BE IT REMEMBERED that on Tuesday, May 2, 1989, commencing at 2:30 p.m. thereof, at 151 Union Street, Suite 551, San Francisco, California, before me, LORNA SCHANZENBACH, a Notary Public in and for the County of San Francisco, personally appeared

MILTON MOZEN, PH.D.,

called as a witness by the Plaintiff, who, having been first duly sworn, was examined and testified as follows:

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Law Offices of John Rapp, 2121 Davies Pacific Center, 841 Bishop Street, Honolulu, Hawaii, represented by JOHN RAPP, Attorney at Law, appeared as counsel on behalf of the Plaintiff.

O'Connor, Cohn, Dillon & Barr, 151 Union Street, Suite 551, San Francisco, California, represented by SUSAN REIFEL, Attorney at Law, appeared as counsel on behalf of the Defendant.

Also present: Chris Bayuk and Marirose Piciucco.

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EXAMINATION BY MR. RAPP

MR. RAPP: Q. Would you state your name for the record, please?

A. Milton Mozen.

Q. Dr. Mozen?

A. Yes.

Q. You work for Cutter?

A. Yes.

Q. What's your position?

A. I'm Director of Biochemical Research and Development.

Q. Are you Cutter's responsible head? Is that the FDA term?

A. No. No and yes.

Q. That's the term, but you're not the person?

A. Yes.

Q. Who is that?

A. Our responsible head is a woman named Carol Moore.

Q. And she works at what location?

A. In Berkeley.

Q. And how long have you been with Cutter?

A. Almost 22 years.

Q. What were your prior positions? Maybe we can work backwards to about 1980 -- or have you had the same

title, Director of Biochemical Research and Development? I think I fouled that up.

A. You mean for the entire time that I was with Cutter?

MS. REIFEL: You're going back to 1980?

MR. RAPP: Yes.

THE WITNESS: In 1980, I think my title was Director of R & D Biologicals.

MR. RAPP: Q. Then what happened?

A. Well, we've had certain consolidations and change in direction of our research so that certain units that I was administering moved into other areas, and we had some just general shifting around. They changed the title.

Q. Since 1980, was there a change in the duties or more just a change in titles?

A. Well, duties were relatively the same. The departments for which I was responsible moved to other areas. As an example, I used to be director of the department of microbiology, and that moved into another director's domain. And I'm not certain, as far as dates are concerned, when all of these things occurred.

Q. Just tell me generally then what have been your duties at Cutter since 1980.

A. Well, in general, I direct the department, or

several departments engaged in research directed toward developing new products. And these products primarily have their origin in human plasma. And the work also includes, or the research also includes product improvement and process improvement.

Q. So I take it you're involved with Factor VIII?

A. Yes.

Q. Did you do anything to prepare yourself to give this deposition today?

A. No.

Q. Just walked in cold?

A. Cold.

Q. Did you review any papers or documents or anything?

A. Just glanced at the notice that you had sent to my attorney regarding the deposition request.

Q. Did you bring any papers with you that have anything to do with AIDS or Factor VIII?

A. No.

Q. Other than your company's attorneys, did you talk to anybody about the deposition, what might come up?

A. No.

Q. Didn't have any discussions with any of your fellow employees about it?

A. No.

Q. Do you have any information about any recalls or withdrawals of any non-heat-treated Factor VIII?

MS. REIFEL: I'm not sure what you mean by "any information." It's pretty vague.

MR. RAPP: Just getting started.

MS. REIFEL: Okay. Does he know whether one ever occurred?

MR. RAPP: All that sort of thing.

Q. Do you have any information about recalls or withdrawals of any non-heat-treated Factor VIII?

A. You mean by our company?

Q. Well, yes.

A. Well, I'm aware that from time to time, we have occasion and reason to recall products.

Q. Factor VIII?

A. Yes.

Q. Non-heat-treated Factor VIII?

A. Yes.

Q. Can you tell me how many recalls or withdrawals of non-heat-treated Factor VIII there have been?

A. No.

MR. BAYUK: With respect to what?

MR. RAPP: Let's see. What company are you

representing?

MR. BAYUK: Miles. But your question is vague. Do you want recalls with respect to AIDS, or --

MR. RAPP: I'd just like to ask that Miles select one representative at the deposition. I don't care who it is, but I don't want to be getting shot at from every conceivable direction. It confuses me.

MR. BAYUK: Okay.

MR. RAPP: But I was talking about recalls for any reason of non-heat-treated Factor VIII.

Q. Who could give me information about these recalls? How many there were?

MS. REIFEL: Well, I would object to the extent you're asking for recalls for any other reason than potential AIDS transmission or plasma from someone who is suspected to have AIDS. If you want to limit it to that question, I'll let him answer it.

MR. RAPP: Okay. Otherwise, you're going to instruct him not to answer?

MS. REIFEL: It's outside the scope of your deposition notice, and it's not relevant to the subject matter of this action.

MR. RAPP: So yes, you are telling him not to answer my question?

MS. REIFEL: Yes.

MR. RAPP: Could you read back that last question, please?

(Record read.)

MR. RAPP: Q. I'll go along with your counselor's suggestion. I'd like to ask you about recalls of Factor VIII because of some fear that it might contain a virus of some sort.

Now, can you tell me whether there have been any such recalls?

A. I'm not aware of any.

Q. Just tell me what recalls there were of non-heat-treated Factor VIII. What year did they take place?

A. I can't answer that. I don't know the answer to that.

Q. Is there somebody else in your company that would be able to tell me the answers?

A. Yes.

Q. Who would that be?

THE WITNESS: Is that within the scope of this deposition?

MS. REIFEL: I don't see anything concerning recalls or withdrawals in the deposition notice.

MR. RAPP: I'm just asking who would be able to tell me.

MS. REIFEL: It's outside the scope of the deposition notice, so limit it to that.

MR. RAPP: Are you going to instruct him not to answer that one?

MS. REIFEL: Yes.

MR. RAPP: Q. Now, there were recalls of non-heat-treated Factor VIII in 1983, right? You can remember that, can't you?

MS. REIFEL: I have a relevancy objection to this entire line of questioning, but I'll let him go ahead and answer.

THE WITNESS: Well, the dates are vague to me. I'm just not certain, and I don't wish to speculate.

MR. RAPP: Q. Were you involved in the decision to make the recalls of non-heat-treated Factor VIII?

A. No.

Q. Were you involved in discussions that led up to those recalls?

A. I was involved in some discussions, yes.

Q. Tell me about those discussions.

MS. REIFEL: What do you want to know? I think that's a pretty vague question.

MR. RAPP: Q. Let's start with who took part in them.

MS. REIFEL: Can we identify which discussion we're talking about, because you've used recalls plural, and I'm not sure he was involved in any more.

MR. RAPP: Q. Let's start with the first discussion you can remember about whether or not some Cutter product should be recalled, Cutter non-heat-treated Factor VIII.

A. You mean for any reason?

Q. Yes. We can exclude things that happened before 1980.

MS. REIFEL: Well, I'm going to instruct him to also exclude any recalls for any other reason than it was suspected that the plasma came from a donor who might have AIDS. That's what we're here talking about today and that's what your deposition notice says.

MR. RAPP: Q. Okay. Go ahead then.

A. The question again, please?

Q. You're supposed to tell us about recalls of non-heat-treated Factor VIII because it was suspected that the plasma came from a donor that had AIDS and the discussions that you heard or were a part of.

A. I thought you asked me something more specific than that. Was there something more specific?

Q. Well, it was first, discussions.

A. And your question is just to tell you about

those discussions?

Q. Yes.

A. Well, we had a committee at Cutter at that time that reviewed various matters related to our product line. And there were a number of discussions at our monthly meetings about issues related to all of our biological products, including Factor VIII.

Q. What's the name of this committee?

A. I think at that time, we called it the Biological Management Committee.

Q. Has its name been changed?

A. It doesn't exist now.

Q. When did it cease to exist?

A. I don't remember.

Q. What's your best recollection on that subject?

A. Two years ago.

Q. Why was it disbanded?

A. Well, largely because many members of our team moved their place of employment to our headquarters in West Haven, Connecticut.

Q. All right. Can you tell me who the members were in 1982, 1983?

A. Not specifically.

Q. Okay. Just name those that you can remember

were members.

A. Well, there was a man named Jack Ryan. There was our Director of Regulatory Affairs; his name was Steven Ojala, O- j- a- l- a. There was our Director of Quality Assurance, who was a man named John Cherry. A number of other marketing people, perhaps Wayne Johnson, Jan Hjorth.

Q. J- a- n?

A. H- j- o- r- t- h.

Q. H- j- o- r- t- h?

A. Right.

Q. And "Jan" is J- a- n?

A. Right.

Q. What was his area?

A. Well, he was largely involved with international affairs as it pertains to marketing our products.

Q. And who else was on the Biological Management Committee?

A. John Hink; Conrad Turner.

I don't believe I remember any others at this time.

Q. If you think of any as we go through -- you know, that always happens, "Oh, yes. So and so, Mr. Cutter was on it" -- let us know.

Now, some of these people are still with Cutter, I

take it?

A. Yes.

Q. Which ones? Jack Ryan?

A. Yes.

Q. Ojala is left, of course. Oh, I miss pronounced that, I bet. Is it "Ojala"?

A. Yes.

Q. John Cherry, is he still with Cutter?

A. No.

Q. Where does he live now?

A. I don't believe I know.

Q. Do you know who he works for?

A. No.

Q. Where did he live when he was here?

A. Somewhere in the GRO-C

Q. Would your company have any information which might indicate where he is now?

A. I don't know.

MS. REIFEL: That calls for speculation.

MR. RAPP: Q. How about Wayne Johnson: Is he still with your company?

A. Yes.

Q. And Jan Hjorth?

A. No.

Q. What's he doing now?

A. He's retired.

Q. Do you know where he lives?

A. No.

Q. Where did he last live?

A. GRO-C

Q. And did he leave your company to go into retirement?

A. Yes.

Q. How about Conrad Turner: Is he still with your company?

A. No.

Q. What happened to him?

A. He took another job.

Q. Where?

A. With Alpha Therapeutics.

Q. Is he still with them, as far as you know?

A. Yes.

Q. Were there any minutes, or notes, or even handwritten notes kept regarding the committee meetings by anybody?

A. I'm not sure what you mean by "kept."

Q. Well, people make notes and stick them in a file, and maybe they're still around someplace.

MS. REIFEL: That calls for speculation to the extent you're asking what people might have done and

whether any notes might still exist.

MR. RAPP: Q. How about it?

A. Maybe.

Q. Did you keep notes?

A. Yes.

Q. Do they still exist?

A. No.

Q. When were they destroyed?

MS. REIFEL: If you remember.

THE WITNESS: I don't remember.

MR. RAPP: Q. What led to the destruction of those notes?

A. I moved my office about a year and a half ago, and I did a lot of cleaning up at that time.

Q. And you think that's when you tossed them?

A. If I had to speculate, I would say that, yes.

Q. Now, were these handwritten notes, or were they typed?

A. Both.

Q. And you had prepared them?

A. The handwritten notes, I would have prepared, yes.

Q. And who prepared the typed ones?

MS. REIFEL: If you know.

THE WITNESS: Well, I know there was a

secretary to the committee, but I don't recall who that was.

MR. RAPP: Q. So there was a practice that you would keep minutes and type them up?

A. Say that again, please.

Q. Was there a practice that this secretary would keep minutes and type them up?

A. Yes.

Q. I see. And where would those -- where were those kept?

A. Each member would receive the minutes. And if they elected to file them and keep them, that's where they would be.

Q. And was there any master set maintained by anyone, the secretary, or the head of the committee, or the company?

MS. REIFEL: If you know.

THE WITNESS: I don't know for certain.

MR. RAPP: Q. Do you know if anyone has checked with the various committee members and the secretary to see if any of these notes or minutes still exist?

A. I'm not aware of any such checking.

Q. Nobody came to you and said, "Hey, do you still have minutes of the committee?"

A. That's correct.

Q. And you didn't go to anybody else and ask for their minutes?

A. That is correct.

MR. RAPP: Well, I'd like to request that someone find out if these minutes do exist and produce them.

MS. REIFEL: Fine. You can make a formal request.

MR. RAPP: We did, and I think this is covered by our request. But you must have forgotten.

MS. REIFEL: I don't know what request you're referring to.

MR. RAPP: I know the latest one covered it. And I think the earlier ones, also.

Q. So your best recollection is that you threw away your set a year and a half ago?

A. That's my best recollection, yes.

Q. And at that time, did you have a complete set of all the typewritten minutes?

A. I think so.

Q. Did these minutes reflect discussions about Factor VIII and AIDS?

MS. REIFEL: I thought that was presumed in your question. I'm going to object on the grounds of

relevancy to the extent you've been asking for biological committee minutes that didn't have to do with this meeting concerning withdrawal of Factor VIII because it was suspected to come from someone with AIDS. I thought all of of that was presumed.

MR. RAPP: You're objecting retroactively?

MS. REIFEL: I suppose so.

MR. RAPP: Okay.

Q. So can you answer my question now?

A. I'll have to hear it again.

Q. These notes did include discussions about Factor VIII and AIDS?

A. To some extent.

Q. Do you know if your minutes, your own set, if copies were ever produced to your company's lawyers?

A. I'm not aware of any.

Q. Do you know if anybody's set of minutes was ever produced to your company's lawyers?

A. I'm not aware of any.

Q. Or to any lawyers that were asserting claims against your company?

A. I'm not aware of any.

Q. So a year and a half ago, you moved your office. That would have been somewhere around December 1987.

MS. REIFEL: What's the relevance of this? Can we move on?

MR. RAPP: I just want to try to find out our best view as to when these were discarded.

Q. Would it have been about December '87?

A. Approximately.

Q. Can you tell me if it was before or after Christmas?

A. Before.

Q. Before Christmas. Why can you say that?

A. Because I said earlier, it was about a year and a half. But now when you pin me down, as I recall, it was towards the end of the summer. So it was probably August of 1987. But that's still within my definition of approximately a year and a half.

Q. That's fine. So now you can remember it was really around August of '87?

A. Yes.

Q. Okay, good. Did you talk to anybody about whether you should dump that file of minutes and notes?

A. No.

Q. Just made the decision entirely on your own?

A. Yes.

Q. Did you ever find out any information about whether the others that had these were throwing theirs

away, also?

A. No.

Q. Did you ever get any general information about retaining documents from anybody else in the company, any kind of documents?

MS. REIFEL: This entire line of questioning is outside the scope of the deposition notice and not relevant. Are you going to move along?

MR. RAPP: Well, I will when you leave me no choice.

MS. REIFEL: I have a continuing relevancy objection if you're going to proceed in this manner.

MR. RAPP: Q. Now, as of August 1987, do you know whether there were any lawsuits pending against your company relating to Factor VIII and AIDS?

MS. REIFEL: Objection. Irrelevant.

MR. RAPP: Q. Unless she tells you not to answer, I think you can, even if she puts her objection for the record. Correct me if I'm wrong, but --

THE WITNESS: Could I hear the question again, please?

MR. RAPP: Q. There were lawsuits pending at that time, were there, about AIDS?

A. I believe so, yes.

Q. Did you think that the notes might have some

usefulness in connection with any of those lawsuits?

MS. REIFEL: Objection. Calls for speculation, irrelevant, outside the subject matter of the deposition notice. You don't have to answer it.

MR. RAPP: Q. Was there any time anybody in your company or outside of your company ever said anything along these lines: "It would be just as well to throw away old papers or documents relating in any way to AIDS and Factor VIII"?

MS. REIFEL: Objection. Vague, overbroad, irrelevant outside the scope of the deposition notice. Don't answer it.

MR. RAPP: Q. I'm sorry. We got off on the side there about those notes, but you were starting to talk about your recollections of these meetings where there were discussions about Factor VIII and AIDS.

Now, are you able to give me any kind of a time frame about when such discussions started or first took place?

MS. REIFEL: You're talking about any discussions in general about fact Factor VIII and AIDS, or discussion about a withdrawal or recall?

MR. RAPP: The former. I guess I shifted gears, didn't I? I'll have to --

THE WITNESS: Well, I suspect, from the

broadness of your question, I would say that mostly through '83, '84, we found those subjects subjects of our discussion, yes.

MR. RAPP: Q. Can you tell me what prompted the first discussion you can recall about the possibility that there might be an AIDS virus in the Factor VIII?

MS. REIFEL: Objection. Calls for speculation. You can go ahead and answer if you know.

THE WITNESS: I don't know.

MR. RAPP: Q. Well, was there a time when -- you know, for the first time you considered the possibility that the AIDS virus might be in the Factor VIII?

A. Yes.

Q. And what prompted your first thinking on that subject?

MS. REIFEL: I'm going to ask you to clarify that question. Are you asking him when he thought the AIDS virus might be in the product, or something that might be responsible for causing AIDS in users? Those are two different questions.

MR. RAPP: Q. Okay. You can answer both of them or give me an answer that's broad enough, if you like.

A. Well, I think perhaps in 1984, as I recall,

early '84, there was a report concerning the transmission of AIDS by a blood transfusion given here in San Francisco to an infant who subsequently developed AIDS, as I recall today was the first time I can think of when it appeared that AIDS was transmissible via blood.

Q. You said that was early 1984?

A. To the best of my recollection, yes.

Q. Is this a 19-month-old infant?

A. I don't remember.

Q. And where did you hear about this from?

A. Probably the first time in the Chronicle.

Q. And before that, had you been involved in any discussions about the possibility that the AIDS virus might be in the Factor VIII?

MS. REIFEL: I object to the form of the question.

MR. RAPP: Q. Can you answer?

A. I can't answer it, not in the time frame of prior to 1984 that you just referred to. You asked me prior to early '84, and that is not a relevant question in that time frame.

Q. Why not?

A. There was no information concerning the etiologic agent responsible for the disease AIDS.

MR. RAPP: Can you mark this as Exhibit 1,

please?

(Plaintiff's Exhibit 1 marked.)

MR. RAPP: Q. Do you recognize Exhibit 1, which is a letter or something dated July 9, 1982, to L.G. Hershberger?

MS. REIFEL: Can you read it?

THE WITNESS: I can't read it, but I believe I've seen it before.

MR. RAPP: Q. Okay. Is this a document that was sent to your company?

A. Yes.

Q. In about July 1982?

A. Yes.

MS. REIFEL: That calls for speculation, but the document speaks for itself.

MR. RAPP: Q. Did you see this document soon after it was received by your company evidently in 1982?

A. I don't remember specifically.

Q. Based upon where you were positioned in your company and the normal procedures that were followed in your company, would you have seen this?

A. Yes.

Q. And after this document was received by your company, was it filed away in the business records of Cutter?

MS. REIFEL: Calls for speculation.

THE WITNESS: I don't know where it would be filed.

MR. RAPP: Q. Did you file a copy anywhere?

A. I don't remember.

Q. Did you put a copy in any kind of folder, or drawer, or --

A. I just don't remember.

Q. Seeing Exhibit 1 now, does this lead you to -- do you want to correct your prior answer or change it in any way about early '84 as being the first thinking you really did on the subject of AIDS and Factor VIII, or do you still stand by that answer?

MS. REIFEL: I think that misstates his prior testimony. We were talking about AIDS and blood previously.

THE WITNESS: I can't answer the question in that form. I'm sorry.

MR. RAPP: Q. Does Exhibit 1 lead you to question the accuracy of any of your prior answers so far in the deposition?

A. No.

Q. It doesn't. Okay.

After Exhibit 1 came into your company, did you have any discussions about it with anybody?

A. Not that I recall.

Q. Do you know whether any writings were generated as a result of Exhibit 1?

MS. REIFEL: By whom?

MR. RAPP: Q. By anyone in your company.

MS. REIFEL: Calls for speculation.

THE WITNESS: No.

MR. RAPP: Q. You don't know. Did you write up any kind of a report --

A. No.

Q. -- or analysis, or see any that anyone else wrote up?

A. Not that I recall.

Q. Did anyone at your company do anything as a result of Exhibit 1?

MS. REIFEL: Objection. Vague and calls for speculation.

THE WITNESS: I don't even know what that means.

MR. RAPP: Q. Well, take any action; undertake any studies; have any discussions; respond; do anything; or did you just say, "Oh, who cares?" That's what I'm getting at.

A. That's too vague.

Q. All right. Was there any kind of action

taken by anyone in your company as a result of Exhibit 1?

A. Not that I'm aware of.

Q. So your best recollection is that no action was taken in response to Exhibit 1?

MS. REIFEL: I object to the form of the question. And it calls for speculation as to what anyone did.

THE WITNESS: I'm not sure what kind of action you're referring to.

MR. RAPP: Q. Well, what I mean is any kind of reaction, or you do anything, or you undertake any discussions, you talk about it.

A. Well, I have to presume that we talked about it, yes.

Q. And would you have taken part in those discussions?

A. Again, I would presume so, yes. But I can't remember specifically.

Q. Do you have any general recollections?

A. No.

Q. As a result of Exhibit 1, did you develop a concern that Factor VIII might contain the AIDS virus?

MS. REIFEL: And you're talking about Exhibit 1 in isolation without any other information?

MR. RAPP: Yes.

THE WITNESS: You're asking me about July 1982, and you're referring to an AIDS virus. That's impossible to answer such a question.

MR. RAPP: Q. All right. I apologize if my questions are lousy. But please tell me why you give that answer, that it's impossible to answer that. Because AIDS hadn't been identified at that time?

A. We didn't know anything about viruses and AIDS in 1982.

Q. You did know after your company received Exhibit 1 that at least three patients who had received Factor VIII had developed this Pneumocystis Carinii pneumonia, right?

A. That's what the document says.

Q. That's some information that your company received about July 1982, right?

A. That's correct.

Q. And that's an unusual disease, isn't it?

MS. REIFEL: Do you know?

THE WITNESS: I know that it was unusual, but it started to become commonly seen about this time in various segments of our population.

MR. RAPP: Q. It was an uncommon disease in the early 1980's, right? You know that?

A. So I've read, yes.

Q. And most of the cases of it since, say, 1982 have been because of AIDS, right?

A. Yes.

Q. That's one of the diseases that people with AIDS develop?

A. Yes.

Q. And the fact that these three patients with this type of pneumonia had received Factor VIII suggested that there was a possibility that the Factor VIII may have had something to do with the pneumonia, right?

MS. REIFEL: Objection. Calls for speculation.

THE WITNESS: It's too speculative to say.

MR. RAPP: Q. Well, as a scientist, that's something that you would feel would deserve further explanation, right?

A. There were any number of explanations that could it be advanced for that, yes.

Q. But when you read this memo, it did cause concern in your mind about the safety of your Factor VIII, right?

A. We're always concerned with the safety of hemophiliacs. That's a very prime concern we have.

Q. And this memo caused added concern, right?

A. Well, it's a very vague memo in terms of a

cause and effect. So that it could be a concern, but I can't describe the level as high, medium, or low.

Q. Didn't this memo hit your company like a bomb shell and really cause a lot of worry about your Factor VIII?

MS. REIFEL: Objection. Argumentative. You don't have to answer the question.

THE WITNESS: I wouldn't answer that question.

MR. RAPP: Q. When you read this memo, no doubt you noticed the last sentence in the second paragraph, "No two of the patients are known to have received concentrate from the same lots," right?

A. Where are you reading, please?

Q. The last sentence of the second paragraph, "No two of the patients are known to have received concentrate from the same lots."

MS. REIFEL: I'm sorry. What was your question with regard to that?

MR. RAPP: Q. Well, you read that sentence, of course, back in July 1982, right?

A. I presume so.

Q. And did that sentence have any meaning to you or significance to you?

A. I couldn't remember that far back.

Q. What's your -- as you read it now, does it have any meaning to you, or did you draw any conclusions from it?

MS. REIFEL: Objection. Irrelevant what he thinks about it now.

MR. RAPP: Q. Can you answer?

A. I don't even understand the question.

Q. Doesn't that last sentence mean that more than one lot of Factor VIII must have -- contain whatever it was that was causing this pneumonia problem?

A. No.

Q. Why not?

A. Because we haven't established that this has anything to do with the pneumonia problem.

Q. Now, you do know that the Factor VIII did have something to do with the pneumonia problem, right?

MS. REIFEL: Objection as to what he knows now.

THE WITNESS: Are we talking about 1989 or 1982?

MR. RAPP: Q. Now we're talking about 1989. We now know that the Factor VIII was causing pneumonia, right?

A. That certainly is the -- in 1989 -- the presumption, yes.

Q. That's the current state of the knowledge?

A. Yes.

Q. And back in July 1982, it wasn't known. It was a possibility that was being explored, right?

A. Perhaps, yes.

Q. In fact, your company was exploring the possibility, right?

A. I don't know what "exploring the possibility" means.

Q. Looking into, trying to get an answer.

A. No.

Q. Your company was not?

A. No.

Q. At any point, did your company try to explore the possibility that the Factor VIII contained the AIDS virus?

MS. REIFEL: Objection. Vague.

THE WITNESS: I don't understand the question.

MR. RAPP: Q. My question is very simple. At any point in time, did Cutter try to explore the possibility that Factor VIII contained the AIDS virus?

MS. REIFEL: Objection. Vague and ambiguous. I don't think he understands what you mean by "explore."

THE WITNESS: It is too vague. I'm sorry.

MR. RAPP: Q. Is my terminology okay about, you know, the AIDS virus? Should I say HIV or something else?

A. That's fine. But we keep jumping in time from '84 to '89 to '82. And it's difficult for me to answer in the context of the time frame that we're dealing with.

MR. RAPP: Q. All right. Did we solve our problem about "explore the possibility," or do we need to talk more about what we mean by that?

MS. REIFEL: I'll continue my objection as vague. Maybe you could ask -- I don't know.

THE WITNESS: You have to understand, in 1982, there were a great number of speculations regarding the cause of AIDS. And they were all very, very tenuous. So there was nothing that one could really do to answer your question of explore -- whatever you asked me we were exploring.

Yes, we read the journals, we talked to people. We were interested in these many ideas that were set forth as to what would cause AIDS. That's all we know: It was a disease, and nobody knew what caused it.

MR. RAPP: Q. Did your company try to do anything to find out whether the Factor VIII was causing AIDS?

MS. REIFEL: Objection. Vague, ambiguous. What time frame are we talking about? And I'm going to object to the term "anything."

MR. RAPP: Q. How about it?

A. I don't know what you mean by "did we do anything to find out."

Q. Well, I meant take any steps, analyze anything, do any tests, do anything at all to try to find out if the Factor VIII was spreading AIDS.

MS. REIFEL: I object again on the grounds it's vague and ambiguous. Are you talking about this Factor VIII that was referenced in the July '82 document? Are you talking about Koate? What time frame? Are you talking about testing the product, following the patients?

MR. RAPP: All those things.

MS. REIFEL: Why don't you ask a specific question.

MR. RAPP: Q. Let me ask it this way: Can you tell me of any steps your company took to try to determine whether Factor VIII --

MS. REIFEL: Cutter's Koate?

MR. RAPP: No, just Factor VIII was causing people to come down with AIDS.

THE WITNESS: When?

MR. RAPP: Q. At any time.

MS. REIFEL: I'm going to continue my objection that it's vague and overbroad. If you can answer it --

THE WITNESS: Yes.

MR. RAPP: Q. What's steps?

A. We read the literature. We tried to learn all we could about the disease AIDS. We went to scientific meetings. We listened to the experts.

Q. Anything else?

A. Not as I understand your question, no.

Q. Now, can you tell me whether before July 1982 there had been any thought given to the possibility that Factor VIII was causing AIDS?

MS. REIFEL: Thought by whom?

MR. RAPP: Anybody.

THE WITNESS: I don't know.

MR. RAPP: Q. Before July 1982, can you tell me whether there was any thought given to that by anybody at your company?

MS. REIFEL: Objection. Calls for speculation.

THE WITNESS: I'm not aware of any.

MR. RAPP: Q. And you certainly didn't think about it before July 1982?

A. Certainly not.

Q. Now, can you tell me that, as a result of receiving Exhibit 1, you did give thought to that subject?

A. I'm not aware of that, no.

Q. Your recollection is that it was not until 1984 that you began thinking about the possibility that the Factor VIII was causing AIDS?

A. I didn't say that.

Q. All right. When did you then first give thought to that possibility?

A. There was no first. It was, as you lawyers like to say, a preponderance of evidence building up over the year from '82 and '83 and '84 that one began to associate perhaps with greater certainty that the Factor VIII may be causing the disease AIDS.

MR. BAYUK: I'm sorry to interrupt. You have a call on Line 9.

MR. RAPP: Yes. Let's take a break.

(Short break taken.)

MR. RAPP: Q. Dr. Mozen, is it true that before July of 1982, you had never heard of any cases of this Pneumocystis Carinii pneumonia in hemophiliacs?

A. Yes.

Q. And looking at the last sentence of the third paragraph, it is true that your company was being told in July of 1982 that the possibility of a transmissible agent

had been suggested for this kind of pneumonia?

MS. REIFEL: The document speaks for itself.

THE WITNESS: If that's what it says.

MR. RAPP: Q. That's what it says. And your company received that information, right, in July of 1982?

A. Yes.

Q. And your company knew that there was concern about the possible transmission of whatever was causing this pneumonia through blood products?

MS. REIFEL: Calls for speculation, and "concern" is vague.

THE WITNESS: The document speaks about there is concern, and I would say it speaks for itself, yes.

MR. RAPP: Q. And you also had that concern after you received this document, correct?

A. I don't know.

Q. At some point, you did develop a concern about the possible transmission through blood products of whatever was causing this kind of pneumonia, right?

A. Yes.

Q. And when was that?

A. I thought I explained earlier that there was no single period or no single time when I can say we had the concern. It was a growing concern as the evidence grew.

Q. So was Exhibit 1 the first little bit of evidence on that subject?

A. It could be considered that, yes.

Q. And the evidence continued to build. And then in 1984, a conclusion was pretty much reached that indeed, Factor VIII was capable of transmitting what became known as AIDS, right?

A. Yes.

Q. Can you tell me whether it was normal or unusual for your company to be receiving a letter like this from the Centers for Disease Control?

MS. REIFEL: Calls for speculation. But if you know --

THE WITNESS: I don't know. I don't know what you mean by "normal" or "unusual."

MR. RAPP: Q. Just, you know, like out of the dictionary. Normal are things that happen frequently; unusual are things that don't happen very often.

A. Well, we had I presume received letters from the CDC from time to time. I can't specifically remember what they are or the subject matter.

Q. Let's focus on 1980 and 1981. Can you tell me about how often your company would receive letters of this nature from the CDC?

A. No, I can't.

MS. REIFEL: Objection. Irrelevant. You can answer if you can remember.

THE WITNESS: No, I can't remember that.

MR. RAPP: Q. Wasn't it quite unusual for the CDC to be sending a letter of this nature to your company?

MS. REIFEL: Objection. Irrelevant.

THE WITNESS: You want my opinion on the definition of unusual in this instance?

MR. RAPP: Q. No, I just want a straight answer to my question, which is: Wasn't it quite unusual for your company to be receiving a letter such as Exhibit 1?

A. Not in my opinion, no.

Q. Why do you give that answer?

A. Because in my opinion, that's their job, the CDC. And they were simply doing their job, and I don't find that unusual.

Q. Can you give me any idea about how often letters of this nature would be received by your company?

A. No.

MS. REIFEL: Objection. Irrelevant.

MR. RAPP: Q. Is there anybody else in your company that could give me a better idea?

MS. REIFEL: Objection. Irrelevant. Don't

answer.

MR. RAPP: Q. The second to the last paragraph of this letter says that, "Cases of opportunistic infections or suspected acquired immunodeficiency should be reported."

Did your company ever make any such reports?

A. Not that I'm aware of.

Q. Does your company in the course of its business learn of cases of opportunistic infections or suspected acquired immunodeficiency?

MS. REIFEL: Objection. Overbroad. Vague and ambiguous. When?

MR. RAPP: Let's say in 1982, '83.

MS. REIFEL: Did the company receive reports of AIDS?

MR. RAPP: Let me just start over.

Q. Did you think this second to the last paragraph applied to your company?

MS. REIFEL: At the time you read it, if you remember.

THE WITNESS: Well, I would assume that it really refers to the treating physician who diagnosis such opportunistic infections to report that to the CDC.

MR. RAPP: Q. Okay. Now, do you have a recollection of discussions taking place in July or August

of 1982 prompted by this letter?

A. No.

Q. If there were any discussions, based upon the way things worked at your company, is it likely that the members of the Biological Management Committee that you named earlier would have been involved in those discussions?

A. Yes.

Q. Have you done any checking with any of these people that were a member of that committee and that are still with your company to see if they had any memories that you don't of those discussions?

A. No.

Q. Has anyone, to your knowledge?

A. Not to my knowledge.

Q. So you can't say that Wayne Johnson, for example, wouldn't have recollections of such discussions that you don't have?

MS. REIFEL: The question has been asked and answered.

MR. RAPP: Q. Will you answer?

A. I can't say.

MR. RAPP: Susan, I'd like to request that the rest of these people who were positioned so that they would have been involved in those discussions be produced,

because they might have knowledge that Dr. Mozen doesn't have.

MS. REIFEL: Make a formal request and include the subject matter that you want them to testify to, because I think it's overbroad and is not contained in your deposition notice today.

MR. RAPP: Well, I think my deposition notice called for all the knowledge of your company on those subjects. And what seems to be apparent is that there are others who may well have knowledge of those areas, and evidently there's been no checking. So my request is that you produce them pursuant to the deposition notice that we're here for today.

MS. REIFEL: Make a formal request. My position is that you have not asked Dr. Mozen a question that is even -- asked him questions that are capable of a response without further clarification. So let's proceed with him, and I think he probably has a lot to tell you.

MR. RAPP: Good. But I hereby am formally so requesting.

MS. REIFEL: Send out a notice.

MR. RAPP: Let's get back to the subject of recalls. I've got a four-page letter here I'd like to be marked as Exhibit 2.

(Plaintiff's Exhibit 2 marked.)

MR. RAPP: Q. Do you recognize Exhibit 2?

A. Yes.

Q. What is it?

A. Well --

MR. BAYUK: Do you need a few minutes to read it, Dr. Mozen?

THE WITNESS: I need a few minutes to look at it. It's information related to a withdrawal of our antihemophilic factors made at the end of October 1983.

MR. RAPP: Q. Is Exhibit 2 something that was sent out by Cutter to various hemophilia treaters?

A. Yes.

Q. You recognize the signature of Jack Ryan --

A. Uh-huh.

Q. -- on page 1?

Do you recognize the signature of John H. Cherry on page 2?

A. Yes.

Q. Was Exhibit 2 filed away in the records maintained by Cutter in the ordinary course of its business?

MS. REIFEL: Calls for speculation.

THE WITNESS: I would presume so.

MR. RAPP: Q. And did you receive a copy yourself in late 1983?

THE WITNESS: I don't remember.

MS. REIFEL: Of any of these four pages?

MR. RAPP: Yes.

THE WITNESS: I don't remember.

MR. RAPP: Q. Were there any recalls or withdrawals of Factor VIII by your company prior to the recalls that are reflected in this exhibit?

MS. REIFEL: Recalls because plasma came from a donor suspected to have AIDS?

MR. RAPP: No, I'll just stand by my question as phrased.

MS. REIFEL: You've asked that question before, and I'll instruct him not to answer once again, limiting -- you can answer if the question is limited to recalls because plasma was thought to come from a donor suspected of having AIDS. Anything else is irrelevant.

MR. RAPP: Q. Go ahead.

A. Irrelevant.

Q. Okay.

MS. REIFEL: Do you want him to answer the question limiting it to AIDS?

MR. RAPP: Yes.

MS. REIFEL: Okay.

MR. RAPP: But I'm not withdrawing my question.

Q. Does Exhibit 2 reflect the first recalls or withdrawals that were made by Cutter of Factor VIII because of a concern that the Factor VIII could be transmitting any kind of a virus?

MS. REIFEL: Objection. Vague. Go ahead and answer if you can.

THE WITNESS: No, because your question contains a premise that it doesn't exist.

MR. RAPP: Q. What do you mean by that?

A. You asked if we -- if there was any other recall that was due because of a concern of a virus. So the premise is that this recall was made because we had a concern of a virus. And that premise is not correct.

Q. I see. Well, let's just say, starting on January 1, 1980, were there any recalls of Factor VIII?

A. Prior to January 1?

Q. No. I want to start January 1, 1980.

A. Yes?

Q. What was the first recall.

MS. REIFEL: Don't answer it unless it was a recall because plasma was suspected to come from a donor with AIDS.

There's a very simple question that you can ask that would speed things along.

MR. RAPP: What?

MS. REIFEL: Ask him about what recalls there were because plasma was believed to come from a donor with AIDS.

MR. RAPP: Okay, great.

THE WITNESS: This is it.

MR. RAPP: Q. This is the first one?

A. Exhibit 2.

Q. This is the first one?

A. The only one I can recall at this time.

Q. First and last?

A. Yes.

Q. Were there any other recalls that had anything at all to do with AIDS?

I mean, your counsel uses very precise wording: Donors suspected to have AIDS. And I don't want to get hung up on whether it was donors or recipients or any other thing that made you or anybody at your company to worry about AIDS.

I want to know: Were there any other recalls that had anything to do with AIDS or the possibility of AIDS or this pneumonia?

A. Not that I'm aware of.

Q. All the other recalls except for that reflected in Exhibit 2 had to do with matters unrelated to AIDS? I'm just restating it, but I want to be sure you --

A. Yes.

Q. Did any of the other recalls have anything to do with hepatitis?

A. In what time frame?

Q. Any time frame.

MS. REIFEL: Objection. Irrelevant.

THE WITNESS: I don't remember.

MR. RAPP: Q. Is there somebody else in your company that would be in a better position to answer that question?

MS. REIFEL: Don't answer. We're not here talking about hepatitis. It's not contained in the deposition notice.

MR. RAPP: Q. Before the recall that's reflected in Exhibit 2, had there been any times where there was discussion about whether or not a recall should be done because of anything related to AIDS or that pneumonia?

A. Not that I'm aware of.

Q. So Exhibit 2 reflects the first time anybody even thought about recalling a Cutter Factor VIII product because of AIDS?

MS. REIFEL: Objection. Calls for speculation and misstates his prior answer.

MR. RAPP: Q. Can you answer?

A. I don't know what people thought.

Q. Well, let's talk about your thoughts and information that you know about as a result of your discussions with other Cutter employees, okay?

A. Okay.

Q. So was Exhibit 2 the first time that there was ever thought given to your knowledge to a recall because of AIDS?

A. Yes.

Q. Tell me what led up to the recall that's reflected in Exhibit 2.

A. It was a donor in a plasmapheresis center from whom we bought plasma in Austin, Texas. And this donor died of AIDS subsequent to donating his plasma for fractionation.

Q. What's the name of that donor?

MS. REIFEL: I have a relevancy objection as they're no evidence that the plaintiff in this case ever received any of the lots that came from that donor.

MR. RAPP: Well, we're working on that.

MS. REIFEL: Pardon?

MR. RAPP: That's what we're working on. Maybe we haven't done it yet.

Q. Anyway, what's the name of that fellow?

A. GRO-A

Q. And the plasmapheresis center in Austin, is that operated by Cutter?

A. Not to my knowledge.

Q. Who operates that?

A. I don't know.

Q. Cutter does operate some plasmapheresis centers?

A. Yes.

Q. Where? Let's talk about 1980 to 1984, that time frame.

A. In many, many locations throughout the country.

Q. How did your company find out that GRO-A died of AIDS?

A. I believe the center manager of the Austin center read it in the newspaper and recognized the name, and that individual had donated at the center.

Q. Was there any kind of procedure or program set up to try to find out about the health of past donors?

MS. REIFEL: I have a continuing relevancy objection to this line of questioning since there is no evidence that plaintiff received a lot that came from the donor in this particular withdrawal.

MR. RAPP: Q. Can you answer? Any kind of program or procedure?

A. Well, all donors undergo a medical examination and laboratory testing to ascertain the health of the donor. And only -- according to federal regulations, only healthy donors are permitted to undergo plasmapheresis.

Q. What I'm getting at, after a fellow has donated plasma, is there any program set up or was there at any time after 1980 to follow their condition?

A. No.

Q. So it was more or less luck that --

MS. REIFEL: Objection. Argumentative.

MR. RAPP: All right.

Q. It was a fortuity that the manager happened to find out that GRO-A had died of AIDS, right?

A. I'm not sure I would select the word "fortuitous." It happened.

Q. It wasn't the result of any procedure, right?

A. No procedure.

Q. Other than GRO-A, has your company gained information on the continuing health of any other donors?

MS. REIFEL: Objection. Irrelevant. You can answer it, if you know.

THE WITNESS: All donors, as I testified earlier, have to meet the criteria of being healthy at the time they donate. Many of them are repeat donors; they

come back week after week. And to that extent, their health is monitored. Many of the donors are transients. And to that extent, after they donate, we don't always know their whereabouts.

MR. RAPP: Q. Other than GRO-A has your company ever received any information or indication that any other donors have seroconverted?

MS. REIFEL: Objection. Irrelevant.

MR. RAPP: Q. Did I use the right word there? Become seropositive?

A. What's the time?

Q. Any time after January 1980.

A. Could you repeat that question?

Q. We know GRO-A came down with AIDS, right?

A. Correct.

Q. Do you know whether any other donors to Cutter Factor VIII either became seropositive or came down with AIDS after January 1, 1980?

MS. REIFEL: Objection. Irrelevant. And I'm going to ask you to limit it to the end of 1985.

THE WITNESS: Well, I can only say that the law does not permit a donor who is seropositive to donate. So the answer would be no, because we adhere very strictly to the regulations as promulgated by the FDA.

MR. RAPP: Q. But you'd agree that it's

Q. Does your company keep track of the buyers of each lot of Factor VIII?

A. Yes.

Q. Why?

A. I don't know why. We just do.

Q. That's from a song.

A. That's right. I know that song.

MS. REIFEL: Just a point of clarification, when you say "buyers," you say the entity that Cutter sells the product to.

MR. RAPP: Yes.

MS. REIFEL: Not the user.

MR. RAPP: Right.

Q. Mr. Ryan says on page 1 of Exhibit 2 that, "Cutter has sufficient inventories of all product codes to meet your needs."

I take it that statement was true?

A. I presume so, yes.

Q. Do you have any personal knowledge on that subject?

A. No.

Q. Do you know whether there was any -- let's say from 1980 through 1989, through the present, would that same statement be generally true throughout that period?

MS. REIFEL: Objection. Irrelevant. And I'm going to limit it to the end of '85. If you can answer -- I wasn't aware that there was any allegation that Cutter didn't provide enough product for plaintiff.

MR. RAPP: Q. Can you answer?

A. I know, from time to time, the availability of Factor VIII is in short supply. But specifically, what years and when that is, I couldn't tell you.

Q. Is there somebody else in your company that would have that information?

A. Yes.

Q. Who?

A. Probably Wayne Johnson as an example.

Q. So your company must have records that show its inventory?

A. Yes.

Q. And people like Wayne Johnson would have that information?

A. Certainly access to that information.

Q. But you can't really give me information about the level of the inventories from time to time?

A. Only that they fluctuate.

MS. REIFEL: I think you're getting beyond the scope of the deposition notice, at least to the extent that I said Mr. Mozen was here to talk about.

MR. RAPP: I'd like to formally request that Wayne Johnson or somebody else with knowledge of the inventory levels be produced.

MS. REIFEL: Fine. Send out a notice defining the subject matter that you want him to talk about. I don't think you've done it yet. It's a little bit late.

MR. RAPP: Not so. I have until May 10. And it's my position it's within the scope of the present notice, but I know you don't agree.

Q. Now, were you personally involved in the discussions that led up to this recall?

A. Yes.

Q. Just generally tell me your recollections of those discussions.

A. Well, my recollection is that the sudden discovery that one of our donors died of AIDS prompted us to check into our production records as to which lots of product were made from that plasma. And that because of the great uncertainties as to the cause of AIDS, but perhaps a growing suspicion that it might be a transmissible disease, it was deemed the safe and prudent thing to do, to recall the product.

Q. So who did you have these discussions with?

A. Mostly our salespeople, our regulatory

people, our quality assurance people, production.

Q. I need some names. Mr. Ojala?

A. Oh, yes. Mr. Ojala, at that time I believe he was our responsible head.

MS. REIFEL: I'd just like to note a relevancy objection again since there's no evidence that this plaintiff in this case got this product, at least no evidence that's been provided to me.

MR. RAPP: Well, that's the guy tommorrow that's going to link that up, right?

MS. REIFEL: He's going to tell us what product your client used? I wish somebody could.

MR. RAPP: No. Where these lots went.

Q. By the way, was your company successful in getting back all of these lots?

A. When you say "getting back all of these lots," you mean every last vial that was out in the field?

Q. Right.

A. No.

Q. You know you were not?

A. Yes, I know we were not.

Q. So some of the product that contained plasma from Mr. GRO-A that ended up dying of AIDS was never recovered?

A. That is correct.

Q. Are there -- is there some way we can find out which of the lots were totally recovered and which were not?

MS. REIFEL: Objection. Irrelevant. Don't answer the question. It's outside the scope of the deposition notice.

MR. RAPP: Q. Well, how many approximately discussions were you personally involved in that led up to this recall?

A. Few. Two or three perhaps.

Q. And let's see. The recall is taking place October 31, 1983. Approximately when were the discussions?

A. Approximately October 1983. I couldn't pinpoint it any closer than that.

Q. So about when did Cutter learn that this GRO-A had died of AIDS?

A. About the same time.

Q. So you moved very quickly in effecting this recall?

A. Yes.

Q. And about how long after Cutter learned that GRO-A had died of AIDS did Cutter decide to recall the product?

A. I don't know precisely. But I think I just

testified that it was a relatively short time.

Q. And who actually made the decision that this recall would be ordered?

A. There would be several people involved in that kind of decision. Mr. Ryan at this time was the division vice president and general manager; our director of quality assurance.

Q. Who was that?

A. That was John Cherry at that time.

And presumably Dr. Ojala would have been involved in that decision.

Q. Anyone else?

A. Not that I'm aware of.

Q. Were you at a meeting where the decision was actually made?

A. Well, you know, when you say "it was actually made," I was certainly at meetings when we were leaning in that direction. I don't know the precise moment that someone said," This is when it will be done."

Yeah, I would say I was.

Q. Now, did anyone suggest that the recall should not be done?

A. Not in those terms.

Q. Well, I gather there were some that were for recall and some that were not. Who was suggesting not?

MS. REIFEL: Objection. Irrelevant.

THE WITNESS: I can't really remember that far back or the specifics. I don't recall.

MR. RAPP: Q. Was every one of like mind about whether or not to have a recall?

A. As far as I recall.

Q. What was your position?

A. My position was that I didn't believe the product would be any more at risk than others. But because of the uncertainties of the causative -- or because of the uncertainties of what was causing AIDS, if we wanted to be ultrasafe, we should do the recall.

Q. So I gather then that because AIDS is deadly, you felt it was appropriate to be ultrasafe?

A. It was what?

Q. Appropriate to be ultrasafe?

A. Yes.

Q. I'm not quite sure I understand this. You say you didn't think that the product was necessarily any more at risk than the rest of the product. Can you explain that?

A. We didn't know that AIDS was transmissible by Factor VIII or by blood or blood products. That was one of the speculations of the time.

Q. It turns out that speculation is true, right?

A. Yes.

Q. I'm sorry for butting in. Go ahead.

A. That's it.

Q. Well, you say you didn't think this particular product that GRO-A had donated to was any more at risk than any others. Why do you say that?

A. Because Mr. GRO-A would have been one donor in a pool of plasma which could represent as many as 10 or 15 thousand donors. And it was hard for me to scientifically acknowledge that, with that kind of a dilution, that the product derived from that pool could transmit a disease.

Q. What do we know now about this dilution issue?

MS. REIFEL: Objection. You don't have to answer what you know today.

THE WITNESS: You have to keep it in the time frame.

MR. RAPP: Q. We do know today that even though there's a dilution, that the AIDS can still be transmitted, right?

A. No.

Q. What is the current state of knowledge?

MS. REIFEL: Objection. Irrelevant. But you can go ahead and answer if you understand the question.

THE WITNESS: I would say what we know today would be that if, in fact, Mr. GRO-A was the only donor in that pool that was infectious, based on today's information, the product derived would not be infectious.

MR. RAPP: Q. Can you explain that? What's the basis for that?

A. The basis is that there are now -- there is no information about, for example, how many virus particles one might expect to find in an infected plasma. We can calculate how much the dilution would be. We know how much of the virus is destroyed during the processing or the manufacture of Factor VIII. And the bottom line is, there wouldn't be enough virus remaining to infect anyone.

Q. So that if there's only one donor with AIDS, all the vials would be safe, or would a certain number of them that happened to get the virus be unsafe?

MS. REIFEL: A certain number of vials or users?

MR. RAPP: A certain number of the vials.

MS. REIFEL: So you're asking whether there's a difference in vials made from the same lot?

MR. RAPP: Q. You seemed to be saying if it's diluted enough, it's probably safe. I want to understand whether they're all safe.

A. Yes.

Q. They're all safe?

A. Yes.

Q. Because they might have some virus, but it takes more than just a few of these viruses to get you?

A. Well, the few viruses you're talking about from the information we have would be inactivated by the processes used to prepare Factor VIII.

Q. Now, are we talking about the days before heat treating?

A. Yes.

Q. You say there's some information. Is this some kind of a study or something?

A. Yes.

Q. What are these?

A. Well, we published some information showing that the virus which we now call HIV when deliberately added to plasma and then fractionated to Factor VIII, even without heat treatment, that a large portion of that virus is inactivated.

Q. Where did you publish these?

A. Well, that particular paper was published in a journal called the Lancet.

Q. And who wrote that?

A. I was one of the co-authors, along with Dr.

Jay Levy from the University of California San Francisco, and another colleague of mine, Dr. George Mitra, M- i- t- r- a, at Cutter.

Q. And do you remember what issue that was?

A. No.

Q. What year?

A. '84 or '85.

Q. Would you be willing to issue a copy to your counsel so she can pass it on to me, please?

A. Certainly.

Q. Did you come up, as a result of any of your work, with a number of donors that would have to go into a pool before it could become infectious?

A. No.

Q. One is not enough, but no idea about how many it would take?

A. No. Because one has to speculate on the level of infectivity, and that will vary considerably with the donor. So I'm just giving you a range. I think I can say with certainty that one would not be enough, but I can't say whether 10 might be enough.

Q. What's the best information you do have on the number it would take?

A. I don't know the number; only that I will say it's greater than one.

Q. Can you give me any better range?

MS. REIFEL: The question has been asked and answered. I think he's told you "no."

THE WITNESS: The best I can do.

MR. RAPP: Q. Have you ever articulated to anybody any range?

MS. REIFEL: The question has been asked and answered.

MR. RAPP: No, it's a little bit different.

Q. I know you say you don't want to now. But in any discussions you've ever had with anybody, have you ever articulated a range?

A. You mean a range of donors?

Q. Yeah. The number of donors that it would take to make a particular pool infectious.

MS. REIFEL: I'm not going to allow him to speculate. If he says he doesn't know, he doesn't know.

MR. RAPP: I'm not asking him to speculate. I'm asking what he said.

THE WITNESS: The answer is "no."

MR. RAPP: Q. You never said to anybody?

A. No, not to my recollection.

Q. Did you ever hear from anybody else any range?

A. Well, there was a publication by the people

at the Food & Drug Administration in which they estimated how many infectious particles it would take. And I presume one could translate that into donors, but I haven't done that.

Q. Any other information you got about a range?

A. No.

Q. Maybe from Dr. Levy or Dr. Mitra, or anybody else saying --

A. Well, Dr. Levy probably talked to me about it, but I don't recall exactly what numbers he came up with.

Q. What's your best recollection?

A. No recollection.

Q. Why did you do this particular study, anyway?

A. Because of our interest in preparing safe products for our users.

Q. Well, let's see. You were heat treating at that time, weren't you?

A. Yes.

Q. And had no plan to sell any non-heat-treated product, right?

A. At what time frame?

Q. At the time you were publishing your article in Lancet.

A. That's right.

Q. Really, the question you were addressing in your work is whether the material that had been sold in the past and wasn't being sold any more was infectious.

MS. REIFEL: Is that a question?

MR. RAPP: Q. Right?

A. Wrong.

Q. Why is that wrong?

A. We were trying to determine whether the heating of the product was doing it any good.

Q. Did you come up with an answer for that?

A. Yes.

Q. What's the answer?

A. We determined that the heat treatment protocol that we developed was effective in destroying the AIDS virus.

Q. That's clear today, right?

A. Pardon?

Q. That's one thing that's clear today?

A. Yes.

Q. And is the heat treating a hundred percent effective in destroying the virus?

A. Yes.

Q. When did that become known?

A. There was no particular certainty. I would say that the studies that I referred to that we published,

which also then included a heat treatment and I have to stress under the protocol that we at Cutter used was effective in inactivating AIDS virus.

Additionally, it took several years of clinical follow-up in patients to ascertain with certainty that there were no further seroconversions following the exclusive use of heat treatment heated by our protocol.

Q. At the time you started selling the heat-treated Factor VIII, was it fairly clear that the heat treating was effective in destroying the AIDS virus?

A. No.

Q. What was the state of knowledge?

A. At the time we were licensed to sell heat-treated product, we still didn't know that AIDS was transmitted by a virus.

Q. Yes. But was it known that the heat treating was effective in killing any viruses that were in there?

A. No, it was not known.

Q. It is known now?

A. Yes.

Q. And was it believed that, in all probability, the heat treating was effective?

A. It was not known.

Q. It was believed though?

A. In science, belief doesn't mean too much.

Q. Why did you start marketing the heat-treated Factor VIII?

A. As a hope.

Q. In the hope that it would be -- wouldn't have those viruses, right, especially AIDS?

MS. REIFEL: What viruses?

MR. RAPP: Any viruses, but especially AIDS.

THE WITNESS: At the time, as I said several times, we didn't know that AIDS was transmitted by a virus.

MR. RAPP: Q. Yes. But the heat-treated product was developed on the assumption that AIDS was transmissible by a virus, right?

A. No. It was hoped that if AIDS or, in fact, a transmissible disease, that whatever the vector of transmission was, it would be destroyed by the heat treatment that we had adopted.

Q. Okay. So let's see now. When did Cutter start selling heat-treated Factor VIII?

A. Early in 1984.

Q. And when did Cutter stop selling non-heat-treated Factor VIII?

A. Later in 1984.

Q. When Cutter stopped selling the non-heat-treated Factor VIII, was there any inventory

left?

A. I don't know.

Q. Who would know that?

MS. REIFEL: Objection. Irrelevant.

THE WITNESS: I suppose some of our marketing people.

MR. RAPP: I'd like people with that knowledge to be produced, please.

MS. REIFEL: Make a formal request. It's outside the scope of your deposition notice and anything that you've asked in this case to date.

MR. RAPP: I think it's within it, and I'd like you to bring that person.

Q. Now, was there discussion within your company when the heat-treated Factor VIII came on line as to whether you should continue selling the non-heat-treated?

A. Yes.

Q. Were you involved in those discussions?

A. Off and on.

Q. What's your first recollection of those discussions?

A. That we discussed that issue.

Q. This is you and who else?

A. Probably members of that committee that I referred to earlier.

Q. And were there different points of view?
A. I presume so. I don't know the specifics.
Q. What was your point of view?
A. That we didn't know yet whether heating was a benefit.
Q. Therefore, may as well keep selling the non-heat-treated?
A. Well, the non-heat-treated was requested by our users until we could provide evidence that heating it, which caused a -- which caused us to have to charge a higher price because of a yield loss. We had to convince the user that a product that's been heated is of some benefit to his patient.
Q. All right. I want to find out the month that you actually started selling the heat-treated and the month that you actually stopped selling the non-heat-treated. You can't tell me from your memory?
A. Well, we were licensed I think in February of '84. And I don't recall when the cessation of selling non-heat-treated occurred.
Q. How can I find that out?
A. You have to ask the right people, I guess.
Q. Who would that be?
A. Somebody in our marketing group.
Q. Marketing?

A. Yes. They're the people who sell the product.

Q. Now, you say there was a difference in price. What's your recollection as to the difference in price back in '84?

MS. REIFEL: Objection. Irrelevant and outside the scope of the deposition notice.

THE WITNESS: I don't recall the price.

MR. RAPP: Q. What's your best recollection?

A. No recollection, other than it was more.

Q. Can you give me an approximate percentage, like 50 percent more?

A. No.

Q. You said that the users were still requesting non-heat-treated?

A. That's correct.

Q. What do you base that on?

A. Fact.

Q. Exactly what kind of facts? They called you up and said, "No, I don't want that lousy heat-treated. I want that good old non-heat-treated"?

A. Correct.

Q. That sort of thing?

A. Correct.

Q. And you tried to convince them they should

consider the heat-treated?

A. Yes.

Q. What did you say?

A. I showed them the evidence for the inactivation of certain viruses.

Q. Go ahead, please.

A. Essentially that.

Q. What evidence was that?

A. Well, we had looked at a few model viruses that were not relevant to human disease, but that we could demonstrate were inactivated by the protocol that we had adopted.

Q. There must be some, like, reports or scientific studies or memos, right?

A. Oh, yeah. We published that information.

Q. Where?

A. Lancet.

Q. Lancet. I'm going to have to subscribe to that.

A. We had another one. I can't recall the name of the journal now. I can't recall.

Q. Well, these would be things discussing possible changes in Factor VIII, right? All these studies you're talking about would be studies of whether there should be changes in the process by which Factor VIII is

manufactured, right?

A. Changes in the sense of subjecting it to a heat treatment process. That's correct.

MR. RAPP: I'd like to ask that you folks be sure to produce this material in response to our previously issued document request.

MS. REIFEL: I'd like to ask you to make a formal request and give us reasonable notice. You've never requested any such documents.

MR. RAPP: Didn't you get my document request in the GRO-A case that we issued April 10? I think it's covered in there, so I hope you guys are digging that out for production.

Q. So you personally had these communications with people where you showed them the evidence that the heat treating protocol Cutter had developed was inactivating viruses?

MS. REIFEL: I think that misstates his prior testimony. But if you want to ask that question --

MR. RAPP: Q. Was my question --

A. Correct.

Q. -- fouled up?

A. No, that's fine.

Q. And these people you were having these discussions with, who were they?

A. Well, in one case, there was something called MASAC, which is the Medical Advisory -- I forgot what it stands for. It's a medical advisory committee to the National Hemophilia Foundation.

Q. And were you successful in persuading them?

A. Reasonably. They issued a statement following my presentation suggesting that physicians consider the use of heat-treated product.

Q. You wish they had gone further, right?

A. I presented the data. The decision was theirs. My personal view was that the heat-treated product offered a degree of safety that was greater than the non-heat-treated product.

Q. You said that there had been a study that had shown model viruses were inactivated by this heat treating. Can you tell me a little bit more about that?

A. Well, this would be a study in which viruses that can be grown to high titer can be added to the Factor VIII product and fractionated through the process, and ultimately subjected to the heat treatment and shown to be inactivated.

Q. Then you have a control that you don't heat treat, right?

A. Yes.

Q. And how do you test it to find out whether

the viruses are inactivated or not?

A. When viruses are active or alive, they grow in certain special cells. And one can measure their growth by various processes or procedures.

Q. Even after the Factor VIII has been heat-treated, you're able to test it to see if it had AIDS, or these model viruses in it?

A. Yes. If the model viruses are there, they'll grow after heat-treated. If they have been inactivated, they will not grow.

Q. Right. So it is possible to take -- process Factor VIII and find out if it has viruses?

A. No.

Q. Why not? I thought that was going to be "yes."

A. It doesn't work.

Q. Why not?

A. I don't know exactly why not, but it doesn't. You mean if you're talking about taking a Factor VIII to which no virus has been added, can we find virus in there?

Q. Yes.

A. The answer is no.

Q. Nobody has ever been able to develop a way to do that?

A. That's correct.

Q. So if I were to give you some vials of Factor VIII, there is no way anybody could test it to find out if it contained the AIDS virus?

A. To my knowledge, there is no way that could be done.

Q. That's because it's just scientifically impossible to test it?

A. Well, it's been tried repeatedly and has not been successful.

Q. The current state of the knowledge is that there is no known way to find out if Factor VIII that has been processed has the AIDS virus in it?

MS. REIFEL: It's been asked and answered.

MR. RAPP: I know. I just wanted to --

MS. REIFEL: Believe it or not.

MR. RAPP: I know. I just wanted to hear it again.

THE WITNESS: Yes.

MR. RAPP: Q. If a patient had saved one vial of every lot of Factor VIII that he ever took in his life, it would be scientifically impossible to test that product and to determine which lot contained the AIDS virus, if one did?

A. That is my opinion.

Q. So if a patient had kept a record or a log of

each lot and brand of product that he took, that wouldn't help find out which particular lot caused him to seroconvert if he had, right?

A. Correct.

Q. Because even with the log, you couldn't do anything to check to find out whether the particular product had the virus in it or not?

A. That is correct.

Q. So a person that has taken Factor VIII over a period of time, there is never going to be any way to find out when he took contaminated Factor VIII, is there?

MS. REIFEL: Objection. Vague overbroad. Calls for speculation.

MR. RAPP: Q. Based on the current knowledge?

A. That would be my opinion.

MR. BAYUK: Dr. Mozen, the log, assuming a patient maintained one, would help identify which fractionators of Factor VIII concentrate the patient did receive, correct?

MR. RAPP: Excuse me. I'd like to object to these kind of information-laden questions in the middle of my examination.

MR. BAYUK: Just following up on the same line, Counsel. If you'd rather we wait until the end,

we'll do that.

MR. RAPP: I really would.

MR. BAYUK: Okay.

MR. RAPP: Q. Do you know if anybody has ever tried to develop a way to find out if the processed Factor VIII has AIDS virus in it?

A. I know it's been looked at in several places without success.

Q. Who has looked at that?

A. Some people at the CDC and at the FDA.

Q. Anyone else?

A. I'm sure there are others, but I couldn't tell you who.

Q. How about any of the fractionators?

A. I couldn't speak for all the fractionators.

Q. Has Cutter ever tied to?

A. No.

Q. Has it ever considered whether to try to?

A. Yes.

Q. What consideration was given to it?

A. We were discouraged by the failure of others, who are more heavily involved in the actual virus research. We were discouraged by their inability to do it.

Q. Was there somebody within the company that

wanted to pursue the issue?

A. It was discussed.

Q. Who wanted to do it?

A. I can't recall.

Q. Did you?

A. Well, if I wanted to do it, I would have wanted to do it outside of the company. We don't have a facility inside that allows us to work with infectious agents of that nature.

Q. Did you actually want to try and develop a test?

A. We discussed it, yes.

Q. You and who else?

A. I can't remember.

Q. And what was their response?

A. I think I just testified that, given the inability of people like the research staff at the CDC -- their inability to do this was something that would discourage us from pursuing that any further.

Q. Was that the only reason given as to why not to try to develop a test?

MS. REIFEL: By whom? I don't understand the question.

MR. RAPP: Given by anyone in your company.

MS. REIFEL: Calls for speculation.

THE WITNESS: Not that I can recall.

MR. RAPP: Q. Do you remember people saying in effect, "Why should we develop such a test? It will just show which product maybe has caused people to come down with AIDS"?

A. No, I don't recall that.

Q. There was no consideration given to anything like that?

A. No.

Q. When a particular lot of Factor VIII is sold by Cutter, does Cutter retain some samples from that lot?

A. Yes.

Q. And how long are they saved?

A. Through expiration.

Q. Through expiration?

A. Correct.

Q. And then what happens?

A. Dumped.

Q. And has that been the practice since 1980?

A. As far as I know, yes.

Q. Why is that the practice?

MS. REIFEL: If you know.

THE WITNESS: Yes. It's because if there is any report from the field that we feel needs to be investigated and the samples retested for certain of the

many released tests that are performed on each lot, then we have samples available to do that.

MR. RAPP: Q. But why does the expiration date mean there won't be any further need for testing?

A. Because it isn't used after that date.

Q. But people might develop problems after that date as a result of using it before and have need to check the product.

MS. REIFEL: Argumentative. Objection.

MR. RAPP: Q. Do you agree?

A. No, not necessarily.

Q. Why not?

A. Because the significance of such tests after expiration are really not meaningful.

Q. I don't understand that.

A. Well, for example, if the complaint were that the product didn't have the potency that was claimed on the label and we tested it after expiration, it wouldn't really give us the answer of whether that potency were there at the time it was used or not.

Q. Okay. I can see that part. But if someone were to develop a test to determine if processed Factor VIII has a virus in it tomorrow, it would be useful to have those old vials, wouldn't it?

A. Perhaps.

Q. Has there been any consideration since 1980 to saving the samples longer?

MS. REIFEL: Consideration by whom? The FDA or --

MR. RAPP: Q. By anybody?

A. I don't know.

Q. I'm not aware of any.

Q. Is it expensive to retain these samples?

A. No.

Q. Wouldn't cost much money to keep them for 20 years?

A. Perhaps.

MS. REIFEL: I need to take a break either now or in a few minutes. I don't know if this is a good stopping point.

MR. RAPP: This is okay.

(Short break taken.)

MS. REIFEL: I've just informed Mr. Rapp that Dr. Mozen is not available for much more than another hour of testimony, and he was leaving for out of town tomorrow. So if Mr. Rapp has indicated that he has many more hours of questions, it appears we'll have to reconvene at another time.

I want to note he has asked questions beyond the scope of the deposition notice which has taken a

considerable amount of time, and that plaintiff was notified that Dr. Mozen was available to begin at 2:30. And I never heard anything until late this morning, any indication that could we perhaps start a little earlier.

MR. RAPP: Well, I thought it was like coming down from the mountain, that I couldn't start before 2:30 because of some problems with somebody else's scheduling. But I was hoping we could keep going.

MS. REIFEL: But I had no indication that you would need more than a day with Dr. Mozen.

MR. RAPP: But I'm only being given a few hours.

MS. REIFEL: It's my position that you barely touched on what's contained in the deposition notice, and we've wasted time discussing other matters. You've indicated a desire to depose other Cutter witnesses, even though this case was filed a year and a half ago and there hasn't been any discovery of Cutter witnesses. And now here we are on the eve of summary judgment and trial, I think this is being done to continue matters. But in any case --

MR. RAPP: We'll save this argument for another day, and everybody reserves all of their positions. And let's use --

MS. REIFEL: My position is, we made him

available today and I didn't know it would take longer than today. But we're going to have to quit about 6:00.

MR. RAPP: Q. Putting aside the lots that were recalled in 1983, has Cutter ever gotten any reason to suspect that there are any other lots that may have contained the AIDS virus?

MS. REIFEL: Objection. Vague as to the term "suspect," but you can answer it.

THE WITNESS: No. Because it's a "when did you stop beating your wife" question.

MR. RAPP: Q. Well, setting aside those recalled lots and the GRO-A situation, have you gotten any information at all whether any other lots contained the AIDS virus?

A. As I testified that once we began heating the product, which was prior to the identification of a virus as the cause of AIDS, the heating procedure was of such a nature that it inactivated the AIDS virus.

Q. All right. So from that, you conclude, I take it, that once all the non-heat-treated product was no longer being sold, then Factor VIII was not going to be spreading AIDS anymore, right?

A. Yes.

Q. But what I want to ask you about is products that were sold in '80, '81, '82, '83, any information that

any of them contained the virus.

A. Was there any information in those years that those products contained a virus?

Q. Well, information on through the present.

A. Only speculation. We know that a large number of hemophiliacs -- we know this retrospectively -- have seroconverted to HIV antibody positive. And by historical analysis of their plasma samples, it's been determined that the vast majority of them seroconverted in the years 1980, '81, '82, '83.

And given that information, it's assumed that the cause of that infection -- the cause of that infection was the Factor VIII concentrates that they were taking. But there's never been any what we would call absolute proof of cause and effect. It's a circumstantial relationship.

Q. In science, often you cannot come up with absolute proof, right?

A. That's often the case.

Q. But you agree that it's reasonable to assume that the Factor VIII did cause the seroconversion in most of the hemophiliacs?

A. Based on the information we have now, yes, that's reasonable to assume.

Q. You say there's information about '80 through '83. Is there information that's broken down any further,

for example, year by year?

A. That information is available on a year-by-year basis, yes.

Q. Where?

A. That's been published.

Q. Where?

A. Well, I'm not certain where. But it has been published.

Q. Does your company have a copy?

A. Yes.

MR. RAPP: I'd like to request that.

Q. Do you have a general recollection of the data, for example, by some point in 1980, what percentage of the hemophiliac population had seroconverted?

MS. REIFEL: Does he personally have that information, or has he read it, or is it available? I don't understand the question.

MR. RAPP: Either way.

THE WITNESS: I've read the studies, and I've heard them reported. And the information starts with 1978 and carries on through well into the '80s on a year-by-year basis. And without having the paper in front of me, my recollection is that the year '81-'82 -- probably '82 was the maximum rate of seroconversion. After '83, it began to fall off somewhat.

MR. RAPP: Q. Do you know of an explanation for that?

A. The fall-off?

Q. Yes.

A. Well, in '83, most manufacturers began excluding donors who had been identified as high risk.

Q. And that produced results?

A. Presumably.

Q. Do you have a recollection as to what percentage of the hemophilia population had seroconverted in 1980?

A. In 1980?

Q. Yes.

A. Very small.

Q. Very small. So from that, do you presume that most of the Factor VIII that had been used through 1980 was not contaminated with the AIDS virus?

A. I'm not sure I could draw that conclusion.

Q. Why not?

A. Well, there may be other -- it may be a question of the extent of the contamination. Perhaps we could conclude that the contamination was not as widespread or as great as it became subsequently.

Q. Let's see. Why can't we conclude that most of the product was without the AIDS virus if not very many

of the people that had taken the product were seroconverting?

A. There are, of course, factors involved in the recipient. There are cases where recipient can be administered an infected product and still not come down with AIDS, depending on the level, depending on the individual response. So that it may be a quantitative matter.

I think the logistics are that the -- I would say that the number of donors who were infected would have been increasing from 1978 on.

Q. So before 1978, is it your belief that the Factor VIII was basically AIDS virus free?

A. Yes.

Q. Then you say that after that, the percentage of the Factor VIII being sold gained more and more of -- well, the percentage of the product that had the AIDS virus was increasing, right?

A. The percentage of the product that had an infectious level of AIDS virus was increasing, yes.

Q. Okay. And would you agree that in 1980, generally speaking, the Factor VIII that was being sold was relatively free of the virus, and in '81 and '82, the percentage of the product being sold had more and more of the virus?

A. Correct.

Q. And that's because there were more and more infected donors that were donating plasma?

A. That's correct.

Q. AIDS was spreading more and more in the population?

A. That is correct.

Q. Do you have a recollection as to what percentage of the hemophiliac population was seroconverted in '82?

A. No, only that -- my recollection is that that was the peak year in the particular study that I alluded to earlier.

Q. If you were to apply those statistics to Cutter's products, what can you tell me about the percent of Cutter's products that probably contained the AIDS virus from year to year?

MS. REIFEL: I don't understand what you mean by applying those statistics to Cutter's product.

MR. RAPP: Q. Can you draw any conclusions as to Cutter's products?

A. I think I said earlier that the -- we would have to presume, based on the retrospective analysis, that the extent of product that was infectious was increasing over those years.

Q. Wouldn't you conclude that, in 1983, the majority of the Cutter product, Factor VIII that was being sold, was infectious for AIDS?

A. It would appear that way from the retrospective analysis.

Q. Now, I said the "majority." Can you give me any better percentage?

A. No.

Q. Would the answer be any different for '82?

A. The answer is that I couldn't give you a breakdown as to how many lots were infectious and how many were not.

Q. By the way, when was that study published approximately?

MS. REIFEL: Which study?

MR. RAPP: Q. About the statistical information you talked about.

MS. REIFEL: I think he's talked about a number of studies.

MR. RAPP: Q. Oh, are there several?

A. There have been several studies referred to in this deposition. I believe the question you were asking is -- which particular study are you alluding to now?

Q. You couldn't remember what magazine or

whatever it was in, but where they published information about the percentage of the hemophiliacs that were seropositive for various years.

A. Oh, that study. Probably 1985 or 1986, it was published.

Q. Is there only one study that you know of on that subject?

A. Well, that's the most well-controlled and including the largest cohort of patients that I'm aware of.

Q. Do you think it's reliable?

A. Yes.

Q. Do you remember who wrote it?

A. Yes.

Q. Who?

A. It was a woman named Elaine Eyster, E- y- s- t- e- r.

Q. Now, looking back in the retrospectroscope, you'd agree that the product, the non-heat-treated product that was being sold in 1984, the majority of that contained the AIDS virus, right?

A. It seems reasonable now, yes.

Q. Probably even a greater percentage than the 1983?

A. Probably.

Q. In fact, wouldn't you agree that most of the product that was being sold in 1984 that was non-heat-treated probably was infectious for AIDS?

MS. REIFEL: Objection. Argumentative.

THE WITNESS: I can only say it's very difficult to assess the impact of our screening program which we instituted in 1983 to remove donors from the donor population who are considered at high risk.

MR. RAPP: Q. Doctor, you'd agree that if we knew now -- no.

If we knew back in 1984 what we know now about AIDS and Factor VIII, you would not have been selling the non-heat-treated Factor VIII once the heat-treated was available?

MS. REIFEL: Objection. Calls for speculation. Don't answer.

MR. RAPP: Q. Doctor, if we could turn the clock back and had a chance to change some of the decisions that were made about Factor VIII and the AIDS problem, are there any things that you would have done differently?

MS. REIFEL: Objection. Calls for speculation. Outside the scope of the deposition notice. Overbroad.

MR. RAPP: Q. Can you answer?

MS. REIFEL: Don't answer.

THE WITNESS: No, I can't answer.

MR. RAPP: Q. That's because your counsel is instructing you not to?

A. Because I can't put myself in 1984 and tell you what I think I would have thought in the light of what I know in 1989.

Q. I mean, we know now that the Factor VIII that was being sold in the early '80s was causing hemophiliacs to seroconvert, right?

A. Correct.

Q. And we know now that the heat-treated product is safe, as far as the AIDS virus, and the non-heat-treated product that was being sold in '81, '82, '83, and '84 was not safe, right?

A. We know that now, yes.

Q. We know that because we can look at all the hemophiliacs that are dying of AIDS, right?

A. That's correct.

Q. And there really isn't any question, Doctor, that if you could turn the clock back, you would not have permitted selling non-heat-treated Factor VIII once heat-treated Factor VIII was available, right?

MS. REIFEL: Objection. Calls for speculation. It's been asked and answered. Or it's been

asked, and he's been instructed not to answer. Excuse me.

MR. RAPP: So you're going to stand by that instruction?

MS. REIFEL: Every time you ask it.

MR. RAPP: How about 10 times? Just kidding.

Q. Doctor, if you could turn the clock back, would you have started using the core test? Do you know what I'm talking about, the anti-hepatitis B core test?

MS. REIFEL: Objection. Calls for speculation.

MR. RAPP: Q. Am I using the right term there? Anti-HB core test?

MS. REIFEL: When?

MR. RAPP: Q. First, you're familiar with that test, right?

A. Yes.

Q. Is my terminology acceptable to you?

A. It's okay.

Q. What should I call it?

A. Hepatitis B core antibody.

Q. Hepatitis B core antibody test.

Doctor, would you agree that if we could turn the clock back, it would be advisable to start using that test much earlier than you did start using it at Cutter?

MS. REIFEL: Objection. Calls for

speculation.

MR. RAPP: Are you going to instruct him not to answer?

MS. REIFEL: Yes.

MR. RAPP: Q. Did Cutter ever start using that test?

A. Yes.

Q. When?

A. I don't recall precisely.

Q. What's your best approximation?

A. Sometime in 1983.

Q. Was it continually used thereafter?

A. No.

Q. What happened?

A. Well, I can't really remember why we stopped using it.

Q. Is there anyone else in your company that could tell me that?

A. Yes.

Q. Who?

A. Our director of plasma procurement.

Q. Who is that?

A. His name is is Sunil Bhonsle.

Q. Can you spell that?

A. S- u- n- i- l. B- h- o- n- s- l- e.

MR. RAPP: I'd like to request that he be produced pursuant to my depo notice.

MS. REIFEL: Make a formal request and include that subject matter in your depo notice.

MR. RAPP: Q. Was the core antibody test reinstituted after it was stopped?

A. No.

Q. So you're not doing it now?

A. No.

Q. Do you know if any of the other fractionators are using that test?

A. I don't know with certainty.

Q. What's your best information?

A. That they're not.

Q. Has anybody ever suggested that the test be used?

MS. REIFEL: Calls for speculation.

THE WITNESS: I suppose somewhere out there in the big wide world someone has suggested that, yes.

MR. RAPP: Q. Have you ever considered it?

A. In what time frame?

Q. 1980 or thereafter.

MS. REIFEL: And for what purpose?

MR. RAPP: Any purpose.

THE WITNESS: It's obvious that we did do it

in 1983. So obviously, somebody had suggested that we do it.

MR. RAPP: Q. What's your view of the test?

MS. REIFEL: With regard to what? That's vague and ambiguous.

MR. RAPP: Q. Do you think the test should be used or not?

A. Now?

Q. Yes.

A. No.

Q. Why not?

A. I don't believe it increases the safety of our product.

Q. Because you're heat treating now. We don't have to worry about AIDS, right?

A. That's correct.

Q. If the test had been used before heat treating was instituted, would it have been effective in determining what plasma might contain the virus, the AIDS virus?

MS. REIFEL: Objection. Calls for speculation.

MR. RAPP: Q. Can you answer?

MS. REIFEL: Don't answer it.

THE WITNESS: No.

MR. RAPP: Q. Does the hepatitis B core antibody test shed any information on whether the donor is likely to carry the AIDS virus?

A. Not in my opinion.

Q. Why do you give that answer?

A. Because I haven't seen any data to suggest that there is a good scientific correlation.

Q. Before your company started using that test in 1983, were there any studies done?

MS. REIFEL: By the company?

MR. RAPP: By the company or anybody that led to that decision being made.

THE WITNESS: We had seen data at scientific meetings that suggested there may be a correlation. But again, going back to that time period, the cause of AIDS was not known.

MR. RAPP: Q. You said data suggested there might be a correlation. So we're clear, correlation between what?

A. Between hepatitis core antibody and what later became known as high-risk donors.

Q. And it was precisely because of that correlation that your company started using the test in 1983, right?

MS. REIFEL: Objection. Argumentative.

MR. RAPP: Q. Can you answer?

MS. REIFEL: Do you know why the company started using a core test in 1983?

THE WITNESS: I presume because we felt there was some benefit to be derived, potential benefit.

MR. RAPP: Q. You thought it might help to make a safer product, right?

A. Well, not precisely. We thought that it would screen out some donors such as Mr. GRO-A But whether it follows that that would make a safer product or not was really not known.

Q. Is that because there were a probability that enough donors would get past that test that would have AIDS that the product would still be unsafe?

A. Yes.

Q. Do you know whether there were any discussions between employees at Cutter and the employees at any other fractionators about whether the companies should institute those tests, the core test, hepatitis B core antibody test?

A. I'm not aware of any.

Q. Were you a part of any such discussions?

A. No.

Q. Have you ever heard about any?

A. No.

Q. On that recall that took place in 1983, do you know whether there was any discussion with employees at any other fractionator about that recall?

A. I'm not aware of any.

Q. Were there any memos or studies done about whether that recall should be ordered?

A. We talked earlier about the discussions.

Q. Now I want to know if there's any writings that we could look at.

A. Not that I'm aware of.

Q. Do you remember seeing any analyses or reports?

A. No, I don't recall.

Q. Do you know if there are any that still exist?

A. I don't recall.

Q. Do you know if anybody has checked for memos or reports about whether that recall should be ordered?

A. I don't know.

Q. Nobody asked you if you have any such memos --

A. No.

Q. -- until I did just now?

A. That's correct.

Q. Now, before that recall was ordered, was

there any discussion about the economic impact of the recall on Cutter?

A. Well, certainly, our accounting and business people had to calculate what the cost of such a recall would be, yes.

Q. Do you have any recollections of what the cost was going to be or turned out to be?

MS. REIFEL: I'll just note my relevancy objection about this whole line of questioning about the recall. I don't know that the plaintiff got any withdrawn product.

MR. RAPP: Q. That's just for the record.

THE WITNESS: Only that it was substantial.

Q. Millions, right?

A. That's my recollection.

MS. REIFEL: I don't understand why we're pursuing this in the limited time you have, but maybe you know something we don't about what product your client got.

MR. RAPP: Q. Dr. Hershberger, do you know where he lives now?

A. Yes.

Q. Where?

A. He lives in Mendocino County.

Q. Do you know what town, or anything like that?

A. The town is called GRO-C

Q. GRO-C

A. GRO-C

Q. And Dr. Sternberg, is he still with your company?

A. Yes, he is.

Q. Dr. Schaeffler, is he still with your company now?

A. I don't know a Dr. Schaeffler.

Q. Was there a Dr. -- maybe I've got this -- I can't read my own writing here. The chief executive in 1982?

A. Oh, Dr. Schaeffler.

MS. REIFEL: I'm going to note my objection that this is outside the scope of the deposition notice.

MR. RAPP: Q. Is he with your company now?

A. Yes.

Q. Ed Cutter, is he still with the company, or is he passed away or something?

A. No. He just moved.

Q. Moved?

A. To another company.

Q. What company is he with now?

A. Slips my mind.

Q. Well, if you think of it as we're going,

please butt in and let us know, or --

A. Clorox.

Q. What town?

A. Oakland.

Q. What was his position?

A. Legal counsel.

Q. Ed Cutter?

A. Yes. That's Ed Cutter III.

Q. Oh, yeah? Starting in 1980, was there another Ed Cutter that was with the company?

A. No. I think he had passed on by then.

Q. And Charlie Stewart, is he with your company still?

A. As far as I know.

Q. How about Jean Huxsoll?

A. No.

Q. Where is she now?

A. A company called Hanna Biologicals.

Q. H- a- n- a?

A. There may be two N's. I can't recall.

Q. Where is that?

A. Alameda.

Q. Do you know when your company first started considering heat treating of the Factor VIII?

MS. REIFEL: Objection. Vague and ambiguous.

You can answer it if you can.

THE WITNESS: Well, it is a vague question because I suspect we thought about it in the early '70s. But it was not a practical thing to do.

MR. RAPP: Q. Why not?

A. We destroyed the product.

Q. What prompted you to think about heat treating in the early '70s?

MS. REIFEL: Him personally?

MR. RAPP: No, the company.

MS. REIFEL: If you know.

THE WITNESS: Yes. Concern about hepatitis transmission.

MR. RAPP: Q. And did you -- I gather your company did some -- made some efforts to try to develop a heat-treating process that would work?

A. Yes.

Q. Without destroying the Factor VIII?

A. That's correct.

Q. And you weren't successful?

A. That's correct.

Q. After the early '70s, when was the next time your company looked at heat treating?

A. The end of 1978.

Q. What will prompted that?

A. Some studies we made about stabilizing reagents that could maintain the activity of proteins, even those subjected to heat.

Q. Were you involved in those studies?

A. Yes.

Q. And what was your result?

A. We discovered some agents that could be added to our products that would render them more stable to heat.

Q. Did it work? I mean --

A. To a limited extent. Instead of losing a hundred percent, we were losing only 60 percent.

Q. Was this the wet heat treating or the dry heat treating?

A. It's come to be called wet.

Q. How long were you looking at that process? '78? Is there a time when you said, "Forget this"?

A. From 1978 until we finally licensed our product in about 1986.

Q. That's a wet process?

A. Yes.

Q. Are you marketing that now?

A. Yes.

Q. Also the dry heat-treated Factor VIII?

A. Yes.

Q. You market both?

A. Yes.

Q. Why do you market both?

MS. REIFEL: Objection. Irrelevant.

MR. RAPP: Q. You can answer.

MS. REIFEL: It's beyond the time frame of anything that's possibly relevant to this lawsuit. But you can answer it.

THE WITNESS: Well, it's a complex issue of economics and availability and what the user is asking for. And I don't see its relevance to what we're talking about.

MR. RAPP: Q. Well, you're probably right. So in '78, did you conclude that the wet heat-treating process was effective in eliminating viruses?

A. No.

Q. Did you reach any conclusions as to the effect that the process had on viruses?

A. No.

Q. That was the purpose of --

A. It was -- 1978 was the beginning of a research program that extended over a number of years ultimately designed to inactivate viruses which, of course, had to be proven by doing the appropriate testing.

Q. Was there some point in time when you reached

a conclusion that the process did inactivate the viruses?

MS. REIFEL: What viruses?

MR. RAPP: Q. Do we need to distinguish?

A. Yes. Because we have to know which viruses we're talking about. The relevant virus that prompted all this work were the hepatitis viruses. Those are much more difficult to inactivate and much more difficult to verify that you, in fact, have inactivated them.

However, one can use so-called model viruses to demonstrate the effectiveness of the process, even though these may be irrelevant with regard to spread of disease.

Q. Is it easier to -- is it more difficult to inactivate the hepatitis virus than it is to inactivate the AIDS virus?

A. Considerably more difficult.

Q. Really? Is the heat treating that you started doing in '84 sufficient to inactivate, not only the AIDS virus, but also the hepatitis virus?

A. The heat treatment that we started in '84, you said?

Q. Yes.

MS. REIFEL: The one that was on the market in '84?

MR. RAPP: Yes.

THE WITNESS: The product that we sell that

was licensed in '84, which we refer to as Koate HT, we believe is safe with respect to the transmission of AIDS. But we have had reports that it still transmits hepatitis.

MR. RAPP: Q. Now, it's true that various viruses come along from time to time, right?

A. I'm not aware of that.

Q. Isn't it true that viruses are always mutating and, like AIDS, there will be a new one that suddenly bursts on to the scene?

MS. REIFEL: Objection. Irrelevant and beyond the scope of the deposition notice.

MR. RAPP: Q. Right?

A. Well, I can't generalize on the basis of one virus. AIDS certainly meets that description. It's something that we didn't know before. It popped up on the scene. I'm not aware of this happening previously with respect to blood and blood products.

Q. But you'd agree that one of the things that Cutter should try to do is make its Factor VIII as disease-free as they reasonably could, right?

A. That's our charge, yes.

Q. When did it come that there was some kind of a heat-treating process, whether wet or dry, that was effective in eliminating or inactivating viruses without destroying the effectiveness of the Factor VIII?

MS. REIFEL: Objection. Vague. But if you can answer it --

THE WITNESS: There never was a specific time. It again is an evolutionary situation.

MR. RAPP: Q. Well, certainly by '84, you had hit that point, right?

A. Right.

Q. How much earlier?

A. Well, again, it's not easy to answer. Because when you say "without destroying the Factor VIII activity," the degree of destruction of the Factor VIII activity has also evolved. So that initial experiments resulted in the destruction of most of the activity, and with refinement and improvement from perhaps 1978 on through, less and less of the Factor VIII was destroyed. Although even today, a significant amount is still destroyed by the heat.

Q. What was the situation in 1980?

MS. REIFEL: With regard to what?

MR. RAPP: What we were just talking about --

THE WITNESS: Are you talking about the research that we were doing, or what was out there in the world?

MR. RAPP: Q. This is an area that you've paid a lot of attention to personally, right?

A. That's correct.

Q. What I'm getting at, in 1980, you had a process that would inactivate the viruses, right?

A. We were working on a process that would allow us to heat the Factor VIII without losing most of it. Whether you could say we already had the process in 1980 I think would be characterizing it as something that is not so.

Q. What was the loss and yield that you were getting in 1980 in order to inactivate the viruses?

MS. REIFEL: Objection. Misstates prior testimony. Do you understand the question?

THE WITNESS: I understand the question. But we -- at that time, in 1980, we really weren't measuring the effect on viruses. We were trying to concentrate on how to retain the activity. So I don't know that the process in 1980 -- other than that we were heating it, I don't know that it was killing viruses at that point. That was only speculation.

MR. RAPP: Q. What was the situation in 1980 as far as yield and loss from your experiments?

A. I can't remember specifically, other than it was substantial.

Q. In 1982, did you have a process, wet process or dry process, that you felt was feasible, considering

the effect on the viruses and also on the Factor VIII?

MS. REIFEL: Objection. Vague and ambiguous. I don't know what you mean by "feasible."

THE WITNESS: You mean a workable process?

MR. RAPP: Q. Yes.

A. It was evolving into that.

Q. But you weren't there yet?

A. No.

Q. How about '83?

A. Here, I think the record pretty much speaks for itself. Because in '83, we began to develop a dry heat process which was licensed in early '84.

Q. Didn't you have a wet process that was workable before '84?

A. Well, workable again is a relative term. It was a process which seemed to work in the laboratory and in the pilot plan but did not work well at the production scale.

Q. Can you explain that?

A. Well, it's very common in chemical processes that, when you scale them up from a bench to a pilot plan and into production, that the circumstances of success will change. What happens in a beaker just doesn't happen the same way in a large, say, hundred gallon tank.

Q. Did you look at the Behringwerke process?

A. We were familiar with it, yes.

Q. You were studying that all along?

A. No, we weren't studying it. We were aware of it.

Q. Didn't that process -- wasn't it workable?

MS. REIFEL: Do you know what he means?

MR. RAPP: I switched and used his words to avoid that problem.

Q. I used your word "workable."

MS. REIFEL: Was Behring's licensed product that was being used workable?

THE WITNESS: I don't know. We never looked at the Behring product in manufacturing.

MR. RAPP: Q. Really. I mean, do you know whether that process eliminated the hepatitis virus without denaturing the Factor VIII?

A. I didn't know that in 1980's.

Q. Really. You know it now though?

A. As of a publication that came out 1988 or '87, I believe.

Q. What publication was that?

A. It was a publication that dealt with the follow-up on a number of patients who had received the product of Behringwerke and were shown to be free of hepatitis.

Q. What publication? What magazine, Lancet?

A. No, I think that was -- I don't remember precisely.

Q. Do you have a copy?

A. Yes.

MR. RAPP: Okay. I'd like to request that along with the rest of my stuff.

MS. REIFEL: Make a formal request and give us reasonable time.

MR. RAPP: It's included in my other request.

MS. REIFEL: No.

It's 6:00. We have to conclude.

MR. RAPP: Let me just ask this one thing.

Q. Do you have any information on the market shares that the various fractionators have?

A. No.

Q. What percent of the market of Factor VIII does Cutter have?

A. I don't know.

MR. RAPP: All right. I'm going to reserve my questions. I'd like to continue with this as soon as we can.

(Examination concluded at 6:00 p.m.)

_____

Signature of Witness

STATE OF CALIFORNIA)
) ss.
)

I, the undersigned, a Certified Shorthand Reporter of the State of California, hereby certify that the witness in the foregoing deposition was by me duly sworn to testify to the truth, the whole truth, and nothing but the truth in the within-entitled cause; that said deposition was taken at the time and place therein stated; that the testimony of said witness was reported by me, a Certified Shorthand Reporter and a disinterested person, and was thereafter transcribed under my direction into typewriting; that the foregoing is a full, complete and true record of said testimony; and that the witness was given an opportunity to read and, if necessary, correct said deposition and to subscribe the same.

I further certify that I am not of counsel or attorney for either or any of the parties in the foregoing deposition and caption named, nor in any way interested in the outcome of the cause names in said action.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my signature this_____day of MAY 15 1989.

GRO-C

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