsel on November 26, 2001.

11   A.    First page or all of it?

12   Q.    You can just look at the first

13   page first. We'll get to the second letter

14   after.

15   A.    Who is this second one from?

16   The second one is from who?

17   Q.    The second letter is your

18   counsel to Axel Johnson, November 27, 2001.

19   This is how they were produced to us.

20   A.    What's your question?

21   Q.    So the first letter dated

22   November 26, 2001, Mr. Johnson from Merck

23   writes to your counsel asking that -- well,

24   the first -- in the first paragraph stating

25   that the Company is willing to modify the

Page 333

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2   draft Agreement by modifying paragraph 11 to

3   include an obligation by the Company to instruct

4   Dr. Emini, Dr. Shaw and Dr. Krah not to

5   disparage your client, but they're not willing

6   to agree to a "positive employment reference."

7             Do you recall asking your

8   attorney to have that amendment added to your

9   severance agreement?

10   A.    I don't remember the details

11   of -- I asked her -- I wanted to get out and I

12   said I wanted to get away from Merck. I don't

13   remember all the details.

14   Q.    Do you remember that we, the

15   company, asked for, in the second paragraph,

16   that your client return all company property,

17   your client signed out notebooks as follows

18   MMRV331-01: notebook 31688, page 217, 218,

19   from September 21, 2001. These notebook pages

20   are missing. Your client must return these

21   pages or identify where they may be found in

22   the lab.

23             Do you see that?

24   A.    I see it.

25   Q.    Did you take that -- those

Page 334

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     notebook pages out of the lab and not return

3     them?

4     A.    I didn't take original notebook

5     pages out of the lab. I had photocopied

6     documents that I had in my possession. But

7     these are referring to primary notebook pages.

8     And I returned, not returned, I never left

9     Merck with them. Those were put in two safe

10    spots in Merck. One was on Krah's desk and

11    the other was the place where you get the

12    notebooks. These are conversations --

13    Q.    You're sure you never took

14    original documents outside of Merck? I want

15    to make sure you stick to that answer.

16    MR. SCHNELL: Do you want to

17    finish your answer?

18    THE WITNESS: Let me finish

19    this. Is this the -- you're talking

20    about correspondence back and forth

21    between the lawyers and you're asking

22    me every little detail. We can talk

23    about the specifics of this, but I

24    haven't seen these documents. I don't

25    recall seeing them. What was your

Page 335

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     question about this?

3     BY MS. DYKSTRA:

4     Q.    Is it your position that you

5     never took original documents outside of the

6     company?

7     A.    What are you talking about

8     taking? When I worked at Merck, I had

9     photocopies of documents. And one of the

10    reasons I had that is because -- well, the

11    main reason I had those is because Suzie and

12    others were asking me to preserve those

13    documents, but I saw documents being destroyed

14    and ripped up such as counting sheets. So I

15    was preserving them while I worked there.

16    These are photocopies of documents. After I

17    left Merck, I continued to preserve those

18    photocopies of those documents.

19    Q.    If you look at the document,

20    the letter Bates-stamped 1088 to 1089.

21    A.    Sure.

22    Q.    Which is a letter from your

23    counsel back to Axel. It states -- your

24    counsel writes on your behalf,

25    "Additionally....," the second paragraph,

Page 336

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     "...with regard to the notebook pages you

3     referenced my client has assured me he does

4     not have any company documents. He has

5     indicated and assured me he has absolutely

6     placed all documents in their appropriate

7     places...."

8     Do you recall having a

9     discussion with your counsel about that?

10    A.    I don't recall a discussion,

11    but this looks true. I did not have whatever

12    we're defining there as company documents. I

13    had photocopies of documents.

14    Q.    So you understood this to mean

15    originals, not photocopies?

16    A.    I don't know what I thought

17    about it back then. What I'm saying is I

18    didn't take any original documents. I didn't

19    deprive Merck of the data they had. I was

20    trying to preserve the data so that they

21    wouldn't continue destroying it.

22    MS. DYKSTRA: Mark this one.

23    - - -

24    (Exhibit Krahling-28, 11/30/01

25    Agreement, MRK-KRA00582394 - 00582397,

Page 337

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     was marked for identification.)

3     - - -

4     BY MS. DYKSTRA:

5     Q.    I'm going to show you what I'm

6     marking as Exhibit 28. This is a November 30,

7     2001, agreement. Is that your signature on

8     the bottom of page 4?

9     A.    Do you want me to read it?

10    Q.    You may read it, yes, if you

11    want.

12    A.    Okay.

13    Q.    Is that your signature on page

14    4, dated December 6, 2001?

15    A.    That is my signature.

16    MS. DYKSTRA: Can we take a

17    quick two-minute break -- five-minute

18    break?

19    MR. SCHNELL: Take five minutes.

20    VIDEOGRAPHER: The time is

21    6:13. We're going off the video record.

22    - - -

23    (A recess was taken.)

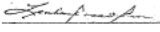
24    - - -

25    VIDEOGRAPHER: The time is

Page 338

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL  
 2 6:21. This begins disc five in the  
 3 videotape deposition of Stephen Krahling.  
 4 MS. DYKSTRA: Thank you,  
 5 Mr. Krahling, we are finished for  
 6 today. I think tomorrow if it works,  
 7 we're not going to go a full seven  
 8 hours tomorrow. If it works for  
 9 everybody, we would propose starting at  
 10 10:00 tomorrow instead of 9:30.  
 11 MR. SCHNELL: How long do you  
 12 think you'll -- I'm not going to hold  
 13 you to it, so we can travel -- make  
 14 travel plans.  
 15 MS. DYKSTRA: I don't think  
 16 more than five hours.  
 17 MR. KELLER: Appreciate it.  
 18 VIDEOGRAPHER: The time is  
 19 6:21. This concludes today's videotape  
 20 deposition of Stephen Krahling.  
 21 - - -  
 22 (Witness excused.)  
 23 - - -  
 24 (Deposition concluded at  
 25 6:21 p m.)

Page 339

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL  
 2 C E R T I F I C A T E  
 3  
 4 I do hereby certify that I am a Notary  
 5 Public in good standing, that the aforesaid  
 6 testimony was taken before me, pursuant to  
 7 notice, at the time and place indicated; that  
 8 said deponent was by me duly sworn to tell the  
 9 truth, the whole truth, and nothing but the  
 10 truth; that the testimony of said deponent was  
 11 correctly recorded in machine shorthand by me  
 12 and thereafter transcribed under my  
 13 supervision with computer-aided transcription;  
 14 that the deposition is a true and correct  
 15 record of the testimony given by the witness;  
 16 and that I am neither of counsel nor kin to  
 17 any party in said action, nor interested in  
 18 the outcome thereof  
 19  
 20 WITNESS my hand and official seal this  
 21 4th day of May, 2017  
 22  
 23   
 24 \_\_\_\_\_  
 25 Linda Rossi-Rios, RPR, CSR  
 Notary Public

Page 340

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL  
 2 INSTRUCTIONS TO WITNESS  
 3 Please read your deposition over  
 4 carefully and make any necessary corrections.  
 5 You should state the reason in the appropriate  
 6 space on the errata sheet for any corrections  
 7 that are made.  
 8 After doing so, please sign the errata  
 9 sheet and date it.  
 10 You are signing same subject to the  
 11 changes you have noted on the errata sheet,  
 12 which will be attached to your deposition.  
 13 It is imperative that you return the  
 14 original errata sheet to the deposing attorney  
 15 within thirty (30) days of receipt of the  
 16 deposition transcript by you. If you fail to  
 17 do so, the deposition transcript may be deemed  
 18 to be accurate and may be used in court.  
 19  
 20  
 21  
 22  
 23  
 24  
 25

Page 341

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL  
 2 - - - - -  
 3 E R R A T A  
 4 - - - - -  
 5 PAGE LINE CHANGE  
 6 -----  
 7 Reason for Change:  
 8 \_\_\_\_\_  
 9 Reason for Change:  
 10 -----  
 11 Reason for Change:  
 12 -----  
 13 Reason for Change:  
 14 -----  
 15 Reason for Change:  
 16 -----  
 17 Reason for Change:  
 18 -----  
 19 Reason for Change:  
 20 -----  
 21 Reason for Change:  
 22 -----  
 23 Reason for Change:  
 24 -----  
 25 Reason for Change:  
 26 -----

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL  
2     ACKNOWLEDGMENT OF DEPONENT  
3     I, \_\_\_\_\_, do  
4 hereby certify that I have read the foregoing  
5 pages and that the same is a correct  
6 transcription of the answers given by me to  
7 the questions therein propounded, except for  
8 the corrections or changes in form or  
9 substance, if any, noted in the attached  
10 Errata Sheet.  
11  
12 \_\_\_\_\_  
13 DATE                   SIGNATURE  
14  
15 Subscribed and sworn to before me this  
16 \_\_\_\_\_ day of \_\_\_\_\_, 2017.  
17  
18 My commission expires: \_\_\_\_\_  
19  
20 \_\_\_\_\_  
21 Notary Public  
22  
23  
24 Assignment: PA 2587889  
25

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA : CIVIL ACTION  
ex rel., STEPHEN A. : NO. 2:10-04374(CDJ)  
KRAHLING and JOAN A. :  
WLOCHOWSKI, :  
Plaintiffs, :  
vs. :  
MERCK & CO., INC., :  
Defendant. :

\_\_\_\_\_ : Master File No.  
IN RE: MERCK MUMPS : 2:12-cv-03555(CDJ)  
VACCINE ANTITRUST :  
LITIGATION :

THIS DOCUMENT RELATES TO: :  
ALL ACTIONS :

- - -  
May 3, 2017

HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY

- - -  
Continued videotaped deposition of  
STEPHEN KRAHLING, taken at the offices of  
Morgan Lewis & Bockius, 1701 Market Street,  
Suite 18-F, Philadelphia, Pennsylvania 19103,  
beginning at 10:09 a.m., before LINDA  
ROSSI-RIOS, a Federally Approved RPR, CCR and  
Notary Public.

- - -  
VERITEXT LEGAL SOLUTIONS  
MID-ATLANTIC REGION  
1801 Market Street - Suite 1800  
Philadelphia, PA 19103



Page 344

1 APPEARANCES:

2

3 On behalf of the Private Plaintiffs

4 SPECTOR ROSEMAN KODROFF & WILLIS, P C

5 BY: JOHN A MACORETTA, ESQUIRE

6 1818 Market Street

7 Suite 2500

8 Philadelphia, PA 19103

9 215 496 0300

10 jmacoretta@srkw-law.com

11

12 On behalf of the Relators

13

14 KELLER GROVER LLP

15 BY: JEFFREY F KELLER, ESQUIRE

16 1965 Market Street

17 San Francisco, CA 94103

18 415 543 1305

19 jfkeller@kellergrover.com

20

21 On behalf of Relators and the Witness

22 Stephen Krahlung

23

24

25

Page 345

1 APPEARANCES (cont'd):

2

3 On behalf of the Defendant, Merck & Co ,

4 Inc

5 MORGAN LEWIS & BOCKIUS LLP

6 BY: LISA DYKSTRA, ESQUIRE

7 and

8 MELINA R DiMATTIO, ESQUIRE

9 1701 Market Street

10 Philadelphia, PA 19103

11 215 963 5000

12 lisa.dykstra@morganlewis.com

13 melina.dimattio@morganlewis.com

14

15 On behalf of the Defendant, Merck & Co ,

16 Inc

17

18 VENABLE LLP

19 BY: MICHAELA F ROBERTS, ESQUIRE

20 750 E Pratt Street

21 Suite 900

22 Baltimore, MD 21202

23 410 244 7400

24 mfroberts@venable.com

25

1 ALSO PRESENT:

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

Page 346

1 INDEX

2

3 WITNESS PAGE

4 STEPHEN KRAHLING

5

6 By Ms Dykstra 348

7

8 E X H I B I T S

9 MARKED DESCRIPTION PAGE

10 Krahlung-29 E-mail chain, 381

11 RELATOR\_00002632 & 00002633

12

13 Krahlung-30 1/29 E-mails 381

14 RELATOR\_00002631

15 Krahlung-31 1/29/04 Supplemental 433

16 Biologics License

17 Application,

18 MRK-KRA0000032 - 00000139

19

20 Krahlung-32 Update: Multistate 460

21 Outbreak of Mumps ---

22 United States, January

23 1--May 2, 2006

24 Krahlung-33 About the Vaccine 465

25 printout from CDC website

1

2 Krahlung-34 Mumps Outbreak --- New 474

3 York, New Jersey, Quebec,

4 2009

5

6 Krahlung-35 8/20/99 Letter with 486

7 attachments,

8 MRK-KRA00018614 - 00018619

9

10 Krahlung-36 E-mail chain, 497

11 MRK-KRA00002281 & 00002282

12

13 Krahlung-37 9/7/01 E-mail, 501

14 RELATOR\_00000746

15

16 Krahlung-38 9/11/01 E-mail, 509

17 RELATOR\_00000750

Page 347

1 DEPOSITION SUPPORT INDEX

2 DIRECTION TO WITNESS NOT TO ANSWER

3 Page Line

4 366 10

5 405 3

6

7

8 REQUEST FOR PRODUCTION OF DOCUMENTS

9 Page Line

10 (None)

11

12

13

14

15 STIPULATIONS

16 Page Line

17 (None)

18

19

20 QUESTIONS MARKED

21 Page Line

22 (None)

23

24

25

Page 348

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2             - - -

3             VIDEOGRAPHER: We are now on

4     the record.

5             Today's date is May 3, 2017,

6     and the time is 10:09 a.m. This is the

7     continuation deposition of Stephen

8     Krahling. The witness was previously

9     sworn in.

10            - - -

11            STEPHEN KRAHLING, after having

12     been previously duly sworn, was

13     examined and testified as follows:

14            - - -

15            EXAMINATION

16            - - -

17 BY MS. DYKSTRA:

18     Q.     Hi, Mr. Krahling. Good morning.

19     A.     Good morning.

20     Q.     You are still under oath, you

21     understand that?

22     A.     Yes.

23     Q.     Yesterday we spoke about your

24     departure from Merck. When was the last time

25     you physically worked at the company? I

Page 349

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     understand you signed a separation agreement,

3     but when was the last time you were physically

4     at Merck?

5     A.     I don't recall the exact dates.

6     I know it was after October 1st and before I

7     signed -- or before the date on the letter

8     that was signed.

9     Q.     So before your separation

10    agreement, but after October 1st, sometime in

11    there was the last time you were at --

12    physically at the company?

13    A.     Definitely it was sometime

14    between October, November, December 2001.

15    Hard to narrow it down further than that.

16    Q.     Since -- we'll just use

17    December 1 for the purposes of the discussion.

18    Since that time, December 1, have you spoken

19    to any people employed by Merck?

20    A.     Yes.

21    Q.     Can you tell me who and when

22    you spoke to them?

23    A.     The who certainly. The when is

24    going to be -- let's start, Jon Gombola, Suzie

25    Maahs, Joan. Jill did -- well, let's start

Page 350

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     with that group there because I saw them all

3     together. I'm not sure when, but it was very

4     shortly -- they still worked there and I

5     didn't. So that's the window for that group.

6     Q.     Anybody else that you had

7     spoken with that was still employed by Merck?

8     A.     Jill DeHaven, but I don't -- I

9     have no -- I don't recall when. Not anything

10    remotely recently.

11    Q.     Okay.

12    A.     Kristin Haas. The question is

13    when I saw them in person, communication,

14    right?

15    Q.     Communication, right.

16    A.     So the general idea here is

17    that I knew them well when I worked there, so

18    when I left, I was probably talking to them

19    regularly and then that faded. So the most

20    recent contact with Kristin would be that up

21    until recently, and it may even be including

22    last year, we still exchanged Christmas cards

23    at the holidays.

24    Q.     That was Kristin Haas you were

25    talking about?

Page 351

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     A.     Yeah. And then DeeMarie Watson

3     was her maiden name, Skulsky was her married

4     name.

5     Q.     When did you talk to her -- or

6     when did you communicate with her last?

7     A.     I communicated with her

8     somewhat frequently for the first few years.

9     I can't remember if we sent Christmas cards or

10    not. But probably by the time of 2010.

11    Definitely by 2010 I wasn't -- I don't know,

12    it would have been before that. I would just

13    say contact within the first few years after

14    that, not really. It's hard to put an end

15    date. I know I wasn't talking to them after

16    2009. Even in -- other than to send Christmas

17    cards.

18    Q.     How do you know that date, is

19    there something specific about 2009 or you

20    just recall?

21    A.     Well, that's the year -- I'm

22    pretty sure that's the year or the year before

23    that I met these guys. And they said -- I

24    mean, they -- I can't say what they said.

25            Oh, I have something more to

Page 352

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL  
 2 add.  
 3 Q. Sure.  
 4 A. Because I haven't looked in  
 5 forever, but I think I'm Facebook friends with  
 6 some of them. So I kind of just left that  
 7 hang. So I'm not sure that counts as  
 8 communication in the sense that -- I don't  
 9 know how that counts as communication, but...  
 10 Q. So in 2009 when you were  
 11 referring to when your communication with the  
 12 employees in the lab ceased, you're referring  
 13 to when you retained your current counsel. At  
 14 that point --  
 15 A. Before you move on, I want to  
 16 make sure that --  
 17 Q. Sure.  
 18 A. Because I met with Kevin --  
 19 Q. Kevin?  
 20 A. -- Szczypiorski, S-C-Z  
 21 something, something P-I-O-R-S-K-I.  
 22 But, I believe I was still  
 23 employed at the time. However, that's --  
 24 certainty on that is maybe 70 percent. So it  
 25 may not have been. It was in 2001, though.

Page 353

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL  
 2 Sam Calarco is another one.  
 3 Q. When do you think you last  
 4 communicated with Sam?  
 5 A. I saw him after I left at least  
 6 one time that I remember. Maybe more. But at  
 7 least one time. And that was at Penn State.  
 8 He came up, he had gone to school there and he  
 9 came up to go out to the bars. We went out,  
 10 had some drinks, hung out.  
 11 Q. Anybody else?  
 12 A. That worked at Merck. It's  
 13 limited to who worked at Merck. Right?  
 14 Q. Yes.  
 15 A. And at the moment I don't  
 16 recall any.  
 17 Q. The group that you mentioned  
 18 you spoke with, I believe you said all  
 19 together, Jon Gombola, Suzie Maahs, Joan  
 20 Wlochowski and Jill DeHaven --  
 21 A. I have another one. Frank  
 22 Kennedy was at that one.  
 23 Q. At this meeting we were just  
 24 talking about with these four people together?  
 25 A. Yeah. Yes, yes.

Page 354

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL  
 2 Q. So we have Frank Kennedy, Jill  
 3 DeHaven, Joan Wlochowski, Suzie Maahs and Jon  
 4 Gombola?  
 5 A. Can you read the list again?  
 6 Q. Yes.  
 7 A. Slowly.  
 8 Q. Jon Gombola, Suzie Maahs, Joan  
 9 Wlochowski, Jill DeHaven and Frank Kennedy.  
 10 A. I'm not sure that Jill DeHaven  
 11 was at that -- I don't remember. The other  
 12 ones were definitely there. I don't know  
 13 whether Jill DeHaven was at that when we got  
 14 together that time.  
 15 Q. When you got together this  
 16 gathering, where was it and when did it  
 17 happen?  
 18 A. I wanted to point out Frank  
 19 Kennedy since we just added him. That was --  
 20 I didn't see him after that time.  
 21 Q. So that was -- this meeting,  
 22 can we call it a meeting?  
 23 A. Yeah, I don't see why we can't  
 24 call it a meeting.  
 25 Q. I just don't want to use the

Page 355

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL  
 2 wrong phrase.  
 3 A. It's fine.  
 4 Q. The meeting that you know Jon  
 5 Gombola, Suzie Maahs, Joan Wlochowski and  
 6 Frank Kennedy were at, and possibly Jill  
 7 DeHaven, that occurred when?  
 8 A. I think the best I can say is  
 9 that I think they still worked there. I'm not  
 10 sure of the contract employees like Jon and  
 11 Suzie because they may still have been in  
 12 school. I'm not sure their -- I'm not sure  
 13 their status. And also that they were  
 14 contract employees. But I seem to remember  
 15 that I wasn't at Merck anymore and they were.  
 16 And to what degree -- I can give you some  
 17 items that I remember that inform on it, but I  
 18 don't want to say that I'm guessing.  
 19 Q. No, what can you remember  
 20 discussing?  
 21 A. I remember Joan's husband  
 22 brought flowers in and sat them on the table.  
 23 I'm trying to think if that was for some  
 24 occasion. And we played croquet, so it was  
 25 warm enough to be outside and play croquet.

Page 356

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     So it seems unlikely it was January. Do you

3     want the temperature?

4     Q.    Sure.

5     A.    It was above 50 degrees and it

6     was below 90. It wasn't July.

7     Q.    Where were you when you met

8     with them?

9     A.    Wherever Joan lived at the

10    time. It was her -- I mean, I don't know if

11    she owned it, house. Her residence.

12    Q.    So you were in her residence,

13    you were at Joan's residence?

14    A.    Her residence.

15    Q.    Okay. Was it just a gathering

16    of friends? Was it some other event?

17    A.    You'll think that's -- I

18    offered the temperature and you wanted it. I

19    should say that I'm talking about the high for

20    the day. I don't know how cool it got at

21    night, but that's just a stupid thing. Go

22    ahead with your question, because you can

23    actually narrow down how many months it was

24    for after that, so I'm trying to be accurate.

25    Q.    I appreciate that. The meeting

Page 357

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     or the gathering was at Joan's residence, you

3     said?

4     A.    Yep. Yes.

5     Q.    Was it just for you all to get

6     together to meet or was there some other event

7     that she was having in her house?

8     A.    She just had people over.

9     Q.    This was on just one occasion

10    that you met with them at Joan's house?

11    A.    That was the only time I recall

12    being at Joan's house. So outside of that...

13    Q.    So I assume you were sitting

14    outside?

15    A.    That was the only time I

16    remember being at Joan's residence when she

17    lived there.

18    Q.    What are you distinguishing

19    from, you were somewhere when she lived

20    somewhere else?

21    A.    Yes.

22    Q.    Tell me about that.

23    A.    Jeff and I went out to see her.

24    Q.    When was that?

25    A.    Sometime between the time I met

Page 358

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     him and before we filed the lawsuit.

3     Q.    You went to Joan's house with

4     Jeff at that -- to meet with Joan?

5     A.    It was to meet with her.

6     Q.    Had you had communication with

7     Joan -- let me go back to the meeting.

8            The meeting in, probably sometime

9     in 2002 at Joan's residence with this group of

10    people?

11    A.    I think we can call it 2002.

12    Q.    In 2002, what did you, Jon,

13    Suzie, Joan, Frank and possibly Jill talk

14    about?

15    A.    Actually you bring up a good

16    point. There's a possibility considering that

17    I left in October, on October 1st, there's a

18    probability that it occurred in October. So I

19    shouldn't narrow that down because when I left

20    in October I had hoped or felt that I wouldn't

21    be back. So it's quite possible we met in

22    October when I still worked there. I mean, I

23    actually can't narrow it down past that. I

24    know they all worked there. So if Jon and

25    Suzie weren't working there back when it

Page 359

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     started to get warm, then it would have had to

3     have been October, November. So I actually

4     can't tell you with any certainty. It would

5     be after October 1st and before it got cold

6     again the next year. Sorry about that.

7     Q.    That's fine. What did you talk

8     about at this meeting at the end of October --

9     at the end of 2001, beginning of 2002,

10    whatever that time frame is, what did you talk

11    about?

12    A.    We didn't really -- whatever

13    happened to be going on at the time. Like

14    Joan had kids. One or both of Suzie or Jon

15    was going to, maybe it was Villanova. You

16    know, light things.

17    Q.    Did you talk about what had

18    occurred in Dr. Krah's lab or your work in

19    Dr. Krah's lab?

20    A.    Not that I recall. But I don't

21    think so. I'm not sure. I don't think

22    anybody wanted to talk about that at that

23    point. Take a day off, who wants to ruin a

24    weekend. So I don't recall.

25    Q.    Did you talk about the FDA

Page 360

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 inspection?

3     A.    At that meeting?

4     Q.    Yes.

5     A.    I think that would be encompassed

6 under I don't recall. I mean, I can guess.

7     Q.    I don't want you to guess. If

8 you have like an educated guess or you think

9 you're right.

10    A.    Educated guess, I know I

11 wouldn't have wanted to talk about it. But --

12 so when I say I don't recall, I have reason to

13 believe I don't recall because it didn't

14 happen.

15    Q.    I assume this may fall under

16 the same topic of your work in Dr. Krah's lab,

17 but you also didn't talk to them about your

18 discussions with the company around your

19 separation or any type of severance agreement

20 or anything like that?

21    A.    I remember that Joan's husband

22 brought flowers, put them on the table. I

23 asked what occasion it was. And he said

24 something like "I just get my wife flowers."

25 I remember meeting Joan's kids and playing

Page 361

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 croquet. I remember that it was warm enough

3 not to be that -- feel that cold playing

4 croquet. And it was mostly sunny. Beyond

5 that, I remember who was there, minus that I'm

6 a little fuzzy on Jill or not. So I don't

7 know. Beyond that, really nothing.

8     Q.    And you said you met with Jill

9 DeHaven and Kristin Haas as well beyond this

10 one meeting at Joan's house?

11    A.    No, not at Joan's house. No,

12 these are separate things.

13    Q.    That was at --

14    A.    These would be -- now put that

15 meeting aside.

16    Q.    Put that meeting aside, right.

17 Then did you -- who else did you meet with?

18 You said you met with -- did you meet with

19 Jill DeHaven after the meeting at Joan's

20 house?

21    A.    I don't know if I met with her.

22 There were communications. I just have the

23 feeling we stayed in touch for a bit because I

24 remember someone getting ahold of me saying,

25 you know, Jill was -- you know, you haven't

Page 362

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 stayed -- Jill mentioned you haven't stayed in

3 touch. And having the memory that, oh, yeah,

4 we tried to stay in touch, but... So I have

5 reason to believe, like, because you're

6 getting along with people, you don't just

7 leave and never talk to them again.

8     Q.    Did you talk to any of the

9 people that you had worked with in Dr. Krah's

10 lab following your departure from the company

11 about what had -- the misconduct that you

12 allege in your complaint?

13    A.    You mean after the time that I

14 was employed there?

15    Q.    Yes.

16    A.    Outside of counsel?

17    Q.    Yes.

18    A.    No.

19    Q.    Did you talk -- this is a yes

20 or no because I don't want to know the

21 substance of the conversations to get into

22 privilege. But did -- who did you and your

23 counsel meet with to discuss the allegations

24 in the complaint from -- I'm going to restate

25 this.

Page 363

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2            Identify the people that you

3 and your counsel met with to discuss your

4 allegations of fraud after you left the

5 company?

6            MR. SCHNELL: You're excluding

7 experts, consultants and all that I

8 assume?

9 BY MS. DYKSTRA:

10    Q.    Yes, I'm talking about the

11 people -- I'm sorry. I'm talking about the

12 people in the lab. Who did you and your

13 counsel meet with from Merck?

14    A.    Could you provide an example

15 that would be responsive to that?

16    Q.    Yes.

17    A.    I can't think of one.

18    Q.    It's a badly worded question.

19    A.    No, it's fine, I just want to

20 make --

21    Q.    So you and Jeff Keller went to

22 visit Joan?

23    A.    Yes.

24    Q.    You talked to Joan?

25    A.    Yes.

Page 364

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q.    About timing and substance?

3     A.    He made sure her husband was

4 out of the room.

5     Q.    Who else did you and your

6 counsel meet with that had been at Merck?

7     A.    Oh, at Merck. Did we call Jon

8 Gombola? Did I call him or did you call him?

9 There was something about reaching out to Jon

10 Gombola. We're restricting to work at Merck

11 so I don't have to think wider than that.

12    Q.    Just current or former employees

13 of Merck.

14    A.    Oh, he would have been former,

15 maybe, I think.

16        MR. KELLER: I would not --

17 just to be clear, anybody that you know

18 or participated in, not something that

19 you may have learned from discussions

20 with your counsel, those are

21 privileged, so...

22        THE WITNESS: I don't really

23 remember anything except maybe I talked

24 to him on the phone because for some

25 reason you said --

Page 365

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2        MR. KELLER: Don't disclose

3 anything you and I talk about. That's

4 privileged.

5        THE WITNESS: I'm not sure I

6 remember. I think I talked to him on

7 the phone.

8        Can I move on to start to think

9 of the other people?

10 BY MS. DYKSTRA:

11    Q.    Sure.

12    A.    All right. That worked at

13 Merck at some point?

14    Q.    Correct.

15        MR. SCHNELL: I want to interrupt

16 for a second.

17        MS. DYKSTRA: Sure.

18        MR. SCHNELL: So you're

19 asking -- just so we're clear on the

20 question, you're asking who -- other

21 people he met with counsel?

22        MS. DYKSTRA: Any meeting that

23 Mr. Krahlung had with counsel and a

24 current or former employee of Merck.

25        THE WITNESS: Wait. Are you

Page 366

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 saying with counsel?

3        MR. KELLER: That's the point.

4 BY MS. DYKSTRA:

5    Q.    Just if meetings occurred and

6 with whom. So if you and your counsel met

7 with a current or former employee of Merck, I

8 want you to identify who those current

9 employees or formers are.

10        MR. SCHNELL: I think this is

11 work product, who we may have discussed

12 and decided was worth talking to. So

13 I'm going to object and instruct the

14 witness not to answer.

15 BY MS. DYKSTRA:

16    Q.    I assume you're going to follow

17 your attorney's instruction?

18    A.    Definitely. He doesn't object

19 very often. I'm not trying to make a joke. I

20 mean that.

21    Q.    Other than meetings with your

22 counsel, did you independently and

23 individually, putting aside meetings with your

24 counsel, did you meet with any current or

25 former employees of Merck following your

Page 367

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 departure from the company other than the

3 meeting you disclosed at Joan's residence?

4    A.    Yes.

5    Q.    Go through those people and

6 tell me what you talked about and when.

7    A.    You're talking meet in person?

8    Q.    Any communication. I'm trying

9 to put aside the meeting at Joan's house.

10    A.    Yeah. So we're moving on to

11 the next people on the list.

12    Q.    To the next people, okay.

13    A.    Who do you want to go with

14 next?

15    Q.    So I guess DeeMarie Watson

16 Skulsky.

17    A.    Yes, DeeMarie.

18    Q.    DeeMarie.

19    A.    She e-mailed me often. Well, I

20 mean, she e-mailed me while I worked at Merck.

21 So when I leave, you know, I leave Merck,

22 people still e-mail you. So if you think of

23 it in terms of -- it's not like -- I wasn't

24 shunned, everybody liked -- well, a lot of

25 people there liked me. So I still stayed in

Page 368

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL  
 2 touch with her. I met her in person at least  
 3 one time. I would say it was within the  
 4 following year or two. And I think it's  
 5 because her husband may have gone to Penn  
 6 State or they had friends at Penn State, but  
 7 she was up at Penn State, knew I was there,  
 8 and she invited us over to go, I don't know if  
 9 it was a tailgate or just a party at her  
 10 friend's place. But it was her and her  
 11 husband and her friend and maybe somebody who  
 12 he -- her, those friends she knew, and it was  
 13 at her friend's place and it was just outside  
 14 of -- might have been in the boroughs they  
 15 called it. It was at Penn State.  
 16 Q. At that time, did you discuss  
 17 anything that had occurred in Dr. Krah's lab  
 18 with DeeMaria?  
 19 A. DeeMarie.  
 20 Q. DeeMarie.  
 21 A. No.  
 22 Q. Did you talk or communicate  
 23 with DeeMarie any other time after that  
 24 occasion?  
 25 A. I think so. I'm not sure when

Page 369

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL  
 2 our communications ended. That kind of  
 3 trailed off. I don't know that I can guess at  
 4 a stop date. I mean, I think she's a friend  
 5 of mine on Facebook. So -- but we don't  
 6 really message on Facebook or do anything like  
 7 that. I don't do -- try not to do that. I  
 8 mean, I think the last I heard from her, she  
 9 was saying that something about, you know, she  
 10 had talked to Jill and Jill wondered why I  
 11 didn't write to her anymore. Something like  
 12 that. But I -- that had to be -- I mean, I  
 13 don't know that I can narrow that down other  
 14 than mid 2000s.  
 15 Q. Okay. That's fine.  
 16 A. It was before -- I'm not sure.  
 17 I can't narrow that down.  
 18 Q. And I think the other two  
 19 people you identified that you had met with  
 20 who were current or former employees at Merck  
 21 were Kevin Szczypiorski and Sam Calarco?  
 22 A. Start with Kevin Szczypiorski.  
 23 Q. Sure.  
 24 A. I hung out with him at that bar  
 25 that is right next to Merck's facility that a

Page 370

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL  
 2 lot of Merck employees go to.  
 3 Q. Did you talk about anything  
 4 that had occurred in Dr. Krah's lab?  
 5 A. I'm pretty sure I still worked  
 6 there at the time, because I certainly  
 7 wouldn't have driven up there just to hang out  
 8 at that bar. So I'm certain -- I'm reasonably  
 9 certain it was after August 2001 but before  
 10 December 2001.  
 11 Q. Did you talk about what  
 12 occurred in Dr. Krah's lab?  
 13 A. Yes.  
 14 Q. Tell me the substance of the  
 15 conversation to the extent that you remember  
 16 it?  
 17 A. Mostly he was informing me of  
 18 things. So I didn't have to tell him much of  
 19 anything because he already knew the FDA came  
 20 in. So he was telling me about how the kind  
 21 of scientific misconduct he sees in that lab  
 22 has been going on long before I was there,  
 23 when he was there.  
 24 And he said, Why do you think I  
 25 got out? He said, you know -- he told me

Page 371

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL  
 2 that, he said, you always liked Colleen and  
 3 got along with Colleen. I told you she was  
 4 like this. But I still defended Colleen as a  
 5 friend. I thought she was good. But I  
 6 appreciated that he was -- he wanted to meet  
 7 with me, he was concerned. And then he said  
 8 that what he heard, that this was a very, very  
 9 big deal with the FDA and I should really be  
 10 concerned about my physical safety.  
 11 Q. In what way should you be  
 12 concerned about your physical safety?  
 13 A. He said I could be killed. He  
 14 thought they'd kill -- like somebody would  
 15 kill me. That it was costing the -- it was  
 16 costing the company so much money.  
 17 Q. What was list position at the  
 18 time that you met with him? Where was he  
 19 working within Merck?  
 20 A. I don't know. He was not in  
 21 Krah's lab anymore. I was under the  
 22 impression -- I mean, it's not like he got  
 23 kicked out of Krah's lab. He was a permanent  
 24 employee during that first year and a half  
 25 where I was a contract employee. So he would

Page 372

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     have been -- he and Colleen were two of the

3     real workhorses in that lab when I first

4     showed up. And so they were basically equal

5     status under Mary. Or I guess you could call

6     it seniority. And Kevin was one of the people

7     when you talked just about training, he would

8     have been like sit down with me, here's how we

9     culture MRC-5 cells, here's how we do VZV

10    potency assays, things like that. So that

11    was -- were you asking his position?

12    Q.    Yes.

13    A.    Yeah, that was his position. I

14    don't --

15    Q.    Do you know what lab he worked

16    in at the time that you were meeting with him?

17    A.    No.

18    Q.    Not Dr. Krah's lab?

19    A.    No, I was going to give you the

20    end of that is I don't recall him doing the

21    PRN testing. So he left -- well, gives you a

22    window. I'm not sure when he left.

23    Q.    Do you know where -- I'll just

24    call him Kevin. Do you know where Kevin works

25    now or lives now?

Page 373

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     A.    I have no clue about him now.

3     Q.    When he made the comment that

4     this was a big deal, and the FDA's inspection

5     was a big deal and you should be, I think you

6     said, afraid for your life --

7     A.    He said something like they're

8     going to -- they'll kill you. It wasn't

9     like -- guys don't talk like, oh, you should

10    be afraid. He's like, dude, don't you worry

11    they're going to kill you. They'll kill you.

12    Q.    Did you think that he was

13    serious that you might actually be -- your

14    life might be in danger?

15    A.    I try not to give into things

16    like that because I was -- yeah, I was still

17    there at the time because he was warning me to

18    get out. I had to have still worked there.

19    But you know what, I mean, even if you think

20    there's only a 15 percent chance he's true,

21    man, it's your life, it starts to gnaw on you.

22    Then you hear it from someone else that says

23    -- Frank Kennedy said I will never get in the

24    car with you. You got to be -- you should

25    look under there every time, it's going to

Page 374

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     blow up. And, you know, I was like, are you

3     joking? I said, Don't say things like that.

4     I don't need that stuff on my mind.

5            He's like, I'm dead serious, I

6     will never get in the car with you. So, yeah,

7     I mean part of you says, ah, these are these

8     guys guessing. But they're Merck employees

9     and this is their employer and they're saying

10    people are upset. This is a big deal, you're

11    costing people money. So it weighs on your

12    mind even if you have every reason to believe,

13    ah, that wouldn't happen.

14    Q.    Did you do anything about --

15    with this information, for example, did you go

16    to the authorities?

17    A.    I just tried to leave Merck. I

18    didn't want to be there.

19    Q.    So, no, you did not report

20    it -- this?

21    A.    That my friends thought I might

22    get killed?

23    Q.    Yes, did you report that to

24    anybody?

25    A.    That didn't seem reportable.

Page 375

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     What's there to report?

3     Q.    And Sam Calarco, when did you

4     last speak to him?

5     A.    Sometime within a year or two

6     after I left Merck.

7     Q.    And did you talk about things

8     that had occurred in Dr. Krah's lab?

9     A.    My God, no. No way.

10    Q.    Why do you say it like that?

11    A.    Because he was up for the

12    weekend. We went out to the bars, didn't talk

13    about Merck.

14            Am I speaking loudly enough?

15            MR. KELLER: Yes, they can hear

16    you.

17    BY MS. DYKSTRA:

18    Q.    So we've gone through the

19    people that you spoke with who were former and

20    current Merck employees about your -- about

21    what occurred in Dr. Krah's lab or who you met

22    with who were former or current employees.

23    Who did you speak to, if anyone, about your

24    allegations or the issues raised in your

25    complaint that were from the media?



Page 376

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 MR. SCHNELL: Object to the

3 form.

4 THE WITNESS: Can you be

5 more -- allegations. Wait.

6 Allegations. So you're --

7 BY MS. DYKSTRA:

8 Q. Did you speak to anybody in the

9 media about the issues raised in your complaint?

10 A. The issues raised in my

11 complaint which could still be prior to the

12 complaint being filed.

13 Q. Correct.

14 A. Yes.

15 Q. Who did you speak to that was a

16 member of the media?

17 A. I believe we listed it in the

18 interrogatories.

19 Q. I think it's Exhibit 6 if you

20 want to refresh your recollection.

21 A. We have it? I had have it?

22 Q. It's already marked.

23 A. Sharyl Attkisson. Right?

24 Q. Yep.

25 A. What page?

Page 377

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 Q. Page 41, I believe.

3 MR. SCHNELL: It's not Exhibit 6.

4 THE WITNESS: There's no page 41.

5 MR. SCHNELL: It's not Exhibit 6.

6 MS. DYKSTRA: It's not Exhibit

7 6. I didn't mark my copy. We'll get a

8 copy for you.

9 MR. SCHNELL: It's 21, Exhibit 21.

10 BY MS. DYKSTRA:

11 Q. Your reference to Sharyl

12 Attkisson is on page 41 of your interrogatories,

13 if that will help you refresh your recollection.

14 A. Page 41?

15 Q. Yes.

16 A. Refreshes my recollection when

17 it was.

18 Q. Do you remember any details of

19 your conversation with Ms. Attkisson?

20 A. I remember she -- we spoke

21 about -- I remember she introduced me to a

22 producer and the guy didn't have time to talk

23 because a journalist had been kidnapped in the

24 Middle East and they had information about him

25 which wasn't public yet or break -- they were

Page 378

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 on some story like that. So things were real

3 short. And I remember when she walked me down

4 when I was leaving, she asked some questions

5 about the HPV vaccine. That's about all I

6 recall.

7 Q. What did she ask you about the

8 HPV vaccine?

9 A. I can't remember. I just

10 remember she seemed interested in the HPV

11 vaccine.

12 Q. Did you have an opportunity to

13 tell her about your allegations or the issues

14 raised in your complaint?

15 A. Did I have an opportunity? I

16 mean, I don't recall what we talked about

17 other than that Middle Eastern thing broke in

18 the middle of it.

19 Q. Did you have any other

20 conversations with her after this initial

21 conversation?

22 A. I don't recall, but I don't

23 think so. I don't think I did. I believe

24 that I don't recall because I did not.

25 Q. Other than -- putting aside for

Page 379

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 the moment the meetings that you may have had

3 with the Department of Justice and your

4 counsel, have you talked to anybody from the

5 government?

6 A. Government. That's a really --

7 Q. Yes.

8 A. The guy who delivers my mail

9 works for the government.

10 Q. Putting aside the postal service.

11 A. That's one small section. I

12 mean, can you be more specific, government?

13 Q. No.

14 A. I don't know who works for the

15 government and who doesn't. Doesn't the

16 government -- one of the largest employers of

17 people in the country? I mean -- oh, you're

18 talking about allegations in the lawsuit,

19 though, being specific?

20 Q. Yes. Any conversations about

21 the issues raised in your lawsuit with any

22 conversations with people who were employed by

23 the government?

24 A. So what I'd have to do is go

25 through the interrogatories and see if the

Page 380

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     people we listed there worked for the

3     government.

4     Q.   Well, I think that the only

5     person you list in your interrogatories seems

6     to be employed by the government currently or

7     formerly is Dr. Silvia Stojanov?

8     A.   Okay. Well, then -- she works

9     for -- does she work for the NIH?

10    Q.   According to your interrogatory

11    answer, yes. According to your --

12    A.   I didn't look at that yet.

13    Should we go there then? Yes. I e-mailed --

14    did I e-mail -- yeah, I -- I think I reached

15    out to her.

16    Q.   It's on page 57 of your request

17    if you'd like to look at the paragraph.

18    A.   57?

19    Q.   57, yes.

20    A.   Obviously there must be an

21    e-mail somewhere, but I think I know the

22    content of it without looking at it.

23    Q.   We'll show it to you. We will

24    mark it Exhibit 29.

25    - - -

Page 381

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     (Exhibit Krahling-29, E-mail

3     chain, RELATOR\_00002632 & 00002633, was

4     marked for identification.)

5     - - -

6     MS. DYKSTRA: And Exhibit 30

7     because there's two.

8     - - -

9     (Exhibit Krahling-30, 1/29

10    E-mails RELATOR\_00002631, was marked

11    for identification.)

12    - - -

13    BY MS. DYKSTRA:

14    Q.   Exhibit 29 is dated January 26th

15    and has two e-mails and Exhibit 30 is dated

16    January 29th. If you could take a look at

17    those.

18    A.   So you're saying there's three

19    e-mails?

20    Q.   There's two e-mails on Exhibit 29

21    and then there's one e-mail on Exhibit --

22    well, two e-mails on Exhibit 30 I guess.

23    A.   There's not an October e-mail?

24    Q.   There's an October e-mail on

25    the bottom of Exhibit 29.

Page 382

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     A.   I didn't see the back.

3     Q.   That's okay. It starts on the

4     bottom of Exhibit 29.

5     MR. KELLER: Lisa, which

6     exhibit is which?

7     MS. DYKSTRA: Exhibit 29 is the

8     January 26th and October 26th chain and

9     Exhibit 30 is just the January 29th at

10    the top.

11    THE WITNESS: All right.

12    BY MS. DYKSTRA:

13    Q.   So on the first e-mail on

14    Exhibit 29 dated October 26th, I think you

15    represented yourself to be Dr. Pequot,

16    P-E-Q-U-O-T?

17    A.   I don't think so.

18    Q.   Who is Dr. Pequot? Is that not

19    you?

20    A.   It's nobody.

21    Q.   It's nobody?

22    A.   I don't know any Dr. Pequot.

23    I'm not Dr. Pequot.

24    Q.   So you produced these to us.

25    Do you know who wrote these e-mails?

Page 383

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     A.   I wrote this e-mail. That's my

3     e-mail address.

4     Q.   Pequot@cyber-rights net?

5     A.   Yes, that was my e-mail at the

6     time.

7     Q.   On Exhibit 30 it's signed

8     Dr. Pequot.

9     A.   Oh, that may be because she

10    made the mistake of calling me that so I went

11    with it. Yeah, because she took that out of

12    my e-mail, so I just stuck with it.

13    Q.   Have you ever used that name

14    any other time?

15    A.   No. It's a weird name. She

16    just saw Pequot and figured that was my name.

17    Q.   So you just went with it?

18    A.   What am I going to sign?

19    Q.   At the e-mail on Exhibit 29

20    that you wrote -- so you wrote this e-mail on

21    Exhibit 29 at the bottom, dated October 26th?

22    A.   See, I didn't sign it

23    Dr. Pequot on that one. That was her

24    response. Wait, what are you saying, I signed

25    it?

Page 384

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q.    I just want you to focus on the

3 e-mail at the bottom, October 26th, right, it

4 goes to the next page.

5     A.    Got it.

6     Q.    You say at the beginning that

7 you're a virologist in vaccine research.

8     A.    Uh-huh.

9     Q.    And this is in 2008. Were you

10 doing vaccine research at this time?

11    A.    Published a paper in 2007. I

12 consider myself a virologist.

13    Q.    And who did you work on to

14 publish the paper in 2007? Who did you work

15 with, I'm sorry?

16    A.    It's on the resume that you had

17 yesterday. It was in Schlegel's lab at Penn

18 State.

19    Q.    That was published in 2007?

20    A.    Uh-huh.

21    Q.    What did you do, what kind of

22 work did you do to publish that paper?

23    A.    Cell-based assay. I was an

24 author on it. One of the authors of the

25 paper.

Page 385

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q.    What work did you do? Did

3 you --

4     A.    I did cell-based assays and I

5 wrote part of the manuscript.

6     Q.    Are you still writing manuscripts?

7     A.    That was the last publication I

8 had.

9     Q.    Why did you give up writing

10 publications?

11    A.    Why did I give it up? I don't

12 understand the question.

13    Q.    You said 2007 was the last

14 publication you had. Correct?

15    A.    Yeah.

16    Q.    Did you -- are you still

17 writing manuscripts?

18    A.    That was the last publication I

19 had.

20    Q.    So you're not working on

21 manuscripts -- did you work on any manuscripts

22 following this 2007 publication?

23    A.    I may have -- I made myself

24 available for people's questions or help in

25 Schlegel's lab, but I mean, that's just what

Page 386

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 you do as a courtesy. So I didn't publish any

3 papers after that.

4     Q.    Are you working on any papers

5 currently?

6     A.    What do you mean by "papers"?

7 Does the complaint count as a paper?

8     Q.    No. Something that's going to

9 be published in a journal or other scientific

10 medium.

11    A.    No, I'm not working on any --

12 I'm not working on that right now, I'm busy

13 with other things.

14    Q.    What other things?

15    A.    What we're doing here today

16 keeps me pretty busy.

17    Q.    Other than working on this

18 litigation against Merck, what else do you do

19 with your time?

20    A.    I take care of my children.

21    Q.    How old are they again?

22    A.    13 and 11.

23    Q.    Girls or boys?

24    A.    One of each.

25    Q.    Anything else that you do with

Page 387

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 your time?

3     A.    Well, I mean, you want my

4 recreational activities?

5     Q.    Sure.

6     A.    The kids, my wife and I like to

7 look at birds. They like golfing. My

8 daughter is really good at tennis. She's

9 left-handed, she has got a nice backhand.

10 There's all sorts of things.

11    Q.    Any other I'll call it

12 professional work that you're doing other than

13 taking care of your children and this

14 litigation?

15    A.    There's not much time left

16 after this. This is probably, other than

17 taking care of my kids, is the most important

18 thing I'm doing.

19    Q.    Going back to these exhibits,

20 did you have any other communications with

21 Ms. Stojanov after this in January 2009?

22    A.    I have no reason to believe I

23 did. I think this is it.

24    Q.    Did you speak with anybody else

25 or communicate with anybody else from the

Page 388

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     government about the issues raised in your

3     complaint other than the communications you

4     may have had with your counsel?

5     A.    If I did, it would be in the

6     interrogatories if they worked for the

7     government. I don't know who does and doesn't

8     work for the government.

9     Q.    And you've said previously, I

10    think, you've never had communications with

11    the FDA or the CDC about the issues raised in

12    your complaint putting aside the issues you

13    discussed with the FDA in 2001?

14    A.    Start with putting aside, can

15    you rephrase it, putting aside so that I can

16    mentally put it aside and then ask your

17    question?

18    Q.    Sure. Putting aside the

19    discussions you had with the FDA in 2001 --

20    A.    Yes, okay.

21    Q.    -- I believe you testified

22    previously that you have had no discussions

23    with the CDC or the FDA around the issues in

24    your complaint?

25    A.    I think that's accurate.

Page 389

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q.    I know you said you talked to

3     and you retained counsel prior to your current

4     counsel, Mr. Moody?

5     A.    Yes.

6     Q.    Did you provide Mr. Moody any

7     documentation related to the issues and

8     concerns raised in your complaint?

9     A.    He went through the same things

10    these guys did. They preserved the documents,

11    don't talk to anyone and then provide him a

12    copy of the copies I had, all of them to make

13    sure I had them all to preserve them. Like

14    preservation. I'm not sure, but he gave me

15    directions to make sure they're in one place,

16    make sure people don't share them, things like

17    that.

18    Q.    Are there any documents that

19    Mr. Moody received from you related to the

20    issues in the complaint that you have not

21    produced here in this litigation?

22    MR. SCHNELL: Are you talking

23    about outside of work product?

24    MS. DYKSTRA: Yes, outside of

25    his work product.

Page 390

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     THE WITNESS: What's work

3     product? What are you talking about?

4     You're looking for something that maybe

5     I gave him that these guys didn't get

6     that wouldn't have been produced to

7     you?

8     BY MS. DYKSTRA:

9     Q.    Yes.

10    A.    No. No. These guys have it

11    all. These men and women.

12    Q.    I missed what you said, I'm

13    sorry?

14    A.    Guys, men and women.

15    Q.    I think I just want to clarify

16    a couple of other things you mentioned

17    yesterday before we proceed on to another

18    topic.

19    You had said that you had --

20    you obviously have complaints about what

21    occurred in Dr. Krah's lab, and you said you

22    had heard from another employee at Merck that

23    there were issues or concerns in an HPV lab.

24    Correct?

25    A.    You could generally characterize

Page 391

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     it as that.

3     Q.    I just want to make sure there

4     were no other concerns or issues raised that

5     you heard or you know about with respect to

6     any other labs at Merck?

7     A.    Any other labs or any other

8     products?

9     Q.    Any other labs.

10    A.    I think so. But I mean, it

11    depends on what you're talking about labs,

12    because Krah's lab worked with other labs so

13    the product itself was the problem, and it was

14    worked on in both labs.

15    Q.    Both labs meaning?

16    A.    Whatever the other lab was.

17    They were working on the HIV adenoviral vector

18    vaccine and they had a big problem with it.

19    Q.    I'm not sure I follow. Are you

20    saying that Dr. Krah was involved in that

21    work?

22    A.    I was, too.

23    Q.    I just want to make sure I know

24    the full scope of where you believe there may

25    have been scientific misconduct. So anything --

Page 392

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     A.    I don't want to use the word

3     fraud. There's legal stuff there. Misconduct,

4     there were problems.

5     Q.    So Dr. Krah's lab, the HP --

6     lab working on the HPV vaccine you mentioned.

7     A.    I would just say that the HIV

8     adenoviral vaccine product would be responsive

9     to your question if you're talking about

10    potential scientific misconduct. I can't

11    make -- legal fraud, I don't know.

12    Q.    Did you ever work in Merck's

13    laboratory operations group in Merck's

14    manufacturing division?

15    A.    I don't know what the -- I

16    don't know what the laboratory operations

17    group is. If you're talking about the

18    physical, wherever it is -- I don't recognize

19    the name. I did work that supported

20    manufacturing.

21    Q.    You mean the work you did in

22    Dr. Krah's lab may have supported manufacturing?

23    A.    No, it did. He explained how.

24    Q.    But other than the work in

25    Dr. Krah's lab, you never worked in any of the

Page 393

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     manufacturing facilities?

3     A.    My labor was not physically

4     present -- I don't even know where that place

5     is. But I -- my labor was done in Krah's lab

6     other than that one time they stuck me in

7     another room.

8     Q.    Have you ever reviewed Merck's

9     quality manuals, SOPs, policies or procedures

10    that are used by Merck's manufacturing

11    division?

12    A.    If I was required to review

13    them for the job, then I reviewed them. I

14    don't recall.

15    Q.    In your work at Merck, did you

16    ever run a TCID50 assay?

17    A.    You're talking about a potency

18    assay?

19    Q.    A specific TCID50 assay.

20    A.    To determine the amount of

21    virus that's present. I don't think I did. I

22    don't recall. I don't think I did, though.

23           MS. DYKSTRA: Let take a break

24    and we'll switch topics.

25           VIDEOGRAPHER: The time is 11:00.

Page 394

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     We're going off the video record.

3     - - -

4     (A recess was taken.)

5     - - -

6           VIDEOGRAPHER: The time is 11:17.

7     We're back on the video record.

8    BY MS. DYKSTRA:

9     Q.    Mr. Krahling, tell me how and

10    where you met Mr. Moody.

11    A.    I met him in Pittsburgh. And I

12    met him through an intermediary.

13    Q.    Who is the intermediary?

14    A.    Liz Birt.

15    Q.    What does Liz Birt do? What is

16    her profession?

17    A.    I don't know.

18    Q.    How do you know Liz Birt?

19    A.    I don't know her anymore.

20    Q.    Well, how did you -- how did

21    she become an intermediary to introduce you to

22    Mr. Moody?

23    A.    How did I meet her?

24    Q.    Yes.

25    A.    I don't recall how I met her.

Page 395

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q.    Who is she, Liz Birt?

3     A.    In what sense, I don't know

4     what --

5     Q.    You said she introduced you to

6     Mr. Moody. Who is -- in what context did you

7     know her?

8     A.    I mean, I was communicating

9     with her, so I knew her in the sense that we

10    communicated.

11           MS. DYKSTRA: What Exhibit is

12    that? 21?

13    BY MS. DYKSTRA:

14    Q.    She's mentioned in your

15    interrogatory responses if that will refresh

16    your recollection. I just want to know who

17    she is, how you met her and how she came to

18    introduce you to Mr. Moody.

19    A.    I don't remember how I met her.

20    Q.    And you don't remember what she

21    did for a living?

22    A.    For a living? No.

23    Q.    Do you know what profession she

24    was in at all?

25    A.    I don't know what profession

Page 396

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 she was in.

3     Q. Did you contact her about

4 meeting Mr. Moody?

5     A. No.

6     Q. How did you come in contact

7 with Ms. Birt? In your interrogatory answers,

8 if it helps you to refresh your recollection,

9 you state that you spoke with now deceased

10 Elizabeth Birt, former staff person to former

11 Congressman Dan Burton, in early May 2003 in

12 Chicago, Illinois about topics relating to

13 your allegations in the amended complaint

14 regarding the mumps vaccine. The two met at

15 the Autism One conference held at Loyola. You

16 spoke to Ms. Birt about your concerns

17 regarding the efficacy of the mumps vaccine.

18     MR. SCHNELL: What page is

19 that, please?

20     MS. DYKSTRA: That is on

21 page 43, I believe.

22     THE WITNESS: Okay. So what's

23 the question?

24 BY MS. DYKSTRA:

25     Q. Is that answer accurate? Does

Page 397

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 that refresh your recollection at all about

3 your conversation with Ms. Birt?

4     A. It doesn't refresh my

5 recollection with my conversations with her,

6 no.

7     Q. Do you recall anything other --

8 anything about your conversations with her

9 other than the fact that you spoke to her in

10 May of 2003 about the allegations in your

11 complaint?

12     A. She introduced me to Dan Burton

13 just to say hi. I can't remember if I knew at

14 the time or if she worked at the time. Like

15 former staff person, I don't know what that

16 refers to, if it was former back then or

17 former now.

18     Q. Well, she's deceased, so she --

19     A. Still former. Well --

20     Q. You don't remember how you

21 first came to know Ms. Birt?

22     A. No.

23     Q. You don't remember any detail

24 of the conversations you may have had with

25 Ms. Birt?

Page 398

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     A. The only thing I can say for

3 certain is that she knew I had previously

4 worked at Merck. Other than that, I don't

5 recall.

6     Q. Do you know whether you reached

7 out to her or she reach out to you in the

8 first instance?

9     A. I don't recall.

10     Q. Do you know how many times you

11 spoke to her?

12     A. Two times that I remember.

13     Q. Tell me about the conversations.

14     A. I don't remember the first one

15 other than that she introduced me to Dan

16 Burton. The second one she introduced me to

17 my lawyer. So that conversation occurred in

18 front of my lawyer.

19     Q. Which conversation, the

20 introduction?

21     A. The second time I would have

22 seen her.

23     Q. How did she know that you were

24 looking for a lawyer?

25     A. I don't know.

Page 399

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     MR. SCHNELL: I'm going to

3 object to that question.

4     THE WITNESS: It assumes I was

5 looking for a lawyer. I don't even

6 recall that -- I can't even -- I can't

7 affirm that that's true.

8 BY MS. DYKSTRA:

9     Q. She introduced you to Dan

10 Burton you said. Is that correct?

11     A. Yes.

12     Q. Who is Dan Burton?

13     A. Who is he now?

14     Q. Who was he at the time when she

15 introduced you in 2003?

16     A. Congressman Dan Burton,

17 Republican Indiana. I don't know if he was a

18 congressman at the time. I had the impression

19 that he was a congressman at the time.

20     Q. Do you remember your discussion

21 with Mr. Burton?

22     A. I remember he said -- it was

23 very short and he said hi. If you need

24 anything or whatever, talk to Liz. He was --

25 something like that. Like he was -- she

Page 400

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 introduced me to him, he was letting me know

3 that she knew him. That was it.

4 Q. Did you talk to him about your

5 concerns that are raised in your complaint?

6 A. That was the extent of the

7 conversation.

8 Q. How long was your conversations

9 with Liz Birt?

10 A. I have no idea. I don't recall.

11 Q. Do you know, was it at -- did

12 you meet Liz Birt and/or Dan Burton at an

13 Autism One conference?

14 A. I met them in Chicago.

15 Q. Did you meet Liz Birt or Dan

16 Burton -- Liz Birt or Dan Burton at an Autism

17 One conference?

18 A. I think they were -- I don't

19 know their involvement. I have the impression

20 he was involved in it. I didn't attend the

21 conference.

22 Q. Your interrogatory answer says

23 the two met, meaning you and Ms. Birt, at the

24 Autism One conference. And you spoke to Birt

25 about your concerns about the mumps vaccine.

Page 401

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 Is that accurate?

3 A. I have no reason to believe

4 that's not accurate except for it was probably

5 at the hotel where that might have been. I

6 didn't attend the conference. I think he was

7 speaking at it or he was involved in it. The

8 point was that's where he was.

9 Q. You said you did not attend the

10 Autism One conference in 2003. Is that correct?

11 A. I didn't attend it in the sense

12 that I didn't go to any of the -- what do they

13 have, well, talks or whatever. I didn't

14 attend any of the talks.

15 Q. Did you attend any of the

16 events other than the speaking engagements?

17 Did you attend, for example, cocktail hours or

18 presentations otherwise?

19 A. I didn't say I attended any

20 speaking engagements.

21 Q. I'm just talking about what you

22 attended at the conference and what you didn't

23 attend at the conference.

24 A. I didn't attend any informational

25 things at that conference that they do. I

Page 402

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 didn't go there to attend the conference.

3 Q. What did you go there to do?

4 A. I was in information gathering

5 mode. I think I had known Liz Birt before

6 that, and I can't remember if she invited me

7 or not.

8 Q. You think you knew Ms. Birt

9 before the conference, is that what you said?

10 A. I don't -- no, I don't recall.

11 I don't want to guess on why I went there. I

12 know what happened when I was there and the

13 fact that she introduced me to Dan. That's

14 the extent of that.

15 Q. What happened when you were

16 there at the conference? What do you remember?

17 A. What do I remember?

18 Q. Well, you just said you know

19 what happened when you were there, you don't

20 remember why you went there, I think is what

21 you said. So I want to understand what

22 happened when were you at the conference that

23 you recall?

24 A. I don't recall what the

25 motivation was for if someone invited me, if I

Page 403

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 thought to go, if I knew before. I know that

3 at some point -- I mean, what I remember is

4 that Liz Birt introduced me to Dan Burton

5 that -- he introduced himself in a way to let

6 me know that I should talk to Liz Birt

7 about -- you know, that I should talk to her,

8 that basically letting me know that he knew

9 her. That was the extent of my talk with Dan

10 Burton at that conference, or in the hotel

11 where I believe the conference was that he was

12 speaking at, if he was speaking at it.

13 Q. Do you believe vaccine causes

14 autism?

15 A. I have no opinion on that.

16 Q. You don't know one way or the

17 other or you don't have a belief one way or

18 the other?

19 A. I don't study autism. I don't

20 know. So I have no opinion.

21 Q. Do you vaccinate your children?

22 MR. SCHNELL: I'm going to

23 object to getting into privacy matters.

24 I don't know what the relevance of that

25 is.

Page 404

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2             MS. DYKSTRA: Well, if you

3     believe or you don't know whether

4     vaccines cause autism, it informs your

5     decision about whether you vaccinate

6     your children generally.

7             MR. SCHNELL: I don't see the

8     relevance and I don't want to get into

9     privacy. You've already tried that

10    information, we objected and we moved

11    on and we're going to maintain that

12    objection.

13            MS. DYKSTRA: Whether or not

14    his children are vaccinated you think

15    is a significant enough issue under the

16    confidentiality and protective order

17    entered in this case that he can't

18    answer that question?

19            MR. SCHNELL: It's a privacy

20    issue.

21    BY MS. DYKSTRA:

22            Q. Are you going to follow your

23    attorney's advice?

24            A. Yes.

25            Q. Well, he didn't instruct you

Page 405

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2    not to answer just to be clear. He objected.

3            MR. SCHNELL: No, I am

4    instructing him not to answer. If you

5    believe that that invades your privacy,

6    then I instruct you not to answer. If

7    you don't believe it invades your

8    privacy, then you're free to answer.

9            THE WITNESS: I'm not answering

10   the question.

11   BY MS. DYKSTRA:

12            Q. You said you were in information

13   gathering mode?

14            A. Uh-huh.

15            Q. What information were you

16   gathering at the Autism One conference?

17            A. I didn't say -- I was -- from

18   the time I left Merck until I found a lawyer,

19   I was curious about what information I knew,

20   what the public knew. I was curious if there

21   was information that the vaccine didn't work,

22   wasn't safe, things like that.

23            Q. What information did you gather

24   at the 2003 autism conference?

25            A. I don't recall.

Page 406

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2            Q. Did you talk to -- you said you

3   talked to Liz Birt about the allegations in

4   your complaint. Correct?

5            A. Well, we want to be very

6   responsive when we write these things, and I

7   knew she knew I worked at Merck.

8            Q. Yes.

9            A. So I believe I may have to some

10   degree, but I don't recall what I discussed

11   with her.

12            Q. Did you talk about the

13   allegations in your complaint or the issues

14   that you saw at Dr. Krah's lab with anybody

15   else at the Autism One conference in 2003 or

16   in the vicinity of the Autism One conference

17   in 2003?

18            A. I believe it's listed here but

19   there were two different points, Kimberly

20   Green, Andrea Rock, they had heard that I

21   worked at Merck.

22            Q. Who is Kimberly Green?

23            A. I remember she said she did

24   something about with film. That's all I

25   remember about her career.

Page 407

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2            Q. Who is Andrea Rock?

3            A. I think she said she was --

4   well, it's got to say in here. What page are

5   we at? It's in here somewhere.

6            Q. I believe it's on page 55.

7            A. It says she's a journalist or

8   at least was a journalist.

9            Q. What did you talk to Ms. Green

10   and Ms. Rock about? Did you talk to them

11   together actually?

12            A. No.

13            Q. What did you talk to Ms. Green

14   about?

15            A. The only thing I recall is that

16   they knew I had worked at Merck. And I didn't

17   deny that. So I felt it was responsive to put

18   it in here.

19            Q. Do you recall speaking with

20   Ms. Green about the allegations in your

21   complaint?

22            A. Like specifics of --

23            Q. What happened in Dr. Krah's

24   lab.

25            A. I don't recall that.



Page 408

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q.   Do you recall speaking about

3   Dr. Krah's lab and what you saw there with

4   Ms. Rock?

5     A.   No, I don't recall that.

6     Q.   You said you were in information

7   gathering mode, and you defined that as being

8   curious about whether the vaccine didn't work

9   or wasn't safe. And in that capacity who did

10  you speak to about whether the vaccine worked

11  or was safe?

12       MR. SCHNELL: Object to the

13   form.

14       THE WITNESS: I didn't seek out

15   information. I wanted to hear what

16   everyone else was saying.

17  BY MS. DYKSTRA:

18   Q.   You didn't ask people at the

19  conference whether they thought the vaccine

20  was effective or safe?

21   A.   I was a fly on the wall.

22   Q.   Did you learn anything about

23  the vaccine's effectiveness at the conference?

24   A.   I don't recall.

25   Q.   You don't recall?

Page 409

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     A.   I don't know why I would have,

3   but I don't recall, no. I don't -- can I

4   answer that -- we're talking about public

5   perception.

6     Q.   Did you do anything else to

7   investigate or in your information gathering

8   mode other than -- well, wait. I'm sorry.

9   Strike that.

10        You said you were listening to

11  what other people had to say about the vaccine

12  as opposed to seeking out answers. Correct?

13   A.   Yeah, people walk by in

14  hallways, do whatever. But meet Dan Burton,

15  go home, see what the general feel there is.

16  I don't recall. Because I wasn't there to be

17  taught by whatever they have at the --

18  whatever the -- I'm not sure how the

19  conference is set up.

20   Q.   So you went on an information

21  gathering trip from Pittsburgh to Chicago but

22  you didn't attend any of the informational

23  sessions at the conference?

24   A.   No, that's -- the reason is Dan

25  Burton was there and he's a representative and

Page 410

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2   he's concerned about vaccine safety which is

3   tied straight with vaccine efficacy and

4   effectiveness. I mean, if you want to say a

5   motivation, it would be to meet somebody with

6   a potential power to do something if that were

7   a possible avenue. Information gathering

8   mode, you're sticking on the part where it's

9   like finding out what people think, whatever.

10  It's also if this fraud is still going on,

11  what options are there. That's information

12  gathering mode. That doesn't require me to go

13  say, hey, do you have an idea. It's what's

14  going on. I have a lot of knowledge from

15  Merck and I don't know what's public and I

16  don't know what's hidden.

17   Q.   So did you or did you not

18  attend any of the informational sessions at

19  the Autism One conference?

20   A.   I didn't attend those.

21   Q.   Where did you meet Mr. Burton,

22  you said in the hotel at the conference?

23   A.   A hallway somewhere.

24   Q.   And that was --

25   A.   I think it was in the hotel.

Page 411

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2   Q.   That was the purpose of your

3   visit, to meet Mr. Burton?

4   A.   I wouldn't say the purpose. I

5   mean, I don't recall whether I -- I don't

6   recall. I mean, there's no purpose. There's

7   no purpose that I recall, like, I went out

8   there.

9   Q.   You said the reason is Dan

10  Burton was there and he's a representative and

11  concerned about the vaccine. If you want to

12  say motivation, it would be to meet somebody

13  with potential power to do something. So I'm

14  asking is that what you're saying, that you

15  went to the conference to meet Mr. Burton?

16   A.   I know I met him there and I

17  thought this guy has power, that's a possible

18  thing, but I didn't know there was an avenue

19  to go forward there or not, because I still

20  didn't know what the FDA was doing at the

21  time. So I didn't want to do anything, I

22  didn't have an avenue forward to stop the

23  fraud if I had any evidence that it was still

24  going on other than the fact that I didn't see

25  it stopped. It's really hard to apply a

Page 412

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     motivation to something I don't recall. I

3     remember I met the guy, he seemed powerful and

4     maybe there was an option there. He empowered

5     Liz, like I know this woman, yes. And then

6     that was it.

7     Q. Did you disclose to him in your

8     brief conversation with him that you witnessed

9     fraud at Merck's laboratories?

10    A. No, I did not.

11    Q. Why not?

12    A. Because I talked to him for

13    about 20 seconds. He produced himself and

14    empowered Liz.

15    Q. Did you tell Liz I witnessed

16    fraud in Merck's laboratories?

17    A. I don't recall what I talked to

18    her about.

19    Q. When did she introduce you to

20    Mr. Moody?

21    A. 2003.

22    Q. Was it at or around this

23    conference, this Autism One conference in

24    Chicago?

25    A. It was in Pittsburgh.

Page 413

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q. Okay. Tell me about the meeting

3     and how she introduced you.

4     A. She was sitting at a table and

5     she introduced Jim Moody. And then Jim Moody

6     started talking.

7     Q. Where was this? Where did this

8     occur?

9     A. Pittsburgh.

10    Q. I know Pittsburgh. Where in

11    Pittsburgh?

12    A. Downtown.

13    Q. Where downtown?

14    A. My best guess would be a hotel,

15    but I'm not sure.

16    Q. Did Ms. Birt live in Pittsburgh

17    or did she fly to Pittsburgh to meet with you?

18    A. No idea.

19    Q. But she arranged the meeting

20    with Mr. Moody?

21    A. From what I understand.

22    Q. And you, Ms. Birt and Mr. Moody

23    met in Pittsburgh in 2003 potentially at a

24    hotel?

25    A. I can't -- I shouldn't guess.

Page 414

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q. Was it a restaurant? Was it an

3     office?

4     A. There was no one else around,

5     we were at a table.

6     Q. And what did you -- the three

7     of you discuss at the initial meeting before

8     you retained him as your counsel?

9     MR. SCHNELL: Well, even if

10    it's before retention, it could still

11    be privileged if they're talking about

12    a potential retention. I wasn't there,

13    I don't know. But I'm going to caution

14    the witness you cannot disclose

15    attorney-client communication to the

16    extent he ultimately became his lawyer.

17    THE WITNESS: I can't answer

18    that, it's privileged.

19    BY MS. DYKSTRA:

20    Q. When you were meeting with

21    Mr. Moody, was Ms. Birt present?

22    A. I think to start the meeting.

23    Q. Tell me about what happened

24    while Ms. Birt was present.

25    MR. SCHNELL: I'm still not

Page 415

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     sure that changes anything, because I

3     don't know what capacity Ms. Birt was

4     there.

5     THE WITNESS: She introduced

6     him by name and me and he immediately

7     started talking.

8     BY MS. DYKSTRA:

9     Q. Was she still sitting there

10    while he started talking?

11    A. I don't recall. At some point

12    she wasn't there.

13    Q. Tell me, to the extent that you

14    recall sitting here today, the conversation you

15    had with Mr. Moody and Ms. Birt?

16    A. It was immediately privileged.

17    Q. Is Ms. Birt a lawyer?

18    A. No, Jim Moody was my lawyer.

19    Q. But Ms. Birt is there, it's not

20    privileged.

21    MR. SCHNELL: Well, we don't

22    know what -- was she working for the

23    Congressman at the time?

24    THE WITNESS: I have no idea.

25    MS. DYKSTRA: She wasn't

Page 416

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 working for his lawyer at the time, so

3 it's --

4 MR. SCHNELL: We don't know if

5 she was a consultant. Could have been.

6 I'm not trying to be difficult. I just

7 don't know what her capacity was at the

8 time.

9 THE WITNESS: She introduced me

10 by name, he started talking, she

11 disappeared.

12 MR. SCHNELL: Well, do you

13 recall what part of the conversation

14 occurred when she was still there?

15 THE WITNESS: When she spoke

16 and said -- and introduced us. She

17 didn't talk again.

18 MR. SCHNELL: But when did she

19 leave? We're trying to separate was

20 there any time she was there when you

21 were talking substantively to Moody?

22 THE WITNESS: He was talking

23 substantively to me.

24 MR. SCHNELL: It doesn't

25 matter.

Page 417

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 THE WITNESS: Okay. She left

3 at some point. I mean, I don't know

4 when. She introduced us. He started

5 talking. She disappeared.

6 MR. SCHNELL: We could quibble

7 about whether she's covered or not, but

8 I would be willing to let him talk

9 about when she was there because I -- I

10 don't know.

11 MR. KELLER: As long as you

12 agree that it's not a waiver to any

13 kind of privilege.

14 MS. DYKSTRA: I would agree

15 that it's not a waiver of his

16 conversation with Mr. Moody after he

17 retained him.

18 BY MS. DYKSTRA:

19 Q. Do you recall in the initial

20 portion of the conversation what Mr. Moody was

21 saying to you prior to Ms. Birt leaving the

22 table?

23 A. Yes. The very first thing he

24 did was hand me some document that described

25 what a qui tam lawsuit was. I had never heard

Page 418

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 of it. He explained it. She wasn't there by

3 the end of that.

4 Q. So at some point during his

5 explanation of what a qui tam lawsuit was she

6 left the table?

7 A. Yeah, that took a while.

8 Q. How long did that take?

9 A. She was gone before he was done

10 with that. I don't know. Probably about the

11 time he was talking about Abraham Lincoln.

12 But that's -- yeah, he talked about Abraham

13 Lincoln.

14 Q. During the meeting with Mr. Moody,

15 was that when you actually retained him as

16 your counsel?

17 A. He said that very quickly.

18 MR. KELLER: I want you to be

19 very careful.

20 BY MS. DYKSTRA:

21 Q. Just kind of a yes or no to the

22 extent that you can answer.

23 MR. KELLER: No. Very

24 carefully. When you sat down with

25 Mr. Moody, were you seeking legal

Page 419

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 advice?

3 THE WITNESS: Yes.

4 MR. KELLER: That's it.

5 BY MS. DYKSTRA:

6 Q. From the time that you met with

7 Mr. Moody at that time, from that point

8 forward, did he become your counsel?

9 A. Yes.

10 Q. He was your counsel from 2003

11 to 2009?

12 A. I'm not sure the end date. I'm

13 not sure how -- the timing of the transition.

14 Q. Did you file -- I apologize if

15 I asked this yesterday, I don't recall.

16 MR. SCHNELL: You did.

17 MS. DYKSTRA: Do you mind if I

18 ask again just to be clear?

19 MR. SCHNELL: No.

20 BY MS. DYKSTRA:

21 Q. Prior to retaining Mr. Keller

22 and Mr. Schnell, did you file a False Claims

23 Act or a whistleblower complaint in any

24 jurisdiction?

25 A. I did answer that yesterday.

Page 420

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2             MR. SCHNELL: You can answer.

3             THE WITNESS: No.

4 BY MS. DYKSTRA:

5     Q. Did you and Mr. Moody attend

6 Autism One conferences together?

7     A. No.

8     Q. Did you attend any other Autism

9 One conferences?

10    A. Define attend.

11    Q. Either attend an informational

12 session or any other portion of the conference.

13    A. No.

14    Q. Did you go to the hotel where a

15 conference was held at the time the conference

16 was held?

17    A. Yes.

18    Q. Which -- in what instances, at

19 what times did you do that?

20    A. I can't recall each year.

21    Q. How many conferences did you

22 attend in the broad way we're speaking?

23    A. I don't know the exact number.

24    Q. Can you give me an approximate

25 number?

Page 421

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     A. Less than half a dozen.

3     Q. Do you know what years you

4 attended these meetings?

5     A. I don't know which years.

6     Q. I think the only one you

7 disclosed in addition to the 2009 is a 2009

8 conference in your answers to discovery. Do

9 you recall attending the 2009 autism

10 conference in Chicago?

11    A. I'm not sure of the exact year,

12 but I didn't attend it, I went to Chicago

13 because that's where Jim Moody was. To meet

14 with Jim Moody.

15    Q. Did you also speak with Stan

16 Kurtz? You have in your answers to

17 interrogatories he's an independent researcher

18 of vaccines and other childhood issues, and

19 you spoke to him and his wife Michelle about

20 topics related to the allegations in your

21 amended complaint at the Autism One conference

22 in 2009. That's on page 53.

23    A. It was in the hotel where the

24 conference was at in 2009 in Chicago, yes.

25    Q. Can you give me any details

Page 422

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 about your conversation with Mr. Kurtz? Tell

3 me what details you remember about your

4 conversations with Mr. Kurtz.

5     A. I remember he said that if I

6 needed new counsel, that he could -- he knew

7 people he could put me in contact with.

8     Q. Did you tell Mr. Kurtz that you

9 were unhappy with your counsel, meaning

10 Mr. Moody?

11    A. I don't recall, but I shouldn't

12 guess at it. I don't recall the details of

13 why he would have said if you need new counsel

14 or if you need counsel. I don't even know

15 that he said new counsel. He basically said

16 he could be an intermediary and get me in

17 touch with lawyers. I'm not sure of the

18 circumstances beyond that.

19    Q. You don't recall what you said

20 that would have instigated that response from

21 Mr. Kurtz?

22    A. No.

23    Q. You don't recall anything else

24 about your conversation with Mr. Kurtz other

25 than he said if you need a lawyer, I can find

Page 423

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 one for you?

3     A. The take-home message, from

4 what I remember, was that he had a possible

5 avenue to be able to talk to another lawyer.

6 That's what I remember about it.

7     Q. And you don't remember one way

8 or the other whether you told him you were

9 dissatisfied with your current lawyer?

10    A. I don't recall.

11    Q. Did you tell Mr. Kurtz that you

12 had been trying to pursue an action against

13 Merck for five or so years?

14    A. I don't remember the details of

15 why he offered to be an intermediary to talk

16 to another lawyer.

17    Q. Would you recommend Mr. Moody

18 as counsel to somebody else?

19    A. For what kind of -- what are we

20 talking about? I mean --

21    Q. If they had a potential False

22 Claims Act case.

23    A. I don't have a whole lot of

24 experience with lawyers to recommend one way

25 or the other.

Page 424

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 Q. Would you recommend Mr. Moody

3 as counsel to somebody else if they had a

4 potential False Claims Act case?

5 A. I would always recommend these

6 guys first.

7 Q. You're not answering my

8 question. Would you or would you not

9 recommend Mr. Moody to somebody else if they

10 had a False Claims Act case?

11 A. Not with a better option

12 available. I'd recommend these, Constantine

13 Cannon, Keller Grover.

14 Q. Other than the 2003 and 2009

15 autism conferences, did you attend any other

16 autism conferences in the broad sense we're

17 speaking, meaning go to the area where the

18 conference is held?

19 A. I'm not sure. I think I

20 went -- I may have gone to Chicago to meet Jim

21 Moody. I don't know the number of times.

22 Q. Did your wife attend the trips

23 to Chicago with you?

24 A. No.

25 Q. Mr. Krahling, you left Merck in

Page 425

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 November/December 2001. Following your

3 departure from the company, did you ever see,

4 other than in connection with this case, any

5 of the submissions Merck made to the FDA

6 around Protocol 007?

7 MR. SCHNELL: Object to form.

8 THE WITNESS: What do you mean

9 in connection with the case?

10 BY MS. DYKSTRA:

11 Q. I know you produced in this

12 case, the company has produced in this case a

13 lot of submissions and filings that the

14 company had with the FDA over a long period of

15 time. You weren't at the company for that

16 entire period of time. So what I'm asking you

17 is other than things that you may have seen

18 through the course of discovery in this case,

19 have you ever seen the actual submissions that

20 Merck made to the FDA in connection with

21 Protocol 007 that postdated your employment?

22 A. Those overlap. If you can

23 rephrase it as prior to filing the lawsuit

24 what submissions would I have seen, then we

25 cut out anything I've seen first time since

Page 426

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 then.

3 Q. Prior to filing the lawsuit.

4 A. Now, what do you mean by

5 "submissions"?

6 Q. Anything that Merck provided to

7 the FDA related to 007.

8 A. Prior to filing the lawsuit, on

9 clinicaltrials.gov Protocol 007 was listed as

10 a completed trial. I had the ProQuad BLA, and

11 I -- there was the language around the label

12 change from 20,000 to 12,500 TCID50. There

13 was an EMA submission -- there was an EMA

14 document that cited an EMA submission that

15 listed Protocol 007 as a pivotal study and it

16 had the final seroconversion rates in it. It

17 was listed as a completed study. So I had at

18 least those things. I can't remember off the

19 top of my head more submissions.

20 Q. Let me just make sure I have

21 those correctly. So prior to filing the

22 lawsuit, you went on clinicaltrials.gov and

23 based on information on clinicaltrials.gov,

24 you had the ProQuad BLA, an EMA submission and

25 I think you said the new label?

Page 427

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 A. Are you saying I got them off

3 of clinicaltrials.gov?

4 Q. That's what it sounded like

5 your answer was.

6 A. No, it was a separate thing. I

7 got the ProQuad BLA from an Internet search.

8 Q. Okay.

9 A. Clinicaltrials.gov is a

10 website. The EMA document that cites the EMA

11 submission off the Internet.

12 Q. So BLA you got off the Internet?

13 A. The CDC contract.

14 Q. The CDC contract, okay.

15 A. I might be leaving something

16 out, but I think we have it detailed in the

17 complaint if you want to go through it.

18 Q. If you think looking at the

19 complaint would be helpful, that's fine.

20 A. No. That's what I got off the

21 top of my head here 17 years later.

22 Q. So you said you got the ProQuad

23 BLA off an Internet search. Correct?

24 A. Yes.

25 Q. I just want to break it down.

Page 428

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 A. Sure.

3 Q. And you got the CDC contract

4 where?

5 A. Someone on our legal team found

6 that. I'm not sure I found it. I don't

7 recall how I had that in front of me.

8 Q. Which legal team are you

9 talking about?

10 A. Which legal team? Do I need to

11 make the distinction?

12 Q. Yes, you do.

13 A. These guys. Oh, wait. I got

14 more. The FDA 483 report.

15 Q. Where did you get that?

16 A. Counsel. The first one.

17 Q. Mr. Moody?

18 A. Yes.

19 Q. How did he get it?

20 A. I have no idea.

21 MR. SCHNELL: I just want to

22 instruct the witness going forward not

23 to identify documents that your counsel

24 may have provided you. So if we can

25 carve out of your answer going forward

Page 429

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 those documents, please do.

3 THE WITNESS: Are these the

4 ones I found on my own?

5 BY MS. DYKSTRA:

6 Q. My question was prior to filing

7 this lawsuit, what did you see?

8 A. Everything I saw prior to 2010.

9 Q. So the ProQuad BLA you

10 mentioned you found yourself from an Internet

11 search?

12 A. I don't know if counsel found

13 it independently, but I remember when I found

14 it, it lit a fire under me.

15 Q. Tell me about that, when did

16 you find it and what did you think?

17 A. I think that they were using --

18 it cited the PRN from Protocol 007 to justify

19 the cutoff for the ELISA. And they were

20 bringing ProQuad to market based on unreliable

21 data that was falsified. So I knew for

22 certain the fraud was ongoing.

23 Q. You don't know whether you

24 found the ProQuad BLA from your own Internet

25 search or Mr. Moody gave it to you?

Page 430

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 A. No, I know I found it.

3 Q. You found it yourself?

4 A. Absolutely.

5 Q. And so that was -- you found

6 that, I'm sorry, on the Internet somewhere?

7 A. Internet search engine somehow.

8 Q. The CDC contract, did you also

9 find that from Internet search or you think

10 you may have got that from counsel?

11 A. I don't recall --

12 Q. I'm trying not to -- I'm trying

13 to say did you find --

14 A. I don't recall how I got it in

15 front of me. The reason I remember the

16 ProQuad BLA so much is it was easily

17 identifiable that they were using Protocol 007

18 ELISA which was absolutely predicated and

19 inextricably linked to that PRN falsification.

20 I know I saw the seroconversion rates in that

21 EMA document that talked about the EMA

22 submission. It was a completed study. They

23 weren't looking at some small sample size.

24 Those stand out quite well. At some point I

25 was looking at a CDC contract. I don't know

Page 431

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 who found it or supplied it.

3 Q. And I think you mentioned the

4 483. Do you know whether you found that by

5 yourself on some FOIA request or an Internet

6 search?

7 A. Let's clarify. I don't recall,

8 I remember that I had it in front of me before

9 I met them. Whether counsel provided or me, I

10 don't think I provided it. I mean, I have to

11 identify who provided it? I shouldn't guess.

12 Q. I don't want you to guess. I'm

13 just asking if you recall how you got it?

14 A. I recall seeing it.

15 Q. What data did you get off of

16 clinicaltrials.gov related to the mumps

17 vaccine?

18 A. One of the most important

19 pieces was that Protocol 007 was a completed

20 study which means the seroconversion rates I

21 was seeing were final. They weren't based off

22 of some interim measure, or however Merck

23 described it.

24 Q. Did you see -- did you pull off

25 of clinicaltrials.gov the final seroconversion

Page 432

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 rates from 007 that were submitted to the FDA?

3     A. I don't know if they were on

4 there. I don't recall that. I recall seeing

5 the final seroconversion rates listed in the

6 EMA submission that the EMA discussed.

7     Q. Other than the documents you

8 just identified, did you see -- let me ask

9 specifically. Again, I'm excluding what

10 you've seen in connection with this

11 litigation.

12     A. Prior to 2010.

13     Q. Prior to discovery in this

14 litigation, had you ever seen the supplemental

15 biological license application that Merck

16 submitted to the FDA on January 29, 2004?

17     MR. SCHNELL: Do you have the

18 document?

19     THE WITNESS: I'd have to look

20 at it to know.

21 BY MS. DYKSTRA:

22     Q. Do you recall seeing it?

23     A. Well, you listed a title. If I

24 saw a document and didn't remember the title?

25     Q. I'm asking you if you recall

Page 433

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 seeing --

3     A. I can't say either way.

4     Q. You don't remember one way or

5 the other?

6     A. No, I didn't say that. I said

7 without seeing the document, I can't know

8 whether I saw it before or not.

9     - - -

10     (Exhibit Krahlung-31, 1/29/04

11 Supplemental Biologics License Application,

12 MRK-KRA00000032 - 00000139, was marked

13 for identification.)

14     - - -

15 BY MS. DYKSTRA:

16     Q. I'm going to mark as Exhibit 31

17 a January 29, 2004, Supplemental Biologics

18 License Application. And you can -- all I

19 want to know is whether or not you saw this

20 document prior to discovery in this lawsuit?

21 I'm not asking if there's a label attached and

22 you may have seen the label. I'm talking

23 about the full submission to the FDA.

24     A. I have seen this document. I

25 don't recall when I first saw it because so

Page 434

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 many pieces of it are familiar.

3     Q. You just looked at the first

4 page.

5     A. I looked through it. There's

6 nothing that looks foreign here. I know that

7 I've seen all this. The question is, which

8 isn't helping you, is, I don't know when I

9 first saw this. I saw this years ago.

10     Q. But you don't know when you

11 first saw it?

12     A. I can't say for certain whether

13 I saw it prior or not. I don't know.

14     Q. Mr. Krahlung, you had answered

15 a series of requests for admissions related to

16 the CDC already stating that you were never

17 asked to communicate with the CDC during your

18 employment at Merck and your job duties did

19 not include directly communicating with the

20 CDC. Do you recall that?

21     A. What exhibit is that?

22     Q. I have no idea. It's

23 Exhibit 6. The supplemental requests for

24 admissions number 50 and 51.

25     Do you see number 50 you state

Page 435

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 that your job duties did not include directly

3 communicating with the CDC. You were never

4 asked to communicate with the CDC during your

5 employment at Merck, and prior to the lawsuit

6 you had no personal knowledge of any nonpublic

7 communications between Merck and the CDC.

8     A. I see those.

9     Q. And the last one I'll point to

10 is number 57, you admitted that you had no

11 personal knowledge of any communications at

12 all regarding Protocol 007 between Merck and

13 the CDC?

14     A. Yeah.

15     Q. In addition, is it also correct

16 that you never negotiated any contract with

17 the CDC on behalf of Merck?

18     A. Hold on. Wait a minute.

19 You're talking about request number 57 now?

20     Q. No. I'm not asking you in

21 addition to those.

22     A. Okay.

23     Q. I have another question.

24     A. Okay.

25     Q. Is it also true that you never

Page 436

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 negotiated any contract on behalf of Merck

3 with the CDC?

4 A. What do you mean by negotiate?

5 Q. I'm not really sure how to

6 define that term other than discuss with the

7 CDC the terms and provisions that go into a

8 final agreement.

9 A. In person or over the phone?

10 Q. In any way. In person, over

11 the phone, communicate in writing?

12 A. I provided content that went

13 into those negotiations. But I did not

14 personally talk to CDC representatives, CDC

15 representatives in person to negotiate prices.

16 Q. What content did you provide

17 that went into the CDC negotiations?

18 A. According to Krah, we would

19 have lost the exclusive licensing right to

20 market that vaccine, which means the CDC

21 wouldn't have bought it. So I was in the lab

22 that committed fraud and the information would

23 have been safety and efficacy information

24 because the CDC -- from what I understand from

25 Krah and generally, that's how the CDC works,

Page 437

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 they want the vaccine to be both safe and

3 effective.

4 Q. Have you ever participated in a

5 meeting with the CDC in any form around the

6 contract?

7 A. In person and over the phone,

8 no. Krah made it clear that Protocol 007 was

9 designed to keep the vaccine on the market,

10 protect the shelf life so that they could

11 make -- first of all, it was to keep it on the

12 market because it could be removed. Protect

13 the label so that it wouldn't be changed and

14 to maintain its exclusivity so that it

15 wouldn't have competitors. That was the

16 financial goal of Protocol 007. He made it

17 clear that you don't start working on a

18 scientific objective unless you understand the

19 financial goal that that exists in pursuit of.

20 I think I cited it in an e-mail to him.

21 Q. So just to be clear, Dr. Krah

22 told you that Protocol 007 was necessary to

23 keep MMR II on the market?

24 A. Yes. Not only that, but they

25 had to take a -- they had to get an early read

Page 438

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 on it to keep it on the market. Because

3 the -- it couldn't maintain its shelf life.

4 Q. You're aware that your

5 complaint is public. Correct?

6 A. You mean published in the

7 public sphere?

8 Q. Publicly available --

9 A. Yeah.

10 Q. -- to people on the Internet?

11 A. Yes.

12 Q. And you're aware that the DOJ

13 talked to the CDC about your complaint?

14 MR. SCHNELL: Object to the

15 form.

16 THE WITNESS: I don't know --

17 what do you mean talked to them?

18 BY MS. DYKSTRA:

19 Q. Communicated the information in

20 your complaint.

21 MR. SCHNELL: Object to form.

22 BY MS. DYKSTRA:

23 Q. Are you aware that the DOJ --

24 that the CDC is aware of your allegations?

25 MR. SCHNELL: Object to form.

Page 439

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 THE WITNESS: In what sense are

3 they aware? I mean, you mean they've

4 read the complaint?

5 BY MS. DYKSTRA:

6 Q. Are you aware that the CDC is

7 in any way aware of your allegations?

8 A. You're talking about the CDC as

9 an institution or people there?

10 Q. Well, it has to be people

11 there. The CDC doesn't work other than

12 through people.

13 A. Am I aware of which people

14 there have read it?

15 Q. Are you aware that anyone at

16 the CDC is aware of your allegations?

17 A. If you said it's public and

18 that they are there to do their job, I can

19 only infer that they've read it, but the DOJ

20 didn't inform me of anything.

21 Q. Do you know whether the CDC has

22 in any way changed its purchasing of the mumps

23 vaccine since you filed your complaint?

24 A. What do you mean changed the

25 purchasing?



Page 440

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q.    Changed any of the terms of

3     their purchasing?

4     A.    I'd have to see the CDC

5     contracts to know that.

6     Q.    I'm asking you if you know

7     sitting here today whether the CDC changed any

8     of its purchasing terms with respect to the

9     mumps vaccine since you filed your complaint?

10    A.    CDC, I haven't communicated

11    with the CDC in any sense about their

12    purchasing terms, have I? I don't think so.

13    I haven't reviewed any CDC contracts other

14    than the one I saw before we filed.

15    Q.    So you don't know one way or

16    the other whether the CDC has changed any of

17    its purchasing terms even though your

18    complaint is public?

19           MR. SCHNELL: Object to form.

20           THE WITNESS: What do you mean

21    even though the complaint is public? I

22    know the CDC changed their website

23    about how well the vaccine works. That

24    seems like a pretty substantial

25    material change.

Page 441

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     BY MS. DYKSTRA:

3     Q.    What did they -- what do you

4     know about that?

5     A.    It changed the efficacy from

6     saying it worked really well to it doesn't

7     work so well. The number went down

8     significantly.

9     Q.    Which number?

10    A.    The number that they list for

11    how well it works.

12    Q.    The effectiveness rate?

13    A.    I don't know what they refer to

14    it on the website. The website used to -- the

15    website, the pink book, I believe it cited

16    possibly the package insert number, something

17    high. They don't cite it anymore. They cite

18    a lower real world effectiveness.

19    Q.    When did you first become aware

20    of this?

21    A.    Prior to -- well, it was after

22    the lawsuit because the change happened after

23    the lawsuit was filed.

24    Q.    Do you believe that your

25    litigation and your lawsuit had any effect on

Page 442

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     the CDC such that it lowered its real world

3     effectiveness rating or the numbers around

4     real world effectiveness on its website?

5     A.    I can't speak for the CDC but

6     you're asking if I believe. I think so. IEC

7     changed their number, too.

8     Q.    What did they change their

9     number to?

10    A.    A much lower number than the

11    package insert states.

12    Q.    When you talk about the package

13    insert, you're talking about the 96 percent

14    seroconversion rate that's referenced in the

15    package insert?

16    A.    Whatever number they had before

17    which was in the 90s. I can't say

18    definitively what it referred to. I don't

19    remember when that dropped.

20    Q.    What did they -- you don't know

21    what the IAC or the CDC changed on their

22    website specifically, what number they changed

23    it to, just a lower number?

24    A.    They changed it to a number

25    that was in the 90s that represented how well

Page 443

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     the vaccine worked to a lower real world

3     effectiveness. I don't recall what citations,

4     but they changed the number.

5     Q.    You understand -- you

6     understand the CDC realizes that the vaccine

7     is not 100 percent effective?

8     A.    What is that? I can't accept

9     that characterization. What do you mean

10    "realize"?

11    Q.    Do you believe the CDC -- well,

12    you said already that the CDC has a lower real

13    world effectiveness on their website.

14    A.    Here's what I realize, that a

15    package insert comes with the product they buy

16    and Merck sticks by their claim on that

17    package insert that just one shot produces

18    96 -- produces mumps neutralizing antibodies

19    in 96 percent of people who get one shot. And

20    CDC is looking at outbreaks, writing papers

21    saying that the 2006 outbreak was

22    characterized by two-dose failure, meaning the

23    kids had two doses of that vaccine.

24           MR. SCHNELL: Lisa, we've been

25    going about an hour, so whenever is a

Page 444

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     good time for a break.

3 BY MS. DYKSTRA:

4     Q.   Do you know what the CDC pays

5 for the Merck's mumps vaccine?

6     A.   Too much. It doesn't work.

7 Any amount is too much.

8     Q.   Do you think it has zero

9 effectiveness, the vaccine?

10    A.   I know from talking to Krah and

11 publications he gave me that having low

12 vaccine efficacy can actually make a disease

13 more dangerous. So when you say any

14 effectiveness, there's kind of an implication

15 there that a lower amount is just a lower

16 amount of a good thing. A lower amount of

17 antibodies that don't neutralize the virus can

18 actually make the disease more severe. He

19 gave me publications that documented that this

20 has already occurred in the measles vaccine

21 and he was concerned about that low efficacy

22 in measles. So, yeah, I mean, a low amount of

23 non-neutralizing antibodies can be a very

24 dangerous thing.

25    Q.   Do you know how -- you used the

Page 445

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 term "diminished efficacy," and you talk about

3 the vaccine having a lower effectiveness.

4 What is your understanding of how effective

5 the vaccine is today?

6     A.   It's not effective against wild

7 type strains and that the efficacy is so low

8 that there's a theoretical potential to make

9 the disease worse.

10    Q.   Can you give me a number that

11 you think that the vaccine is effective, a

12 percentage?

13    A.   A percentage that it works?

14 I'm telling you that once it gets low, you

15 don't characterize it in terms of works.

16    Q.   What do you believe to be the

17 vaccine's effectiveness today?

18    A.   I think the vaccine sucks.

19    Q.   What do you believe to be the

20 vaccine's effectiveness today in numbers?

21    A.   It doesn't work. There are

22 outbreaks in highly vaccinated populations

23 where the kids have had two doses of the shot.

24 I think we need an effective mumps vaccine and

25 we don't have one.

Page 446

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q.   Can you give me a number with

3 respect to what you believe to be the

4 vaccine's effectiveness today?

5     A.   I can give you a relative

6 number. It's significantly below what Merck

7 claims it is.

8     Q.   Can you give me a range or an

9 estimate of what you believe the vaccine's

10 effectiveness to be today?

11    A.   I can give you a range based on

12 what I saw in Krah's lab. He had tested using

13 a standard PRN against a panel of wild types,

14 he saw efficacy, you know, 70, 60 percent. He

15 saw efficacy as low as zero percent against

16 some wild type strains. So against some it

17 doesn't work at all. Against some there may

18 be a neutralizing response but we don't know

19 if it's in the danger zone.

20    Q.   Yes, we looked at some of that

21 yesterday for --

22    A.   Absolutely none of the wild

23 type strains were anywhere near 90 percent.

24 Krah said that's the reason they needed to

25 test against the vaccine strain. When they

Page 447

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 were able to negotiate calling a low passage a

3 wild type strain even he didn't believe it.

4 In his own documents he put wide type in

5 quotes. I said, why did you put wild type in

6 quotes? And he said, because it's not a

7 vaccine -- or it's not a wild type strain,

8 it's a vaccine strain. His rationale, the

9 AIGENT assay, his rationale, the objective

10 listed it as identify a mumps neutralization

11 assay format testing against a, in quotes,

12 wild type mumps strain that will permit

13 measurement of greater than or equal to 95

14 percent seroconversion in MMR II vaccinees.

15 That, I said why is wild type in quotes. He

16 said because it's not wild type. Low passage

17 is not wild type.

18           So I don't believe that the

19 results they got against the low passage

20 represent what they would have got against the

21 wild type strains when he tested against those

22 wild type strains, got nowhere near 90

23 percent. Some of them were as low as zero.

24 That's my belief of why the efficacy rates or

25 how well it works is so much significantly

Page 448

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     lower than what Merck claims is delivered by

3     their product with just one shot. I hope that

4     answers your question.

5     Q. Not necessarily. You saw

6     yesterday, we showed you documents that Merck

7     had shared with the FDA its seroconversion

8     rates with the LO-1 wild type strain, and we

9     saw numbers that were zero and 50 percent. Do

10    you recall that?

11    A. I recall that the Swiss isolate

12    wasn't in there where there was zero percent.

13    I also remember saying Krah had -- they had

14    to -- the FDA knew they were testing against

15    wild type. They had to go to the FDA with

16    their best case scenario against a wild type

17    so that they could argue to test against the

18    vaccine strain. Not the low passage, they

19    wanted to test against the full throttle

20    vaccine strain. Because -- and the rationale

21    was that's the only way they could get the

22    number that he targeted that they must have

23    beforehand.

24    Q. You're aware that CBER approved

25    a low passage Jeryl Lynn strain to be used in

Page 449

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     the PRN assay?

3     A. I don't know what you mean by

4     "approved."

5     Q. That CBER said it was okay for

6     Merck to use a lower passage Jeryl Lynn strain

7     in the PRN assay?

8     A. They were aware that Merck was

9     going to test against that low passage, yes.

10    Q. Can you tell me what you

11    believe the effectiveness of the vaccine to be

12    today in numbers, what percentage?

13    MR. SCHNELL: Object to form.

14    He's already asked and answered that

15    several times.

16    MS. DYKSTRA: He hasn't give me

17    a single percentage. He just said it

18    sucks.

19    THE WITNESS: I said more than

20    it sucks. I gave you that whole panel

21    of wild type. It's as low as zero

22    percent against some wild types. You

23    know, you talked about the FDA

24    approving or being aware of the use.

25    Krah let us know that. Of course we

Page 450

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     knew that. And yet he still put wild

3     type in quotes after he knew that we

4     were going to be able to do it. I

5     asked him after the FDA was letting

6     them do that, he's putting wild type in

7     quotes. He did not believe it was a

8     wild type virus. And I agree with him.

9     The reason they chose it is because

10    they couldn't get the answer they

11    wanted without it.

12    VIDEOGRAPHER: There's five

13    minutes left on the tape.

14    MS. DYKSTRA: We can take a

15    break then if the tape is running out.

16    VIDEOGRAPHER: The time is

17    12:21. We're going off the video

18    record.

19    - - -

20    (A recess was taken.)

21    - - -

22    VIDEOGRAPHER: The time is

23    12:40. This begins disc two in the

24    videotape deposition of Stephen

25    Krahling.

Page 451

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     BY MS. DYKSTRA:

3     Q. Mr. Krahling, are you familiar

4     with ACIP as part of the CDC?

5     A. What do you mean by familiar

6     with it?

7     Q. Do you know what ACIP is?

8     A. Generally speaking, I think so.

9     Q. What is your understanding of

10    ACIP?

11    A. I think one of the things they

12    do is talk about recommendations for

13    vaccination. Other than that, I'm not really

14    familiar with them.

15    Q. Are you aware that the CDC

16    currently recommends two doses of MMR II be

17    given to children in the first 12 to 15 months

18    and the second in the four to six years? The

19    first dose in children 12 to 15 months and the

20    second dose in children four to six years?

21    A. I haven't looked at it, but I

22    don't think you're wrong. That sounds -- I

23    mean if you're reading it, that sounds right,

24    two doses.

25    Q. Do you know whether the CDC has

Page 452

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     changed its recommendation for immunization in

3     the context of mumps?

4     A.    I saw some -- maybe some

5     publications that were by people from the CDC

6     where they were talking about discussion of

7     the possibility of needing a third dose of MMR

8     because two doses wasn't protecting and

9     preventing outbreaks of the disease.

10    Q.    Do you have an opinion whether

11    a third dose is appropriate at this point in

12    time?

13    A.    A third dose of an ineffective

14    vaccine would not be appropriate. I think

15    they need an effective vaccine.

16    Q.    What in your mind would you

17    characterize as an effective vaccine?

18    A.    Such a broad question.

19    Q.    When you say they need an

20    effective vaccine, what do you mean?

21    A.    You're talking in terms of the

22    CDC. I can give you an ostensive example that

23    the CDC monitors outbreaks and they identified

24    mumps as an eradicable disease and they said

25    an elimination goal to have mumps eradicated

Page 453

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     by 2010 and they believe they can do that

3     based on Merck's claim of how well the vaccine

4     works. 2010 has come and gone and the number

5     of cases, of reported cases of mumps has

6     increased in the last 15 years.

7     Q.    But what in your mind would be

8     an effective vaccine?

9     A.    When the CDC identifies that a

10    disease can be eradicated and disease can go

11    down, it should do what they think it can do

12    from the CDC's point of view.

13    Q.    Do you think a mumps vaccine

14    that is 70 percent effective or has an

15    effectiveness rate of 70 percent is -- qualifies

16    as an effective vaccine?

17    A.    The CDC published a document

18    that said a vaccine with effect that low

19    wouldn't be able to eradicate disease.

20    Q.    I understand that. Do you

21    think that a vaccine with an effectiveness

22    rate of 70 percent in real world effectiveness

23    terms is an effective vaccine?

24    A.    So in the example I gave you of

25    what the CDC stated as an elimination goal and

Page 454

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     what they needed for a effective vaccine, that

3     would not be able to get the job done in that

4     example.

5     Q.    I understand that you're saying

6     it wouldn't eradicate the disease. A vaccine

7     that's 70 percent effective. Correct?

8     A.    All right.

9     Q.    I understand that. I

10    appreciate that answer. Do you think a mumps

11    vaccine that is 70 percent effective qualifies

12    as an effective vaccine?

13           MR. SCHNELL: Object to form.

14           THE WITNESS: That's so vague.

15    There's not even a vaccine out there.

16    Do we even know if there's a vaccine

17    that's 77 percent effective? We're

18    talking about real world data?

19    BY MS. DYKSTRA:

20    Q.    What do you believe to be the

21    real world data with respect to the mumps

22    vaccine?

23    A.    Real world?

24           MR. SCHNELL: Object to form.

25    BY MS. DYKSTRA:

Page 455

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q.    Yes.

3     A.    Real world data? Can you

4     rephrase that?

5     Q.    Yeah, sure. You said the CDC

6     monitors reported cases of mumps. Correct?

7     A.    They do, yes.

8     Q.    Do you know what the CDC

9     believes to be, what has stated to be the real

10    world effectiveness of the mumps vaccine?

11           MR. SCHNELL: Object to the

12    form.

13           THE WITNESS: You're talking

14    about the CDC as an agency?

15    BY MS. DYKSTRA:

16    Q.    Uh-huh. Yes.

17    A.    I can't speak for them.

18    Q.    But you believe the mumps

19    vaccine -- I'm sorry, I didn't mean -- strike

20    that.

21           What do you believe to be the

22    effectiveness of the current mumps vaccine?

23           MR. SCHNELL: Object to form.

24    Asked and answered.

25           THE WITNESS: You keep

Page 456

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     rephrasing that question. I think it

3     doesn't work. It doesn't prevent

4     outbreaks even when the population is

5     highly vaccinated. That's an

6     observation the CDC made even when the

7     kids have had two shots of it.

8     BY MS. DYKSTRA:

9     Q.   Based on your experience with

10    the mumps vaccine, can you tell me what range

11    of effectiveness the vaccine has? I'm looking

12    for a number.

13    A.   You're saying effectiveness

14    now, talking real world. My experience in the

15    lab was lab immunogenicity as a surrogate for

16    efficacy, that's a different thing.

17    Q.   What do you believe -- can you

18    give me either one in terms of a percentage

19    what you believe real world effectiveness is

20    or what you believe the true immunogenicity is

21    of the current mumps vaccine?

22           MR. SCHNELL: Object to the

23    form.

24           THE WITNESS: First of all,

25    you're looking for a number.

Page 457

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     BY MS. DYKSTRA:

3     Q.   Yes, or a range.

4     A.   Exactly. You're looking for a

5     range that includes zero according to the wild

6     type data we saw in Krah's lab, but that's

7     not -- that's immunogenicity data that is a

8     surrogate for efficacy. You're talking about

9     real world efficacy where everybody is getting

10    two doses. Do you want real world

11    effectiveness of one shot?

12    Q.   Why don't we start there.

13    A.   Well, everybody is getting two

14    shots, so there's not even -- where is your

15    population that's getting one shot? How could

16    you even speak to effectiveness when everybody

17    is getting two, and like you pointed out or

18    somebody pointed out the CDC is debating

19    whether there should be a new vaccine or a

20    third shot of the one that's not working.

21    That was my characterization at the end there.

22    But the observation by the CDC was that 2006

23    outbreak was characterized by two-dose

24    failure.

25    Q.   So can you give me your

Page 458

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     estimate of the effectiveness rate of two

3     doses of the vaccine, of the current vaccine?

4           MR. SCHNELL: Objection. Asked

5     and answered.

6           THE WITNESS: I don't know how

7     many times they can go over this.

8     BY MS. DYKSTRA:

9     Q.   I want you to give me a

10    percentage, a range that you believe Merck's

11    mumps current vaccine has in real world

12    effectiveness terms?

13           MR. SCHNELL: Objection. Asked

14    and answered.

15    BY MS. DYKSTRA:

16    Q.   You can answer.

17    A.   I've already answered.

18    Q.   You haven't given -- you said

19    it sucks. You said it doesn't work.

20    A.   Well, that's my -- I answered

21    way more than that.

22    Q.   But I want to know what you --

23    you said that Merck represents vaccine to

24    impact children by protecting them and causing

25    96 percent seroconversion rate. And you say,

Page 459

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     in fact, the real world effectiveness is

3     significantly less than that. Correct?

4     A.   Efficacy is significantly less

5     than that.

6     Q.   What do you believe efficacy to

7     be of the vaccine?

8     A.   I've gone over this every

9     possible way I can. I've cited Krah's

10    immunogenicity data which is supposed to be a

11    surrogate of efficacy. This shows a range of

12    seroconversion rates against wild type

13    circulating diseases -- disease strains that

14    are significantly below what they claim in

15    their label. In the real world the CDC said

16    if this vaccine worked as well as Merck said

17    it does, we should be able to eradicate the

18    disease. They set a goal. The goal was seven

19    years ago. It's not eradicated. The rates

20    have been going up since then. The real world

21    observation is that it is not working. It's

22    not preventing -- it certainly can't eradicate

23    disease. It's not even preventing outbreaks.

24    There's your real world observation. The

25    numbers in the lab show that it doesn't have

Page 460

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     the immunogenicity that parallels their label

3     claim from the 1960s. And on the label they

4     say specifically that that 96 percent number

5     parallels what they found in field efficacy

6     trials. They know that's not true. They have

7     more accurate information that says it no

8     longer parallels it. In fact, that number,

9     whatever it may be, would be significantly

10    lower. The number that they tested in the lab

11    against wild type was as low as zero percent.

12    That's a pretty thorough answer.

13             - - -

14             (Exhibit Krahling-32, Update:

15             Multistate Outbreak of Mumps --- United

16             States, January 1--May 2, 2006, was

17             marked for identification.)

18             - - -

19    BY MS. DYKSTRA:

20        Q.    I'm going to mark as Exhibit 124,

21        Krahling-32. This is Exhibit 32. It's the

22        May 26, 2006, MMWR report from the CDC.

23        A.    Do you want me to read it?

24        Q.    Have you ever looked at these

25        types of reports issued by the CDC discussing

Page 461

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     -- this one in particular is an update on

3     mumps outbreaks from 2006?

4        A.    I've seen some things like this

5     MMWR. I don't recall if I've seen this exact

6     one.

7        Q.    You'll note, if you can, look

8     at the third page.

9        A.    I want to read the whole thing.

10       Q.    Okay.

11       A.    Thanks. Okay.

12       Q.    Can I direct your attention,

13     please, to page 4 of 9.

14       A.    Yes.

15       Q.    At the top of this page in the

16     first full paragraph, the CDC states that

17     "High vaccination coverage with 2 doses of MMR

18     vaccine, especially in school-aged populations

19     in the United States, likely prevented

20     thousands of additional cases of mumps in this

21     outbreak."

22             Do you agree or disagree with

23     that statement?

24       A.    I see the qualification likely,

25     and in the second --

Page 462

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2        Q.    I think I read that in --

3        A.    Yeah.

4        Q.    Yes, okay.

5        A.    That's a qualification, it's

6     not a statement of certainty. But in the

7     second to the last paragraph it says, "The

8     data presented in this report are

9     preliminary...." And in the page before it

10    says, "...no data on implementation and

11    evaluation of the 2-dose college admission

12    requirement are available...."

13             So with this being preliminary

14    data and this saying that "...implementation

15    and evaluation of 2-dose college admission

16    requirement are available.... Thus....," this

17    is preliminary stuff. I would think that the

18    CDC review of this outbreak which was

19    published a couple of years later where they

20    said that this outbreak was characterized by

21    two-dose failure, would supersede pretty much

22    everything here. We should look at a more

23    current review of this outbreak if we want

24    accurate information, which was also published

25    by the CDC, it's more recent than this. So I

Page 463

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     wouldn't take a qualified statement like

3     likely. I would go to the more recent review

4     of that outbreak. That's what I think of that

5     sentence.

6        Q.    In the next sentence it says,

7     "Postlicensure studies conducted in the United

8     States during 1973 and 1989 determined that 1

9     dose of mumps or MMR vaccine was 75 to 91

10    percent effective in preventing mumps with

11    parotitis that lasted less than two days...."

12    [As read.]

13             Do you agree with that data?

14       MR. SCHNELL: Object to form.

15       THE WITNESS: So those are

16    retrospective observational studies.

17    Those aren't the same as clinical

18    efficacy studies, so I'm not going

19    to -- that statement exists there.

20    BY MS. DYKSTRA:

21       Q.    Are you familiar with those

22    post-licensure studies?

23       A.    What do you mean by "familiar"?

24       Q.    Have you looked at any

25    post-licensure studies other than the PRN

Page 464

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     assay that you ran -- that you worked on?

3     A.    That's not a post -- oh, that's

4     a clinical study. These aren't clinical

5     studies I don't think they're citing.

6     Q.    What do you think that they're

7     citing here?

8     A.    I'll tell you, let's look at 5.

9     Where are the references?

10    Q.    Page 5 of 9 is the references.

11    A.    That's a textbook. I don't

12    know what they're citing here, but --

13    Q.    Do you -- go ahead.

14    A.    I don't know what they're -- I

15    don't know what they're citing as

16    post-licensure studies. I know that if you

17    want the most accurate information on this

18    outbreak and you want use CDC as a source, you

19    should go to the review they wrote once all

20    the data came in.

21    Q.    What do you recall of that

22    review?

23    A.    That the author said that the

24    outbreak was characterized by two-dose

25    failure.

Page 465

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q.    Do you recall anything else

3     about their conclusion?

4     A.    If I read the document. It was

5     a public document. I'm not citing the

6     research. I'm not going to sit here and try

7     and see how much I remember of one document.

8     What I know is it's more recent than this, and

9     it doesn't say -- it doesn't talk about

10    these -- you know, it's more recent and would

11    supersede this.

12    - - -

13    (Exhibit Krahlung-33, About the

14    Vaccine printout from CDC website, was

15    marked for identification.)

16    - - -

17    BY MS. DYKSTRA:

18    Q.    I'm going to give you what's

19    been marked as Krahlung-33 from the CDC's

20    website. In the middle of the page is where

21    I'm going to -- well, you can read the whole

22    document, it's comparatively short.

23    A.    What date was it downloaded?

24    Q.    This was downloaded on

25    November 22, 2016.

Page 466

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     A.    It's short. I can look over

3     it, right?

4     Q.    Yes, you may.

5     A.    Okay.

6     Q.    Do you see that the CDC

7     characterizes the effectiveness of the mumps

8     MMR II vaccine as -- mumps component of the

9     MMR II vaccine as 78 percent effective for

10    mumps, range 49 percent to 92 percent?

11    A.    I see that line.

12    Q.    Then you see for two doses the

13    CDC states that the MMR II -- MMR, two doses,

14    has an 88 percent effectiveness for mumps

15    ranging between 66 to 95 percent?

16    A.    You have read the document

17    accurately. I see that line also.

18    Q.    Do you agree that those are

19    valid rates of effectiveness, of effectiveness

20    for the Merck mumps vaccine?

21           MR. SCHNELL: Object to form.

22           THE WITNESS: These lines don't

23    indicate the conclusion you're making,

24    you're reading into that.

25    BY MS. DYKSTRA:

Page 467

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q.    I'm not sure I understand your

3     answer.

4     A.    You drew a conclusion from two

5     lines.

6     Q.    I was explaining --

7     A.    Do I agree with your

8     interpretation of those two lines?

9     Q.    Sure.

10    A.    I don't know what the CDC -- I

11    mean, read it again. If you're asking if I

12    agree with your conclusion about what those

13    two lines mean, rephrase it like that.

14    Q.    I'm just reading what the CDC

15    published on their website and asking if you

16    agree with the CDC's conclusion?

17    A.    There are no conclusions.

18    Where is the conclusion, you read two lines?

19    That was your conclusion. Where did you read

20    me a conclusion?

21    Q.    I'm stating what the CDC

22    published as its determination of vaccine

23    effectiveness.

24    A.    I see those two lines.

25    Q.    Do you agree that that is an

Page 468

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     accurate statement of the vaccine's

3     effectiveness?

4             MR. SCHNELL: Object to form.

5             THE WITNESS: What -- this is

6             2016.

7     BY MS. DYKSTRA:

8         Q.    Yes, November 22, 2016.

9         A.    Where is the screenshot from

10        before our lawsuit was filed?

11        Q.    I'm sorry, can you repeat your

12        question to me? I didn't hear you.

13        A.    I thought I was supposed to

14        answer your questions.

15        Q.    I know, but you asked me a

16        question.

17        A.    I was saying you have --

18        Q.    You wanted me to provide a

19        screenshot before your lawsuit was filed?

20        A.    Yes.

21        Q.    I do not have the CDC's

22        screenshot before the lawsuit --

23        A.    How do you know the numbers

24        didn't change in any way?

25        Q.    They may have. I'm not

Page 469

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     suggesting that they didn't change. I'm not

3     suggesting one way or the other whether they

4     changed. I'm just saying this -- and I'm

5     going to correct the record. This was not

6     printed on November 22, 2016. This is last

7     updated November 22, 2016, just to be clear.

8     So we printed this more recently, but the CDC

9     website was updated November 22, 2016, and

10    these are the effectiveness ranges that the

11    CDC posted on its website. What I'm asking

12    you is whether you agree that these are the

13    effectiveness rates for the mumps vaccine?

14    A.    I can agree that these are not

15    efficacy rates and I can agree that these are

16    not the efficacy rates that Merck claims how

17    well their vaccine works with just one shot.

18    Q.    I'm going to ask my question

19    again and I want you to answer my question and

20    then you can explain whatever you would like

21    to explain on the record. What I would like

22    to know is, the CD -- this Exhibit 36 is a

23    printout of the CDC's -- I'm sorry, Exhibit 33

24    is a printout from the CDC's website last

25    updated November 22, 2016. On this website

Page 470

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     the CDC has posted the vaccine effectiveness

3     for one dose and two dose of MMR. What I'm

4     asking is if you agree that the vaccine is

5     78 percent effective for mumps with one dose

6     and 88 percent effective for mumps with two

7     doses as posted on the CDC's website?

8             MR. SCHNELL: Object to the

9             form.

10            THE WITNESS: No. Let me

11            explain why you're drawing a

12            conclusion. These are effectiveness

13            rates, and you seem to be implying that

14            there is no other data that the CDC

15            relies on. These are two lines printed

16            here.

17    BY MS. DYKSTRA:

18        Q.    I'm not saying anything about

19        what the CDC relies on. I'm just telling you

20        that this is on the CDC's website and I want

21        to know whether you agree with the CDC's

22        publication?

23        A.    I can agree --

24            MR. SCHNELL: Object to form.

25            THE WITNESS: I can agree that

Page 471

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     these two lines are written here. The

3     conclusions you're drawing from them

4     that imply there's no other data or

5     that perhaps this is the end-all,

6     be-all of that data, these are

7     effectiveness rates that are usually

8     retrospective. These aren't efficacy

9     rates.

10    BY MS. DYKSTRA:

11        Q.    I did not say that they were

12        efficacy rates. I'm asking you whether or not

13        you agree that these are the right

14        effective -- the accurate effectiveness rates

15        for the mumps vaccine?

16            MR. SCHNELL: Object to form.

17            THE WITNESS: Effectiveness as

18            in what studies are they citing? I

19            mean, I can agree they're printed

20            there. I don't know what the CDC

21            relies on to draw the conclusion you're

22            making, or even if they draw that

23            conclusion. It looks to me like they

24            printed a range to encompass what might

25            happen in the real world. I don't see



Page 472

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 anything beyond that.

3 BY MS. DYKSTRA:

4 Q. Do you agree that the CDC has

5 posted on its website a range of effectiveness

6 for one dose of 49 to 92 percent and a range

7 of effectiveness of 66 to 95 percent for two

8 doses per mumps vaccine?

9 A. If you read that right, that's

10 what this says here. A range would -- I mean,

11 a range would -- a range indicates that based

12 on whatever type of study that is, they might

13 get a range in there. These aren't efficacy

14 rates.

15 Q. When we first started our

16 discussion yesterday, you used the term

17 efficacy and effectiveness interchangeably and

18 you said that's how they're discussed in the

19 lab. Correct?

20 A. I don't agree with that.

21 Q. Can you tell me the difference --

22 A. I did not --

23 Q. -- between efficacy and

24 effectiveness then?

25 A. I did not use them interchangeably.

Page 473

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 What I said is when I was speaking of

3 efficacy, I was using it the way we did in the

4 complaint, which to me means generally how

5 well the vaccine works.

6 Q. So what is the difference

7 between efficacy and effectiveness?

8 A. Did we use effectiveness in the

9 complaint?

10 Q. Yes.

11 A. Can you show me where?

12 Q. No. Just tell me what you

13 believe the difference between effectiveness

14 and efficacy --

15 A. I don't know that I -- I don't

16 know that I believe that we used it in the

17 complaint. I'd have to see it.

18 Q. I don't -- I'm not referring to

19 the complaint. Do you believe -- you stated

20 there was a difference between efficacy and

21 effectiveness. I need you to explain that to

22 me, what you believe the difference to be.

23 A. Where did I state that there

24 was a difference?

25 Q. Just now.

Page 474

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 A. Uh-uh. I said I didn't use

3 them interchangeably. I didn't confirm

4 whether they were interchangeable or not.

5 Q. Do you believe that there is a

6 difference between efficacy and effectiveness?

7 A. I believe, I know that there

8 are different definitions of efficacy used so

9 much so that publications come out that

10 delineate the different way efficacy can be

11 used as a definition, which is why I'm trying

12 to be real clear with how I use the definition

13 of the word efficacy. I don't want you to

14 equivocate effectiveness with how I'm using

15 the word efficacy which is how we used it in

16 the complaint which is to say generally how

17 well Merck's vaccine works.

18 Q. Let's look at what we'll mark

19 Exhibit 34.

20 - - -

21 (Exhibit Krahling-34, Mumps

22 Outbreak --- New York, New Jersey, Quebec,

23 2009, was marked for identification.)

24 - - -

25 BY MS. DYKSTRA:

Page 475

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 Q. You can put that on the bottom

3 of your document, please. Thank you.

4 You can read as much of this as

5 you want. I'm going to be asking you about

6 page 4 of 8.

7 A. Are you focusing just on this

8 second paragraph so I don't have to read the

9 whole thing?

10 Q. The second paragraph of page 4,

11 yes.

12 A. You're not going to go outside

13 that?

14 Q. I'm not going to ask you about

15 anything else other than that.

16 A. All right. We're good.

17 Q. In this study of the mumps

18 outbreak published November 12, 2009, the CDC

19 states that "Mumps vaccine effectiveness has

20 been estimated at 73 percent to 91 percent for

21 1 dose and 76 percent to 95 percent for 2

22 doses." [As read.]

23 Do you see that?

24 A. Yes.

25 Q. Do you agree that those are

Page 476

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     valid or reasonably accurate effectiveness

3     rates for the vaccine?

4             MR. SCHNELL: Object to form.

5             THE WITNESS: Obviously valid

6     and reasonably, but let me try to

7     answer the question so that we keep --

8     don't keep going around in circles.

9     This is a range. This is effectiveness.

10    What I know is that Krah said if we

11    don't produce immunogenicity data as a

12    surrogate for vaccine efficacy, that

13    didn't match the label and wasn't 95

14    percent effective, they wouldn't be

15    able to sell their vaccine. They

16    would -- and not only that, they would

17    lose their exclusive right to be the

18    only one on the market. That's what I

19    know about. How the CDC interprets or

20    the decisions they make from this, I

21    can't speak for the CDC.

22    BY MS. DYKSTRA:

23         Q. What do you mean when you say,

24    "exclusive right to be the only one on the

25    market"?

Page 477

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2         A. What I mean that is how I heard

3    Krah use it, which was if they didn't get 95

4    percent efficacy, and he used the term

5    efficacy, seroconversion rates for Protocol

6    007, that they wouldn't be able to -- they

7    wouldn't be able to maintain the shelf life in

8    the short term and they wouldn't be able to be

9    the sole provider of the vaccine long term.

10   Exclusive rights mean they're the only one on

11   the market. We spoke and we used the word

12   market.

13             He also said that Protocol 007

14   was necessary, and he wrote this and I cited

15   this so many times, that the mumps

16   neutralization assays were to support process

17   changes. The process changes is a

18   manufacturing change that we're not just

19   talking about Protocol 007 testing to get 95

20   percent efficacy. He needed 95 percent

21   efficacy at those lower doses so they could

22   stop putting so much virus in the vaccine.

23   That's the process change. So it's not

24   just -- they're not out there to say at this

25   release dose it works this well. They were

Page 478

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2    there to try and say it worked as well as they

3    claim on the package insert at a lower dose

4    because he said they had to put -- recently

5    they had to put more into it and they wanted

6    to stop putting more into it because upper

7    management had questions that the vaccine

8    wasn't safe.

9         Q. Do you know how much more virus

10   the company put into the vaccine prior to

11   finishing 007?

12         A. Prior to it, I didn't know how

13   much. I only knew that he represented it as

14   an amount so high that it had never been

15   clinically tested in a perspective

16   clinically -- like the kids -- where the kids

17   knew what they were getting and had informed

18   consent before they got that dose. He said

19   the only information they had, and that upper

20   management was doing a wait and see strategy

21   which was the stuff they had sent out at the

22   highest doses which had never been clinically

23   tested, they were going to wait and see what

24   adverse reports came back to see if it was

25   safe.

Page 479

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2         Q. Did you know --

3         A. And that was one of the

4    important aspects of Protocol 007. Because if

5    they could show that it was effective, 95

6    percent efficacy at this lower dose and Krah

7    was aiming originally for 3.7, they could stop

8    putting so much virus, mumps virus, in the

9    vaccine.

10         Q. Do you know whether the company

11   ever stopped, quote/unquote, putting so much

12   mumps virus in the vaccine, end quote?

13         A. I know that they -- that that

14   overflow lasted well beyond the time that I

15   worked there. I don't know that -- that's all

16   I can say about that.

17         Q. How do you know that the

18   overflow lasted well beyond the time you

19   worked there?

20         A. I saw the documents you

21   produced that say that you're putting -- some

22   of the documents say as much as 400,000

23   TCID50, some say as much as 500,000 TCID50.

24         Q. So based on what you've seen in

25   this litigation, you understand that the

Page 480

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 company continued to overfill the vaccine

3 higher than 4.3 TCID50?

4 A. I don't know that they overfill

5 it at 4.3 TCID50.

6 Q. I just said higher than.

7 A. Oh, higher than.

8 Q. Overfill --

9 A. Could you repeat the question

10 then?

11 Q. Sure. You talked about the

12 company was putting more virus in the vaccine

13 pending the outcome of 007. That was my

14 words. Is that a fair assessment of what you

15 said?

16 A. That's somewhat accurate, yeah.

17 Q. You said you looked at

18 documents to -- and it's your understanding

19 that the company continued to overfill the

20 vaccine. Do you know whether the company

21 still does that?

22 A. I can't say for sure if they're

23 doing it today. Back then I knew that they

24 were overfilling and it was a lot. Now I have

25 a number. The other thing I have -- I'm not

Page 481

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 going to volunteer it. You'll see it.

3 Q. What's the other thing you

4 have? This is your deposition. This is your

5 opportunity to explain it.

6 A. I don't want to talk about

7 produced documents, that you produced that say

8 that Krah was right in all the things he was

9 stressed out about.

10 Q. I'm sorry, I'm not sure what

11 you're talking about. A document that Krah

12 was right about all the things he was stressed

13 out about. What document are you talking

14 about?

15 A. Is there a question pending?

16 Q. Yes. What document are you

17 talking about?

18 A. Which document? No, I didn't

19 say he's stressed out about. That's my

20 experience with him. I didn't see a document

21 that said he was stressed out. He was

22 stressed out over completing the Protocol 007

23 trial by fall. And stressed out, you know, he

24 said this is the most important thing he was

25 working on in his life. In his life it was

Page 482

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 the most important thing because it was

3 Merck's marquis vaccine and it was already on

4 the market, he was protecting it.

5 Q. You never conducted any studies

6 of the vaccine at this higher potency meaning

7 the vaccine that included the overfill.

8 Correct?

9 A. Can you redefine that?

10 Q. You mentioned that the company

11 put more virus in the vaccine --

12 A. Yes.

13 Q. -- while Krah's test was still

14 ongoing before the label was changed?

15 A. Before. You got one thing

16 wrong in it, but I don't want to tell you what

17 you got wrong.

18 Q. Tell me what I got wrong.

19 A. Say it again.

20 Q. Well, I'll tell you what I just

21 said and then you can tell me what I got

22 wrong.

23 A. You may have corrected it.

24 Q. Well, okay. I said, you never

25 conducted any studies of the vaccine at the

Page 483

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 higher potency, meaning the vaccine that

3 included the overfill that you referenced.

4 A. You rephrased that. What do

5 you mean I didn't -- now, you got rid of the

6 other point. Can you read that again?

7 Q. Yes.

8 A. I need the definition of higher

9 potency because I don't know what you're

10 saying there.

11 Q. Let's talk about that first.

12 A. Yeah.

13 Q. You understand that the company

14 put more virus in the vaccine?

15 A. More mumps virus in the MMR

16 vaccine.

17 Q. Yes, put more mumps virus in

18 the MMR vaccine.

19 A. Yes.

20 Q. Do you know when that increase

21 occurred?

22 A. Krah talked to me about it

23 around 1999 or 2000, and he spoke of it in

24 terms of it being very recent. So I don't

25 know the exact day, but back during the year

Page 484

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     and a half when he and I got along very well,

3     that's when he notified me. So he would have

4     told me about that before 2001 when I came --

5     no, 2000 December. It would have been before

6     December 2000 that he told me that Merck had

7     to put more mumps in the mumps vaccine.

8     Q.    So let's use the 1999-2000 time

9     frame. So in that time frame you understand

10    that Merck put more virus in the mumps -- more

11    mumps virus in the MMR II vaccine. Correct?

12    A.    Yes.

13    Q.    Do you know whether Merck today

14    continues to include that same amount of virus

15    in the mumps vaccine?

16    A.    I do not know today what amount

17    of virus they are filling with today.

18    Q.    Do you know, did you ever run

19    tests on the mumps component of the MMR II

20    vaccine at this higher potency with this

21    overfill?

22    A.    Which higher potency?

23    Q.    The one that began in 1999.

24    A.    You're not being clear enough.

25    There's degradation all through the process.

Page 485

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Some lots are released at different potencies.

3     Nobody did a clinical safety study of the

4     highest amount Merck was releasing. A

5     prospective clinically gathered study, not

6     only did Krah say that, and that's why they

7     were concerned about safety -- well, let me

8     just stick with that's what Krah said because

9     it's been borne out by the documents.

10    Q.    What has been borne out by the

11    documents?

12    A.    That the highest dose that

13    Merck had any clinical safety study for was

14    5.2. At least at that time. Just like Krah

15    was saying they were doing a wait and see,

16    they were simply relying on passage

17    surveillance to see if any kids got hurt from

18    the higher dose. The kids didn't know they

19    were getting that high of a dose when they got

20    it, nor did their parents.

21    Q.    Just to be clear, just so the

22    record is clear, I think it may be mistyped,

23    you said highest dose that Merck had any

24    clinical safety for was 5.2?

25    A.    There's a document that you

Page 486

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     produced that said the highest dose that they

3     have clinical safety data for is 5.2.

4     Q.    Give me one second, please.

5     Grab something.

6     A.    That's 5.2 log.

7     MR. SCHNELL: About another

8     five, ten minutes and then break for

9     lunch?

10    MS. DYKSTRA: Sure.

11    - - -

12    (Exhibit Krahling-35, 8/20/99

13    Letter with attachments,

14    MRK-KRA00018614 - 00018619, was marked

15    for identification.)

16    - - -

17    BY MS. DYKSTRA:

18    Q.    We're going to mark as

19    Krahling-35 a letter from the FDA dated

20    August 20, 1999. And there's an attachment to

21    this letter dated June 30, 1999, and a prior

22    approval supplement dated June 18, 1999. I'm

23    only going to be talking about the first

24    letter in this stack, but you can take as much

25    time to review this as you need. I will tell

Page 487

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     you my question so that you can hear it before

3     you review the document and then you can

4     decide how much you need to review; first of

5     all, have you ever seen this before; and

6     second, to confirm that you understand that

7     CBER understood that Merck was going to

8     formulate all mumps-containing vaccine lots

9     manufactured on or after September 13, 1999,

10    to contain at least 5.2 log<sub>10</sub> TCID<sub>50</sub>.

11    A.    The first question, I have seen

12    this before.

13    Q.    Do you know when you've seen

14    this?

15    A.    I may have, I'm not sure of the

16    rest of this, but I may have seen this while I

17    was at Merck. I'm not sure. But I have

18    definitely seen it since then.

19    Q.    And just so we can clarify what

20    we're talking about with respect to the

21    increased potency, in the middle of this

22    letter CBER states, We understand that you

23    will formulate all mumps-containing vaccine

24    lots manufactured (filled) on or after

25    September 13, 1999, to contain at least 5.2

Page 488

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     log10 TCID50. These lots will be released by

3     CBER with a dating period of 24 months based

4     upon the CBER potency testing criteria

5     described above. Furthermore, all

6     mumps-containing lots submitted for CBER

7     release, regardless of the manufacturing date,

8     will be subject to the described CBER release

9     requirements as of November 8, 1999.

10    You see that, correct?

11    A.    Sure.

12    Q.    Is this the overfill clinically

13    that we were talking about in your -- talking

14    about in your answers?

15    A.    I don't want to narrow the

16    overfill to just that, but this is an example

17    of an overfill. And this -- I mean, this is

18    an overfill of the vaccine in around 1999. I

19    think this is probably quite correct at this

20    point.

21    Q.    My question is, have you ever

22    done any potency testing at all on vaccine

23    that contained this overfill?

24    A.    Potency testing?

25    Q.    Yes.

Page 489

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     A.    Just to determine how much is

3     in the vaccine?

4     Q.    Yes.

5     A.    I didn't do potency tests to

6     see how much is in the vaccine. All I was

7     getting at with that high dose was that Krah

8     said they were very concerned about the fact

9     that they had no clinical safety data. I

10    don't know if they shared that. I mean, all

11    this confirmed is that Krah was right in the

12    first part of it, that they did overfill. I

13    wasn't making -- yeah. I mean, that's --

14    MS. DYKSTRA: I think we can

15    break for lunch.

16    VIDEOGRAPHER: The time is

17    1:29. We're going off the video

18    record.

19    - - -

20    (A recess was taken.)

21    - - -

22    VIDEOGRAPHER: The time is

23    2:22. We're back on the video record.

24    BY MS. DYKSTRA:

25    Q.    Mr. Krahling, I want to follow

Page 490

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     up on a couple of things we talked about prior

3     to lunch.

4     You mentioned -- I don't want

5     you to disclose any communications from

6     counsel or anything that's privileged. You

7     mentioned, though, that you met with Joan

8     Wlochowski and your counsel around 2009, 2010.

9     Is that accurate?

10    A.    Yeah, about that time frame.

11    Q.    Did you meet with any other

12    former lab members and your counsel, without

13    telling me what occurred during that time

14    frame?

15    MR. SCHNELL: I already

16    objected to that line of questioning.

17    MS. DYKSTRA: Who he met with?

18    MR. SCHNELL: Yeah, who counsel

19    decided was worth meeting or not worth

20    meeting is work product.

21    MS. DYKSTRA: I disagree. So

22    you're not going to disclose who you

23    met with, who you and Mr. Krahling

24    talked to about the allegations in his

25    complaint?

Page 491

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     MR. KELLER: Why don't you do

3     it this way.

4     MS. DYKSTRA: Sure.

5     MR. KELLER: Do it in the

6     negative. Did you meet with anybody

7     else with your counsel.

8     BY MS. DYKSTRA:

9     Q.    Okay. Did you meet with

10    anybody else that used to work in the lab with

11    your counsel around the allegations in the

12    complaint?

13    A.    No.

14    MR. KELLER: Just trying to

15    shortcut it.

16    MS. DYKSTRA: That's fine. I

17    appreciate that.

18    BY MS. DYKSTRA:

19    Q.    Did you meet with Joan

20    regarding the issues in your complaint without

21    your counsel present?

22    A.    I don't recall. I had the

23    meeting that I described. I met with her with

24    Jeffrey who is my counsel. Outside of that,

25    no. But at that first meeting, as I pointed

Page 492

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     out, we didn't talk about anything.

3     Q.    Did you ever reach out to

4     Dr. Krahl around your concerns about what

5     occurred in the lab after you left Merck?

6     A.    No.

7     Q.    Did you ever reach out to

8     Emilio Emini or Dr. Shaw about your concerns

9     in the lab after you left Merck?

10    A.    No.

11    Q.    How about Dr. Suter -- Mr. Suter?

12    A.    Same question?

13    Q.    Same question.

14    A.    No.

15    Q.    One of your interrogatory

16    answers you noted that you talked to your -- a

17    colleague or professor at Penn State about

18    your allegations. Do you recall that?

19    A.    Where is it at? 21? Exhibit 21?

20    Q.    Yes.

21    A.    Page 55?

22    Q.    Yes. There's two notes here.

23    One you talk -- on page 54 you say you talked

24    with University of Helsinki Professor Heikki

25    Peltola via e-mail. On page 55 you note that

Page 493

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     you talked with Robert Schlegel, your lab

3     supervisor at Penn State. Can you go through

4     each of those, what you recall the discussions

5     with each of those individuals?

6     A.    Start with the Heikki Peltola.

7     I think we produced the e-mails. That was the

8     extent of it.

9     Q.    Other than those e-mails, you

10    didn't have any verbal communications with

11    her?

12    A.    With who?

13    Q.    With Heikki Peltola.

14    A.    Did you say her?

15    Q.    I don't know. Is she a man?

16    A.    I don't know. I was

17    thinking -- I didn't think it was a woman.

18    Q.    Did you have any verbal

19    communications with Heikki Peltola other than

20    the e-mail communications?

21    A.    No, I wasn't even sure the

22    gender there. When you said her, I thought

23    you knew.

24    Q.    I don't.

25    A.    I don't either.

Page 494

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q.    Did you -- tell me about your

3     communication with -- well, tell me who

4     Dr. Robert Schlegel is and how long you worked

5     with him.

6     A.    He was the former head of the

7     molecular and cell biology department at Penn

8     State University. And I worked in his lab, if

9     you would go look at the CV, for the years

10    described there.

11    Q.    You spoke to him in person

12    between 2002 and 2004 about your concerns

13    around the efficacy of the vaccine?

14    A.    I don't know what we talked

15    about, but we may have -- I don't recall what

16    we talked about, but I know we wanted to be

17    responsive to this so we listed it. I don't

18    remember the details of it.

19    Q.    Do you remember whether you

20    told him that you were going to -- looking or

21    interested in filing a complaint against the

22    company?

23    A.    I don't remember the details.

24    I talked to him over a thousand times in my

25    life and I was seeing him almost every day

Page 495

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     back then, so -- I don't know the details.

3     Q.    Did you provide any data or any

4     other document, any documents related to your

5     work at Merck to Mr. Schlegel -- Dr. Schlegel?

6     A.    No.

7     Q.    Did you -- okay. Other than

8     the conversations between 2002 and 2004, did

9     you talk to Dr. Schlegel after that about this

10    litigation, or even recently?

11    A.    I haven't seen him recently.

12    So no.

13    Q.    Other than in connection with

14    discussions with your counsel and your experts

15    in this case, have you talked to anybody, any

16    professors or any of your colleagues at Penn

17    State around this litigation?

18    A.    Outside of counsel and everyone

19    I've spoken to in any way is listed in the

20    interrogatories, and these are accurate, that

21    I don't have any people to add to it.

22    Q.    I know you showed us, we went

23    through some of the documents that you

24    photocopied from Merck's lab. Do you recall

25    those documents, the counting sheets and the

Page 496

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     like that you produced in this litigation?

3     A.    I don't even remember them.

4     Yeah, I -- if you're going to ask a question,

5     yes, I understand.

6     Q.    Did you share those documents

7     with anybody outside of the company? And if

8     so, who?

9     A.    I did not share them or show

10    them to anyone outside of counsel.

11    Q.    So outside of Mr. Moody and

12    outside of your current counsel, you did not

13    share that data with anybody?

14    A.    No.

15    Q.    Mr. Krahlung, when you were

16    considering leaving the lab in June of 2001,

17    you informed David Krah that you were looking

18    for a job at Penn State but then informed him

19    that you did not get the job at Penn State.

20    What job were you looking for and what job did

21    you apply for?

22    A.    I'm not sure what you're

23    talking about.

24    Q.    I'll try and find the document

25    to produce it to you, but there's a June 19th

Page 497

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     e-mail from you to Dave Krah.

3     A.    In 2001?

4     Q.    In 2001. That states -- I'll

5     wait until we get it.

6     - - -

7     (Exhibit Krahlung-36, E-mail

8     chain, MRK-KRA00002281 & 00002282, was

9     marked for identification.)

10    - - -

11    BY MS. DYKSTRA:

12    Q.    I'm going to mark this as

13    Krahlung-36. Your e-mail is the first in the

14    chain.

15    A.    Which means where?

16    Q.    The bottom.

17    A.    And back?

18    Q.    Yes.

19    A.    What's your question?

20    Q.    In your e-mail you state that

21    you did not get the job at PSU. I was

22    wondering what job that was you were applying

23    for?

24    A.    I have no idea what that refers

25    to. This is -- I have no idea what that

Page 498

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     refers to.

3     Q.    You don't recall applying to a

4     job at Penn State during this time?

5     A.    No, I don't. I don't -- what I

6     remember about June 19th is that I called the

7     FDA.

8     Q.    What time of day did you call

9     the FDA on June 19th?

10    A.    The morning.

11    Q.    The same day that you wrote

12    this e-mail to David Krah?

13    A.    It was written on June 19th.

14    Q.    So you called the FDA the same

15    day you said to him "I think lab lunches are a

16    good idea..." and --

17    A.    You don't think I called the

18    FDA? Suter told me that I had to play ball

19    and archive things in e-mails that showed I

20    was playing ball and being decent toward these

21    people. I know that June 19th I was concerned

22    with stopping fraud and I called the FDA to

23    get that done. That's what I remember about

24    June 19th.

25    Q.    Do you have any documentation

Page 499

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     of your call on June 19th?

3     A.    No.

4     Q.    In this e-mail you state that

5     you think lab lunches are a good idea but I

6     have to agree with Joan's sentiments about

7     what happened at Jenny's B-day lunch. It

8     contributed to a hostile work environment.

9     What happened at Jenny's B-day lunch?

10    A.    I have no idea.

11    Q.    Is it true that you thought you

12    were living in a hostile work environment?

13    A.    I don't remember this e-mail.

14    I told you what I remember about June 19th.

15    June 19, 2001.

16    Q.    Do you remember in detail

17    anything specifically that you told the FDA on

18    that one call?

19           MR. SCHNELL: Object to form.

20           THE WITNESS: Can you restate

21    it?

22    BY MS. DYKSTRA:

23    Q.    Do you remember anything

24    specific about what you told the FDA on

25    June 19, 2001?

Page 500

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     A.    Specific?  What I told the FDA

3    was that Krah and Merck were committing fraud.

4    That I worked in a lab where fraud was being

5    committed.

6     Q.    Any more detail or is that the

7    two sentences you --

8     A.    I think we went over this

9    yesterday.

10    Q.    We did.

11    A.    It was a short call.  That was

12   the main point.  We exchanged contact

13   information so she could get back to me.

14    Q.    Were you disappointed that the

15   FDA wasn't taking you seriously?

16    A.    Come on.  Your characterization.

17   When did I ever say they weren't taking me

18   seriously?

19    Q.    That was a question.  Were you

20   disappointed that -- did you think the FDA was

21   not taking you seriously?

22    A.    You said was I disappointed

23   they weren't taking it seriously.  At no time

24   did ever I think they weren't taking it very

25   seriously.

Page 501

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     Q.    So you understood -- it was

3   your belief that the FDA was taking your

4   complaint seriously?

5     A.    Absolutely.

6     Q.    In this e-mail you also state

7   to Dr. Krah that as far as weekend work goes,

8   you are available for some weekend work but

9   you won't work a sixth and seventh day during

10  any week until all employees are expected to

11  consistently work a fifth.  Can you explain a

12  little more about what that means?

13    A.    I can't speak to this e-mail.

14  What I remember about June 19th is that I

15  called the FDA and reported Merck for

16  committing fraud.

17           - - -

18           (Exhibit Krahling-37, 9/7/01

19           E-mail, RELATOR\_00000746, was marked

20           for identification.)

21           - - -

22  BY MS. DYKSTRA:

23    Q.    I'm going to mark as Krahling

24  Exhibit 37 a September 7, 2001, e-mail to

25  Mr. Suter.  If you can take a look at this

Page 502

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2   e-mail.

3     A.    Okay.

4     Q.    You state that you wanted an HR

5   representative to be present if you speak to

6   David Krah.  Is that accurate?  Is that

7   accurate what was happening at the time?

8     A.    I recall the purpose of this

9   e-mail.  The purpose of this e-mail was that

10  Suter had informed me in person that no one

11  knew I had called the FDA.  And I pointed out

12  to him that I told Emini I was going to call

13  the FDA.  I said, of course, they know.

14  Colleen knows I called the FDA.  And other

15  people in the lab knew I had called the FDA.

16  Dave had told me he knew I had called the FDA.

17  And then sometime around now Dave switched

18  gears and said nobody knows who called the

19  FDA.  Suter told me to avoid putting anything

20  in an e-mail where I said that I called the

21  FDA or that Dave knew I called the FDA.  "He

22  also denied knowing why the FDA was here even

23  though yesterday he told me they were here

24  because of me."  The entire e-mail exists for

25  that sentence.  Suter told me I could not go

Page 503

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2   to him for any reason unless I had an HR

3   complaint.  That's why that e-mail exists.

4     Q.    You mean Suter told you you

5   couldn't go to Suter with allegations of

6   fraud, only allegations of HR issues?

7     A.    He said he wouldn't talk to me

8   unless I had a human resource complaint which

9   is why he always made me bring lists or do

10  lists of something that I could say about

11  personnel or administrative things in the lab.

12    Q.    Did Mr. Suter tell you he would

13  not listen to your concerns around data

14  manipulation or lab fraud?

15    A.    The very first time I met him,

16  he said that was -- said something to that

17  effect, that he wasn't going to be able to --

18  he couldn't -- he could only listen to

19  administrative complaints.

20    Q.    Did you speak to anybody else

21  in HR when he told you that or any other time?

22    A.    I don't recall.

23    Q.    So you don't recall?

24    A.    If there was anyone else

25  present or -- I don't recall, no.



Page 504

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 Q. When you got an answer that you

3 didn't like from Mr. Suter, did you go to

4 anyone else in HR?

5 A. Who said I got an answer that I

6 didn't like?

7 Q. Did you find Mr. Suter's advice

8 helpful?

9 A. In what sense helpful? Suter

10 turned out to be a way to get a face to face

11 with Emini. I like that aspect of how it

12 worked out.

13 Q. Did you talk to anybody else in

14 HR?

15 A. I don't know. I don't recall.

16 Q. So all of the complaints, the

17 HR-type administrative complaints that are in

18 your letter to Dr. Emini that we looked at and

19 in your other correspondence with Mr. Suter,

20 those are real complaints or fake complaints?

21 A. What do you mean fake

22 complaints?

23 Q. Well, were they real HR issues

24 or were they just HR issues you made up to put

25 in e-mails?

Page 505

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 A. I did not make up any issues.

3 Q. So they were real HR issues?

4 A. I don't recall those things.

5 What I know is that Suter said you can't

6 come -- that I couldn't come to him unless I

7 had an HR-related complaint. And he gave me

8 an assignment to compile things. That's what

9 I remember about that.

10 Q. And your compilation of HR-type

11 issues were real, accurate HR issues?

12 A. I have no reason to believe

13 they wouldn't be accurate, but I don't know

14 what they are.

15 Q. Well, they're the ones that we

16 went through in the letter you wrote to

17 Dr. Emini.

18 A. What I'm saying is looking at

19 these, I can't detail what they're referring

20 to or what they are.

21 Q. Why don't we look back at the

22 letter to Dr. Emini which is Exhibit -- the

23 August 8, 2001, letter, if you can find it in

24 that stack. I don't have it in front of me.

25 MR. SCHNELL: 17?

Page 506

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 MR. KELLER: 17.

3 MR. SCHNELL: 17, I think.

4 THE WITNESS: Okay.

5 BY MS. DYKSTRA:

6 Q. In your letter to Dr. Emini of

7 August 8, 2001, you list a series of HR-type

8 complaints. For example, you state that Dave

9 has highly personal relationships with female

10 employees, he gives gifts, holiday gifts, work

11 anniversary gifts, gifts for no reason,

12 baskets of candy, that is causing strain and

13 tension. Is that accurate or inaccurate?

14 A. What I remember about this

15 letter is that these HR related things are

16 what Bob Suter wanted. And that Bob Suter

17 wanted me to bring these things to him so that

18 he might talk about some of them with Emini,

19 and that I was to do it anonymously. I jumped

20 through Bob Suter's hoop with these details.

21 And what I did is signed the letter, put it

22 directly in Emini's mailbox and talk about

23 mumps testing all throughout this letter.

24 That's the part that I remember because that's

25 the part that mattered.

Page 507

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2 Q. I'm going to read my question

3 back to you and can you answer it, please?

4 In your letter to Dr. Emini of

5 August 8, 2001, you list a series of HR-type

6 complaints, for example, you state that Dave

7 has personal relationships with female

8 employees, he gives work anniversary gifts,

9 gifts for no reason, and is causing strain and

10 tension. Is that an accurate statement or

11 not?

12 A. I don't have anything further

13 to add to my previous answer.

14 MS. DYKSTRA: Are you going to

15 permit him not to answer the question

16 whether it's accurate or not?

17 MR. SCHNELL: He answered all

18 these questions yesterday, so...

19 MS. DYKSTRA: I just want to

20 know whether it's accurate or not.

21 MR. SCHNELL: He answered that

22 yesterday and he told you.

23 MS. DYKSTRA: He did not tell

24 me yesterday.

25 THE WITNESS: She's saying

Page 508

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     accurate. I did answer it. I said I

3     don't have a recollection of the HR

4     things that Bob assigned to me to jump

5     through that hoop. What I do recall --

6     BY MS. DYKSTRA:

7     Q. I'm not asking -- maybe there's

8     miscommunication. I'm not asking about what

9     Bob assigned to you.

10     MR. KELLER: Let him finish.

11     MS. DYKSTRA: I'm going to --

12     let me clarify my question.

13     BY MS. DYKSTRA:

14     Q. I'm not asking what Bob

15     assigned you or didn't assign you. I'm asking

16     if what you wrote in the letter to Dr. Emini

17     are accurate representations of what you

18     experienced in the lab?

19     A. Not recollecting the HR details

20     I was told to list, I have no reason to

21     believe they would be inaccurate.

22     Q. Did you seek any therapy for

23     the constant source of strain and tension

24     caused in the lab?

25     MR. SCHNELL: Objection. Come

Page 509

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     on.

3     BY MS. DYKSTRA:

4     Q. I'm serious. You can say yes

5     or no, you don't have to tell me the details

6     of that. I'm just asking --

7     MR. SCHNELL: If you don't want

8     to answer it, you don't have to.

9     THE WITNESS: But she's

10     serious. I'm not answering that.

11     - - -

12     (Exhibit Krahling-38, 9/11/01

13     E-mail, RELATOR\_00000750, was marked

14     for identification.)

15     - - -

16     BY MS. DYKSTRA:

17     Q. I'm going to mark as Exhibit 38

18     a September 11, 2001, e-mail.

19     A. What's the question?

20     Q. Do you remember this e-mail?

21     A. It was September 11, 2001. I

22     remember the day.

23     Q. Yes, it was 2:30 on September 11,

24     2001. Do you remember writing this e-mail to

25     Mr. -- Dr. Krah?

Page 510

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     A. I wrote this e-mail so that I

3     could hand it to HR because Dave was

4     continuing to just yell at me all the time,

5     things like that. I wanted to be able to

6     get -- this is after the FDA came in, and I

7     was trying to get away from the lab or at

8     least get out and start to feel safe with

9     things. So I felt like I needed to document

10     something there for HR. It was quite an

11     emotional day that day.

12     Q. You state that you're writing

13     this e-mail in response to the verbal abuse

14     and hostility you bestowed upon me during our

15     last meeting. Do you remember that meeting

16     that you're referring to?

17     A. I remember him yelling again on

18     September 11th, but I don't remember the

19     details.

20     Q. Do you remember what he was

21     yelling about?

22     A. No.

23     Q. Do you remember whether it was

24     about your work in the lab or something

25     completely extraneous to the lab?

Page 511

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     A. No. I don't remember what it

3     was about. I remember the day. That's the

4     only reason I can anchor that e-mail.

5     Q. I'm assuming you remember the

6     day because it was September 11th, not for

7     some other reason?

8     A. Yeah, that's why I remember the

9     day. I didn't feel like getting yelled at on

10     that day.

11     Q. What you wrote here, though,

12     even though you said that this was -- you were

13     documenting this so that you could send it to

14     HR, your statements in the e-mail, are they

15     accurate or inaccurate?

16     A. What I remember is that

17     September 11, 2001, was happening and Krah

18     yelling at me while those buildings were about

19     to collapse. I didn't feel like being yelled

20     at and I thought I'm just going to document

21     this and hand it to HR. That's the reason I

22     can remember the fact that I wanted to just

23     write that and do that so I didn't have to

24     deal with him that day.

25     Q. Did you work the whole day on

Page 512

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL  
 2 September 11, 2001?  
 3 A. No.  
 4 Q. When did Dr. Krah laugh at you  
 5 and said you -- tell you you have no  
 6 intelligence?  
 7 A. I wouldn't know what day that  
 8 was.  
 9 Q. Sometime before this e-mail?  
 10 A. If you're talking about it  
 11 being documented here, I would guess. I don't  
 12 know. I can't speak to the detail. I just  
 13 know why I wrote it and turned it in to HR.  
 14 Q. Did Dr. -- did you see Dr. Krah  
 15 yell at anybody else in the lab?  
 16 A. I'm sure he did occasionally.  
 17 Q. Did you see Dr. Krah yell at  
 18 anybody else in the lab?  
 19 A. I think I detailed one instance  
 20 of that in the letter I sent to -- the letter  
 21 given to Emini. I only remember that because  
 22 I read it yesterday. I mean, I don't pick it  
 23 out right now off the top of my head.  
 24 Q. The lawyer that you used for  
 25 your separation agreement, Tonia Torquato, did

Page 513

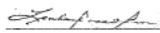
1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL  
 2 you ever use her for any other legal work  
 3 other than in connection with your separation  
 4 agreement?  
 5 A. What are you referring to as a  
 6 separation agreement?  
 7 Q. The agreement pursuant to which  
 8 you received payment from the company. We can  
 9 point to it, we marked it as an exhibit.  
 10 A. Did you mark it as an exhibit?  
 11 Q. Yes, we did. I'll give you the  
 12 number in a second. That's it. What number  
 13 is that, Mr. Krahling?  
 14 A. Exhibit 28.  
 15 Q. Yes. Did you work with that  
 16 lawyer who represented you in that -- in  
 17 connection with that agreement, did you work  
 18 with her at any other time in connection with  
 19 any other legal matter?  
 20 A. I don't recall.  
 21 Q. You don't recall?  
 22 A. No, I don't recall.  
 23 MS. DYKSTRA: Can we take a  
 24 two-minute break? We may wrap up.  
 25 VIDEOGRAPHER: The time is

Page 514

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL  
 2 2:56. We're going off the video  
 3 record.  
 4 - - -  
 5 (A recess was taken.)  
 6 - - -  
 7 VIDEOGRAPHER: The time is  
 8 3:01. We're back on the video record.  
 9 MS. DYKSTRA: Mr. Krahling,  
 10 thank you for your time. We don't have  
 11 any additional questions.  
 12 MR. KELLER: Thank you.  
 13 MR. SCHNELL: Thanks.  
 14 VIDEOGRAPHER: The time is  
 15 3:02. This concludes the videotape  
 16 deposition of Stephen Krahling.  
 17 - - -  
 18 (Witness excused.)  
 19 - - -  
 20 (Deposition concluded at  
 21 3:02 p m.)  
 22  
 23  
 24  
 25

Page 515

1 STEPHEN KRAHLING - HIGHLY CONFIDENTIAL  
 2 CERTIFICATE  
 3  
 4  
 5 I do hereby certify that I am a Notary  
 6 Public in good standing, that the aforesaid  
 7 testimony was taken before me, pursuant to  
 8 notice, at the time and place indicated; that  
 9 said deponent was by me duly sworn to tell the  
 10 truth, the whole truth, and nothing but the  
 11 truth; that the testimony of said deponent was  
 12 correctly recorded in machine shorthand by me  
 13 and thereafter transcribed under my  
 14 supervision with computer-aided transcription;  
 15 that the deposition is a true and correct  
 16 record of the testimony given by the witness;  
 17 and that I am neither of counsel nor kin to  
 18 any party in said action, nor interested in  
 19 the outcome thereof  
 20  
 21 WITNESS my hand and official seal this  
 22 5th day of May, 2017  
 23  
 24  
 25

  
 \_\_\_\_\_  
 Linda Rossi-Rios, RPR, CSR  
 Notary Public

Page 516

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     INSTRUCTIONS TO WITNESS

3     Please read your deposition over

4 carefully and make any necessary corrections.

5 You should state the reason in the appropriate

6 space on the errata sheet for any corrections

7 that are made.

8     After doing so, please sign the errata

9 sheet and date it.

10    You are signing same subject to the

11 changes you have noted on the errata sheet,

12 which will be attached to your deposition.

13    It is imperative that you return the

14 original errata sheet to the deposing attorney

15 within thirty (30) days of receipt of the

16 deposition transcript by you. If you fail to

17 do so, the deposition transcript may be deemed

18 to be accurate and may be used in court.

19

20

21

22

23

24

25

Page 518

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     ACKNOWLEDGMENT OF DEPONENT

3     I, \_\_\_\_\_, do

4 hereby certify that I have read the foregoing

5 pages and that the same is a correct

6 transcription of the answers given by me to

7 the questions therein propounded, except for

8 the corrections or changes in form or

9 substance, if any, noted in the attached

10 Errata Sheet.

11 \_\_\_\_\_

12 \_\_\_\_\_

13 DATE                   SIGNATURE

14

15 Subscribed and sworn to before me this

16 \_\_\_\_\_ day of \_\_\_\_\_, 2017.

17

18 My commission expires: \_\_\_\_\_

19 \_\_\_\_\_

20 \_\_\_\_\_

21 Notary Public

22

23

24 Assignment: PA 2587892

25

Page 517

1     STEPHEN KRAHLING - HIGHLY CONFIDENTIAL

2     -----

3     E R R A T A

4     -----

4 PAGE LINE CHANGE

5 -----

6 Reason for Change:

7 \_\_\_\_\_

8 -----

9 Reason for Change:

10 \_\_\_\_\_

11 -----

12 Reason for Change:

13 \_\_\_\_\_

14 -----

15 Reason for Change:

16 \_\_\_\_\_

17 -----

18 Reason for Change:

19 \_\_\_\_\_

20 -----

21 Reason for Change:

22 \_\_\_\_\_

23 -----

24 Reason for Change:

25 \_\_\_\_\_