1 FEDERAL TRADE COMMISSION

2 I N D E X (PUBLIC RECORD)

3

4 WITNESS: DIRECT CROSS REDIRECT RECROSS

5 Lauda 4338 4376 IC

6

7 EXHIBITS FOR ID IN EVID

8 Commission

9 None

10 Schering

11 None

12 Upsher

13 None

14

15 OTHER EXHIBITS REFERENCED PAGE

16 Commission

17 CX 689 4399

18 CX 1042 4382

19 CX 1111 4428

20 CX 1379 4415

21 CX 1382 4419

22 CX 1383 4426

23 Schering

24 SPX 2 4345

25 SPX 6 4346

1 Schering

2 SPX 7 4352

3 SPX 8 4353

4 SPX 11 4354

5 SPX 12 4355

6 SPX 13 4356

7 SPX 15 4358

8 SPX 251 4357

9 Upsher

10 None

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1 FEDERAL TRADE COMMISSION

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3 In the Matter of:)

4 SCHERING-PLOUGH CORPORATION,)

5 a corporation,)

6 and)

7 UPSHER-SMITH LABORATORIES,) File No. D09297

8 a corporation,)

9 and)

10 AMERICAN HOME PRODUCTS,)

11 a corporation.)

12 ----------)

13

14 Wednesday, February 20, 2002

15 9:30 a.m.

16 TRIAL VOLUME 19

17 PART 1

18 PUBLIC RECORD

19 BEFORE THE HONORABLE D. MICHAEL CHAPPELL

20 Administrative Law Judge

21 Federal Trade Commission

22 600 Pennsylvania Avenue, N.W.

23 Washington, D.C.

24

25 Reported by: Susanne Bergling, RMR

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

2 - - - - -

3 JUDGE CHAPPELL: Good morning, everyone.

4 ALL COUNSEL: Good morning, Your Honor.

5 JUDGE CHAPPELL: Anything before we get

6 started?

7 MR. NIELDS: I don't think so, Your Honor.

8 JUDGE CHAPPELL: Okay, Mr. Nields, call your

9 next witness.

10 MR. NIELDS: Our first witness will be Thomas

11 Lauda. As the Court may recall, he's in charge of

12 global marketing at Schering, and he was Mr. Audibert's

13 boss.

14 JUDGE CHAPPELL: Okay.

15 MR. NIELDS: And he's walking in.

16 JUDGE CHAPPELL: Raise your right hand, please.

17 Whereupon--

18 THOMAS C. LAUDA

19 a witness, called for examination, having been first

20 duly sworn, was examined and testified as follows:

21 JUDGE CHAPPELL: Thank you.

22 State your full name, please.

23 THE WITNESS: Thomas C. Lauda.

24 JUDGE CHAPPELL: Thanks.

25 You may proceed.

1 DIRECT EXAMINATION
2 BY MR. NIELDS:
3 Q. Mr. Lauda, how are you employed?
4 A. I'm employed as executive vice president of
5 Schering-Plough for global marketing.
6 Q. And can you briefly describe your educational
7 background?
8 A. I have a Bachelor of Science from Monmouth
9 College in business administration.
10 Q. And when did you get your Bachelor's?
11 A. In 1970.
12 Q. And can you briefly outline your job history
13 since you got your Bachelor's?
14 A. When I left college, I started at Peat, Marwick
15 & Mitchell, a public accounting firm. I held various
16 positions there over a four-and-a-half-year period, and
17 then I joined Schering-Plough in their internal
18 auditing group, and that was in 19 -- July of 1975.
19 I spent roughly four years, maybe four and a
20 half years, in the internal audit group, and then I was
21 offered an opportunity to go to Brazil as the
22 controller for Latin America. I accepted that
23 position. That was in 1979. I did that for about a
24 year and a half to two years, and then I went to Mexico
25 as a director of administration and finance for about

1 another two years.
2 I came back as head of the finance and --
3 finance for the Latin American division. That was a
4 position I held for a couple of years, and then I went
5 to Mexico, and that was in around 1984, as a general
6 manager.
7 Q. What is the job of general manager?
8 A. General manager is responsible for our business
9 in that country, all aspects of the business in that
10 country.
11 Q. Okay. What --
12 A. I -- sorry.
13 Q. I interrupted you. How long did you stay
14 there? And then continue.
15 A. I stayed there about three years. I came back
16 to Kenilworth, our headquarters, in 1988 as a vice
17 president of finance for the international division.
18 From there I accepted a -- I also took on a position as
19 vice president of our operations for Latin America. I
20 did that for about -- and Asia also, did that for a
21 couple of years, and then I was asked to take a
22 position of vice president of our international
23 marketing group, which I did for about three years.
24 Q. When did you take over as vice president for
25 international marketing?

1 A. That was -- oh, I can't recall exactly the
2 date, John. It was probably in around '94, somewhere
3 there, thereabouts.
4 Q. And then what jobs have you held since then?
5 A. Since then, I -- that job was expanded into
6 global marketing, where I took the position senior vice
7 president of global marketing, and then I was made
8 executive vice president of global marketing. I have
9 held that job since '96.
10 Q. Now, just to be clear, when you went from
11 senior vice president to executive vice president, was
12 that a change in title or a change in responsibilities
13 or both?
14 A. It was a recognition in what the job's role was
15 in Schering-Plough. So, it was just a change in title
16 that was to recognize the position of global marketing
17 in the company.
18 Q. And you said you were -- before you became
19 senior vice president in charge of global marketing,
20 you were vice president in charge of international
21 marketing. Was international marketing a little bit
22 like the precursor to global marketing?
23 A. Yes, it was.
24 Q. And how did the functions change when it became
25 global marketing?

1 A. When it moved into global marketing, we had a
2 much more direct responsibility for acquiring products
3 and developing the pipeline for the company, and also I
4 had taken on responsibility for the U.S. business at
5 the time also.
6 Q. Now, what are the functions of global marketing
7 at Schering?
8 A. We like to think of global marketing as
9 creating the future for the company. We primarily work
10 in three areas. The first area is the business
11 development for the pharmaceutical operations, that is
12 conducted through global marketing, and business
13 development is licensing, acquisitions or divestitures.
14 We also work with our research organization to
15 develop internal products, the profiles of the
16 products. We work through the development process and
17 into the registration process so that, you know, our
18 role is to maximize the label in the shortest period of
19 time so that we have a competitive product for the
20 marketplace.
21 And the third issue is we work with the
22 subsidiaries, both in a preapproval and a post-approval
23 way, to prepare them for the marketing of the products
24 and to help them adjust to the marketplace as they go
25 into the market with a product.

1 And then there's a cadre of other
2 responsibilities which include public affairs, drug
3 information, labeling, and some other minor roles that
4 all roll through the global marketing function.
5 Q. How large is global marketing in terms of the
6 number of people who are in it?
7 A. There's between 135 and 150 people in global
8 marketing.
9 Q. And who do you report to at Schering-Plough?
10 A. I report to the CEO, the chief executive
11 officer.
12 Q. And what are your functions as executive vice
13 president in charge of global marketing?
14 A. I provide the leadership, overall leadership to
15 the group, and I also monitor the projects as they are
16 implementing the projects.
17 Q. Now, did you while you were in global marketing
18 have involvement in a license opportunity regarding a
19 sustained release niacin product?
20 A. I did. I did.
21 Q. And when did that occur?
22 A. That occurred in around June of 1997.
23 Q. And how did it come about?
24 A. It came about based upon a phone call that I
25 received from Ray Kapur, who told me that he was

1 working on a licensing agreement. He had told me that
2 the main product in that agreement, although there were
3 several, was a product called Niacor, which was a
4 sustained release niacin. Ray -- Ray had indicated
5 that that product was the major focus of the licensing
6 agreement and that in order for us to acquire a license
7 to that product, it would have a cost of around $60
8 million.
9 Q. And did he ask you to do anything?
10 A. Yes, he asked me to perform an assessment of
11 the product to see if, in fact, it was worth $60
12 million.
13 Q. And did he tell you who the licensor was?
14 A. He did.
15 Q. And who was that?
16 A. That was Upsher-Smith.
17 Q. Now, did he say anything else to you during
18 that conversation?
19 A. Yeah, he had indicated to me that he had
20 received a data package that had all of the profile of
21 the product, both commercially and also from a
22 scientific standpoint, and that he would send that
23 along to me.
24 Q. Do you recall, Mr. Lauda, if he mentioned
25 anything about a time frame within which he wanted the

1 evaluation?
2 A. You know, I don't recall, John, specifically
3 that that was mentioned, but, you know, in
4 preparations, it's pretty clear to me that that
5 probably was mentioned.
6 Q. Now, did he make any reference that you can
7 recall to any patent litigation that was pending or
8 anything like that?
9 A. No.
10 Q. And what did you do after you spoke with Mr.
11 Kapur?
12 A. I spoke with Jim Audibert, who's my head of --
13 he heads up the cardiovascular unit in global
14 marketing. I told him that Ray and I had had this
15 conversation. I summarized the conversation for him.
16 I mentioned to him that we needed to do an assessment
17 and that Ray was sending a package, a data package,
18 over for us to look at.
19 Q. And did you get a package, a data package?
20 A. We did. I don't recall if it came directly to
21 me or it came to Jim directly, but we did receive a
22 data package.
23 Q. And did you see that package at some point?
24 A. Yes, I did.
25 Q. And what happened next?

1 A. Well, Jim proceeded to do his assessment of the
2 product based upon the data and his knowledge of the
3 field.
4 Q. You have some binders in front of you. There's
5 one that has written on the front of it Binder 1. I
6 would like you to pick that up and turn to a document
7 that is marked SPX 2.
8 A. SPX, excuse me?
9 Q. SPX 2.
10 A. Okay.
11 Q. It's sort of -- it's about two-thirds of the
12 way -- do you have it?
13 A. Yeah.
14 Q. And what is that?
15 A. This is a transmittal letter from me to Ray
16 Kapur, and it's advising him that we've completed our
17 assessment.
18 Q. Does it attach something?
19 A. Yeah, it attaches Jim Audibert's assessment of
20 Niacor.
21 Q. And did you discuss Jim Audibert's assessment
22 with Mr. Audibert?
23 A. Yes, I did.
24 Q. And was that before it was finalized and sent?
25 A. Yes, it was.

1 Q. Now, I'd like you to look at I think the last
2 page of that exhibit, it's headed Table II, and I'll
3 ask you what that is.
4 A. Table II is Jim's projection of the sales that
5 we could expect to receive off of Niacor and the market
6 share that we would expect it to do, along with the
7 assumptions that he made in getting to that projection.
8 Q. And did you discuss those projections and
9 assumptions with Mr. Audibert?
10 A. I did.
11 Q. And then if you can turn to the next tab, which
12 is SPX 6, and can you tell us what that is?
13 A. That's a transmittal letter from Jim Audibert
14 transmitting the profit and loss statement for the
15 Niacor sales projections that we previously looked at.
16 Q. And did you discuss that with Mr. Audibert?
17 A. I did.
18 Q. And do you know why or do you recall why that
19 was sent separately from the rest of the assessment?
20 A. My recollection is that there were issues that
21 we had changed and made some adjustments, and Jim had
22 to make those adjustments, and so I wanted Ray to have
23 the package, and so I had asked Jim to send it over,
24 and he had to -- he had to make some changes on the
25 profit and loss statement, sent it later.

1 Q. Now, did you reach a conclusion about whether
2 this Niacor licensing opportunity was worth $60 million
3 to Schering?
4 A. Yes, we did.
5 Q. And what was the conclusion?
6 A. That it was worth much more than that to
7 Schering-Plough.
8 Q. And what was the basis of that conclusion?
9 A. The basis of the conclusion was that this --
10 that the financials and the analysis that Jim made told
11 us that we had a product that, number one, was rather
12 straightforward in the marketplace. It -- it was well
13 known, it's been in the market for 20 years, efficacy
14 proven. We had a sustained release technology that we,
15 Schering-Plough, were familiar with and was kind of a
16 standard in the industry. So, we knew we had a product
17 that worked.
18 We were working in a marketplace that we knew
19 very well. We were preparing ourselves for future
20 entry there. And we -- we expected that the product
21 would easily garner the share, and so it was -- it was
22 considered to be -- that's where our assessments came
23 out.
24 Q. Did you reach a conclusion about whether
25 Niacor-SR could be approved in the geographic areas

1 that you were taking a license for?
2 A. Yeah, we thought it would be approved, very
3 little risk of not being approved.
4 Q. And what was the basis for that?
5 A. The basis was, again, a product that was well
6 characterized, known to work, was being used in the
7 management of lipids. So, we didn't have any concern
8 with the fundamental active component.
9 Again, the sustained release technology is
10 something that we were very well aware of. We didn't
11 expect any problems in that sustained release
12 technology being applied.
13 And thirdly, we had received a package of
14 clinical data that supported the product's performance.
15 Q. Were there any other reasons that Niacor-SR was
16 an appealing opportunity for Schering-Plough?
17 A. Yeah, it fit very well with Schering's
18 strategic direction. We had a major product, probably
19 going to be our largest product in the history of
20 Schering-Plough, which is a cholesterol-absorbing agent
21 called ezetimibe. That product was in development. It
22 was looking very good. So, this represented a major
23 strategic fit for us as a precursor to launching
24 ezetimibe.
25 It gave us an opportunity to get into the

1 marketplace, know the physicians, know the opinion
2 leaders, you know, get the audiences down and set
3 the -- really the path that we would launch ezetimibe
4 into the market with.
5 Q. Now, did you pass on your conclusions to Mr.
6 Kapur?
7 A. I did.
8 Q. In what form?
9 A. I had a phone conversation with Ray in which I
10 told him I had reviewed it. I told him the project
11 looked very good, and it was something that we were
12 interested in.
13 Q. Did you also send him the written reports?
14 A. I did.
15 Q. And what was your understanding of what Mr.
16 Kapur was going to use the evaluation for?
17 A. Well, I assumed he was going to use it in the
18 licensing arrangements that he was working on.
19 Q. And did there come a time when you learned that
20 a deal had been struck with Upsher-Smith?
21 A. I did.
22 Q. And what happened after that? Did global
23 marketing have any further responsibilities?
24 A. Yeah, Ray called me, and he had mentioned that
25 the deal had been struck. Ray indicated that he

1 would -- that global marketing was to take the
2 leadership role in working this product through to the
3 registration and marketing process, which was quite
4 normal in Schering-Plough.
5 Q. And what did you do about that?
6 A. I called Jim Audibert and told Jim that the
7 project had been approved, that he would take on as one
8 of his responsibilities the preparation and organizing
9 of the product.
10 Q. And what was the general plan of action at that
11 time in terms of working on the -- bringing the product
12 to market?
13 A. The plan of action was to let Upsher finish its
14 clinical work, finish its dossier, provide us with the
15 dossier. Jim was to coordinate the internal
16 Schering-Plough assets that would be needed, people
17 primarily, that would be needed to convert the NDA or
18 the filing that Upsher was to make in the U.S. into a
19 European format.
20 And so he was just arranging the timing and
21 trying to make sure that the people had the time frames
22 clear so that they could do the project and get it
23 converted to a European filing.
24 Q. And at what -- when were you expecting to get
25 the dossier or whatever information you needed from

1 Upsher-Smith?
2 A. It was late in the third quarter of 1997.
3 Q. And so what needed to be done between the time
4 the deal was struck and the time that you would get
5 this dossier?
6 A. Just really informing the people that it was
7 coming and getting them scheduled that they would be
8 available to make the conversion.
9 Q. Now, what actually happened? Did you get the
10 dossier late in the third quarter?
11 A. No.
12 Q. And why not?
13 A. Well, it seems like that they were delayed in
14 Upsher-Smith.
15 Q. Did anything else relevant to this project
16 happen at about that time?
17 A. Yeah, there was a similar type of niacin
18 sustained release product in the marketplace called
19 Niaspan. It was launched by a company called Kos. The
20 product was not doing well in the marketplace, and
21 there was a lot of fanfare around it not meeting its
22 expectations.
23 Q. And what eventually happened to this project?
24 A. Eventually, Upsher did not continue to prepare
25 the dossier, did not finish the filing, and we made a

1 decision not to proceed on the product.
2 Q. You mean proceed separately from Upsher?
3 A. Proceed separately, right.
4 Q. And what was the reason for that decision?
5 A. Well, I -- as we looked at our ability to
6 commercialize it and based upon what happened to Kos
7 and based upon our view of the marketplace, we just
8 didn't think that it was going to even reach the shares
9 that we thought originally. So, we just didn't see
10 this as commercially viable.
11 Q. Now, Mr. Lauda, I'd like you to turn to a
12 document in your first binder which is SPX 7. It's
13 most of the way back but not all the way back. Do you
14 see that?
15 A. Yes.
16 Q. And what -- it's a --
17 A. It's a letter from Ray Kapur to me.
18 Q. Okay, it's dated the 2nd of July, and what is
19 this letter about?
20 A. It's Ray telling me that the -- it's a letter
21 from Ray telling me that Upsher will closely cooperate
22 with us and that Ray is asking me to assign a project
23 leader to conduct the bringing of this product to the
24 marketplace.
25 Q. And did you do that?

1 A. I did.
2 Q. And who was that again?
3 A. It was Jim Audibert.
4 Q. And up at the upper right-hand corner, there's
5 some handwriting. Whose handwriting is that?
6 A. That's mine.
7 Q. It says, "To Jim Audibert, please see me
8 urgently, Tom"?
9 A. That's correct.
10 Q. And did you speak with Mr. Audibert at about
11 that time on the 2nd?
12 A. I did. I did.
13 Q. Now, I'd like you to turn to a document marked
14 SPX 8. It's also dated the 2nd of July, and it is from
15 R. Kapur to Mr. Cesan.
16 A. Right.
17 Q. And at the bottom paragraph it says,
18 "International registration and marketing of the
19 principal product, Niacor-SR, will be the
20 responsibility of global marketing."
21 A. Right.
22 Q. And then there's some handwriting at the
23 bottom. Whose is that?
24 A. That's mine.
25 Q. And who are you addressing there?

1 A. Jim Audibert.
2 Q. And what are you telling him?
3 A. I'm telling him that I think he needs to assign
4 somebody specifically to get this project into the
5 development mode.
6 Q. Now, I'd like you to turn to a document marked
7 SPX 11. It's a memorandum dated August 21, 1997.
8 A. Right.
9 Q. It shows from Jim Audibert to Ray Kapur, and it
10 shows a copy to T. Lauda. Is that you?
11 A. That's me.
12 Q. And did you receive a copy of this?
13 A. I did.
14 Q. And what is this document about?
15 A. This is Jim writing to Ray -- and Jim was
16 becoming a little bit frustrated in terms of what kind
17 of data he was getting, and it was him writing to Ray
18 asking for Ray to help him to coordinate with Upsher
19 the -- you know, sending us the data that we needed to
20 make the filing.
21 Q. It mentions somebody named J. P. Osselaere.
22 Who is that?
23 A. J. P. Osselaere is our head of regulatory in
24 Europe.
25 Q. And it makes reference to an ISS and ISE. What

1 are those?
2 A. That's the integrated summary of safety and the
3 integrated summary of efficacy that are the primary
4 documents in a U.S. filing for registration, an NDA.
5 Q. Are those the documents you were waiting for
6 from Upsher-Smith?
7 A. Yes.
8 Q. And did you discuss these matters with Mr.
9 Audibert at the time?
10 A. Yes.
11 Q. And can you describe what your conversation
12 was?
13 A. Fundamentally, it was Jim was becoming a little
14 frustrated with the data not coming forward and was
15 wondering, you know, what was Upsher's commitment to
16 getting this data done on time.
17 Q. Now, I'd like you to turn to a document marked
18 SPX 12. Do you have that in front of you?
19 A. Yes.
20 Q. This one is dated November 7th, 1997, and it
21 says it's from Mr. Kapur to Mr. Audibert.
22 A. Um-hum.
23 Q. It says, "I ran into Mr. Ian Troup at the NWDA
24 meeting last week, and we discussed very briefly my
25 October 22 fax. My Troup agreed that he would send the

1 Niacor-SR Health Registration Dossier to you in
2 segments with information in a format to enable you to
3 make an evaluation instead of waiting for the entire
4 Health Registration Dossier to be completed."
5 A. Right.
6 Q. Do you remember if you spoke to Mr. Audibert
7 about this matter or this subject at about that time?
8 A. I'm sure that we spoke about the general delays
9 in the project. I think what this is doing is Ray was
10 very well aware that we were pushing hard to get the
11 data, and I think this letter is saying, okay, we'll
12 send you pieces of it as we have it ready. So, there
13 was signs of progress that we were getting the data we
14 needed to make a filing.
15 Q. Is it unusual in your experience in the
16 pharmaceutical industry for delays like this to occur
17 in clinical data?
18 A. No, it's probably more like -- usual that you
19 have delays in the filing.
20 Q. Now, I'd like you to turn next to a document
21 marked SPX 13. It's dated 15 April 1998. It's from
22 Ray Kapur to Messrs. Audibert and Lauda. What is this
23 about?
24 A. This was a -- it was a letter of
25 confidentiality Ray was transmitting to me asking me to

1 sign it as an eligible officer to allow us to get the
2 data from Upsher-Smith.
3 Q. And this was data on Niacor?
4 A. On Niacor.
5 Q. And was that stated in this cover memorandum?
6 A. Yes.
7 Q. And then I'd like you to look in your other
8 book, binder 2, at SPX 251. Do you have that in front
9 of you?
10 A. I do.
11 Q. It's a cover letter from Desiree Malanga,
12 secretary to Mr. R. Kapur, to Vickie O'Neill, director
13 of business development at Upsher-Smith, and the cover
14 letter says, "We request that complete information with
15 regard to Niacor be sent directly to Mr. Thomas Lauda."
16 Do you see that?
17 A. Yes.
18 Q. And then there's a document attached. What is
19 that?
20 A. That's the signed confidentiality agreement.
21 Q. And whose signature does it bear?
22 A. Mine.
23 Q. And again, what was the purpose of this?
24 A. This was, once again, to drive them to send us
25 the data and provide them with the legal document that

1 maintained it confidentially.
2 Q. Now, I'd like you to look at a document bearing
3 Exhibit Number SPX 15. I think that's at the end of
4 binder 1. It's a memorandum from Jim Audibert to Tom
5 Lauda. It's dated September 25th, 1998, and the first
6 sentence says, "On September 24, Ray Kapur and I had a
7 phone conversation with Ian Troup of Upsher-Smith to
8 review the status of Niacor-SR."
9 Do you have a recollection of talking with Mr.
10 Audibert about that conversation before it actually
11 occurred?
12 A. Yeah.
13 Q. And what do you recall about it?
14 A. Well, I think we were suspecting that, you
15 know, Upsher was moving -- backing away, and Jim and I
16 had discussed, you know, how do we go about getting
17 this data, and I had asked him to go forward and find
18 out clearly what their intentions were.
19 Q. And did you talk with Mr. Audibert after his
20 phone conversation?
21 A. I did.
22 Q. And what do you recall about that?
23 A. Well, he had told me that it was clear in the
24 discussions from Upsher that they were not going to
25 proceed forward with a filing of an NDA in the U.S.,

1 that their concerns were principally over the fact that
2 the marketplace was not receptive to a sustained
3 release Niacor as shown by the Kos product and that
4 they felt that they had a product that was somewhat
5 inferior, and they had other things to do with their
6 resources, and so they were going to abandon the
7 product.
8 Q. Now, the document -- if you look at the bottom
9 of the first page, it says, describing this
10 conversation, "Uptake of Niaspan in the U.S. has been
11 poor."
12 A. Um-hum.
13 Q. "Sales for the first six months of 1998 total
14 $3.8 million."
15 A. Right.
16 Q. "And in August 1998, after being in the market
17 one year, Niaspan's new Rx share for the month is only
18 1.1 percent. Furthermore, judging by the response of
19 the investment community, the prognosis of Niaspan is
20 poor. The current price of Kos' stock is 5 and 7/16s,
21 down from 44 last October."
22 Then at the top of the next page it says, "The
23 fact that Upsher-Smith is not currently moving forward
24 with the NDA means considerable more resources would be
25 required by SP --" that's Schering-Plough?

1 A. That's right.
2 Q. "-- to assemble an HRD --" that's a filing
3 overseas?
4 A. That's correct.
5 Q. "-- and the time to approval would have to be
6 considerably later than the late 1998 time frame used
7 for our forecast. Once the clinical data has been
8 received and reviewed, I will provide you with a final
9 assessment, but at this time, the outlook is bleak."
10 A. Right.
11 Q. Did you eventually get the clinical data?
12 A. No.
13 Q. And did you make a final decision about the
14 product?
15 A. We did.
16 Q. And what was that?
17 A. That we weren't going to launch the product.
18 Q. And what were the reasons for that?
19 A. The reasons were that we did not see it
20 financially viable in the marketplace.
21 MR. NIELDS: Your Honor, I'm probably talking
22 to myself, but in a very short time, we will be going
23 into some in camera material. We're not quite there
24 yet, but it will be coming up very soon.
25 JUDGE CHAPPELL: Okay, just let me know when

1 we're ready.
2 MR. NIELDS: I will do that, I hope.
3 JUDGE CHAPPELL: Thank you, or have someone
4 throw something at you on your side.
5 MR. NIELDS: They are very ready to do that.
6 BY MR. NIELDS:
7 Q. Mr. Lauda, during the time you've been at
8 global marketing, how many licensing deals have you
9 worked on roughly?
10 A. Upward of 20 to 25 deals.
11 Q. Now, in deciding whether to in-license a
12 product and in deciding how much to offer or what to
13 offer for an in-license of a product, are there certain
14 factors that Schering considers?
15 A. Yes.
16 Q. And what are those?
17 A. Well, we primarily consider five factors. One
18 would be the total investment required in the project
19 to get it to a state of registration. Two would be the
20 financial returns that we expected to get from the
21 project. Three would be the strategic nature of that
22 product and strategic fit to Schering-Plough. Four
23 would be what are the risks involved in making -- in
24 bringing that project to the marketplace. And fifth
25 would be the amount of resources that would be required

1 by Schering-Plough to get the project into the
2 marketplace.
3 Q. I have put a -- something on the screen, Mr.
4 Lauda, which is titled License Deal Factors. It says
5 Economic Value first, Degree of Risk negotiation,
6 Strategic Fit next, Whose Research Resources next, and
7 Total Investment next. Are those the factors that
8 you've just given us?
9 A. Yes.
10 Q. Now, what do you mean exactly by "economic
11 value"?
12 A. Economic value is the return that we could
13 expect on the project given the investments that we
14 were going to make.
15 Q. And how does Schering, in evaluating a license
16 deal, how does Schering go about figuring out the
17 economic value?
18 A. We prepare an analysis, an assessment of the
19 underlying asset, the license, the product, how well
20 it's going to do in the marketplace, what we expect its
21 profitability to be, and we time value that, and we add
22 in the investment, including all of the costs of that
23 investment, and we apply a time value to the money, and
24 that helps us to understand what the economic return
25 will be on the project.

1 Q. And do you do sales projections?
2 A. Yes, we do.
3 Q. So, is this essentially similar to what Mr.
4 Audibert did for Niacor-SR?
5 A. Yes.
6 Q. Now, what do you mean by "degree of risk"?
7 A. Every product's different, and it has --
8 inherently the project has risks in it. What stage of
9 development the product's in will be a clear factor of
10 what risk it's in. Is there a proof of principle of
11 the product? Are there safety issues around it? So,
12 each and every product has elements of risk in it.
13 Q. When you speak of "proof of principle," what is
14 that?
15 A. That means does the drug have efficacy in the
16 targeted disease that you plan to treat.
17 Q. How important is this factor, the degree of
18 risk, in deciding whether to do a deal and how much to
19 offer?
20 A. Very important.
21 Q. Now, the next one listed is strategic fit.
22 What do you mean by "strategic fit"?
23 A. Schering is -- we are in a number of therapy
24 areas that are strategic to us. We have the scientific
25 resources and the commercial resources in those areas,

1 and what we look for are projects that fit and allow us
2 to leverage that expertise in the marketplace. So, you
3 know, it's a -- it would be a major issue for us that
4 it falls within the strategic focus of Schering-Plough.
5 Q. And what would be some examples of license
6 deals in which you thought there was a strategic fit?
7 A. ICN, Niacor.
8 Q. And what was ICN?
9 A. ICN was an antiviral product that we licensed
10 for treating hepatitis C. It was a companion product
11 to our PEG interfuron and our interfuron products.
12 Q. And you mentioned Upsher-Smith. In what way
13 did -- was there a strategic fit regarding Niacor-SR?
14 A. Niacor fit within the cardiovascular area where
15 we had our scientific resources, we were building the
16 commercial resources to launch our major product,
17 ezetimibe. So, this was a precursor to us in the
18 marketplace.
19 Q. And does Schering -- does Schering from time to
20 time license in products where there isn't a strategic
21 fit?
22 A. Yes, we do.
23 Q. Now, the next item is research resources. I
24 think maybe you -- well, in any event, what do you mean
25 by that?

1 A. That's the -- that's basically our research
2 organization, our scientists, our laboratories, our
3 microscopes and the -- you know, the resources that we
4 have working on projects that Schering-Plough has
5 ongoing.
6 Q. And why does that matter? Why is that a
7 criterion that you consider in licensing?
8 A. These folks are focused in on projects that are
9 of interest to Schering-Plough in our commercial
10 business. So, if we have to use some of those
11 resources in a licensed project, we are going to have
12 to discontinue something else. So, it then becomes a
13 decision process, and we start comparing external
14 versus internal projects.
15 Q. And then the last item is total investment, I
16 think you said total investment needed to get it to the
17 point where it could be approved.
18 A. Right.
19 Q. What do you mean by that?
20 A. That includes the up-front payment that you
21 might make, any payments that you would make during the
22 process before approval to compensate for the
23 licensor's research costs or to induce the licensor
24 into certain types of, you know, clinical efforts. And
25 it includes also any research costs that we would

1 invest in the project to bring it to an approvable
2 state.
3 Q. Would it include under some circumstances
4 purchase of stock?
5 A. Yes.
6 Q. And so I think you've said it would include
7 fees, up-front fees to the licensor?
8 A. Right.
9 Q. It would include fees paid to the licensor --
10 let me ask you, would it include fees paid to the
11 licensor for, say, the beginning or the finishing of a
12 clinical trial?
13 A. Yes.
14 Q. Where the money was committed and had to be
15 paid before you would know whether the project would be
16 approved?
17 A. Yes.
18 Q. And it would include your own anticipated
19 research and development expenditures before you would
20 know whether the product is approved?
21 A. Absolutely.
22 Q. Now, complaint counsel's expert on licensing,
23 Dr. Levy, said -- and this is at page 2177 of the
24 record, I'll just read you a question and answer:
25 "QUESTION: In your redirect just a second ago,

1 you said something about the fact that you didn't --
2 you didn't consider Schering's anticipated research and
3 development costs when you were evaluating the other
4 Schering deals. Is that correct?
5 "ANSWER: Yes, that's correct."
6 My question is, does Schering consider
7 anticipated research and development expenditures when
8 it makes a decision about going forward or not going
9 forward with a licensing deal?
10 A. Always. Always.
11 Q. And are -- when you bring a licensing deal
12 before either the board of directors or Schering-Plough
13 Operating Committee or a PRB, do you routinely inform
14 them of the anticipated research and development costs
15 that would be required by the product -- project before
16 you would know whether it would be approved?
17 A. Always.
18 Q. Now, I'm going to put on this ELMO a chart, a
19 bar graph chart that Dr. Levy used --
20 Oh, I'm sorry, I'm now in camera, Your Honor.
21 Thank you.
22 JUDGE CHAPPELL: Okay, I am going to have to
23 ask the public to leave the courtroom as we enter an in
24 camera session.
25 (The in camera testimony continued in Volume

1 19, Part 2, Pages 4443 through 4484, then resumed as
2 follows.)
3 JUDGE CHAPPELL: So, let's recess until 11:35.
4 (A brief recess was taken.)
5 MR. CURRAN: Your Honor, with Mr. Nields'
6 indulgence, I would like to raise a scheduling issue,
7 if I may, for a moment.
8 JUDGE CHAPPELL: All right.
9 MR. CURRAN: And this is not in camera, so if
10 it can be addressed before we get back into that.
11 Your Honor heard Mr. Nields say yesterday that
12 Schering was doing some trimming of its witness list
13 and was moving the case along a little quicker than
14 earlier anticipated, and Mr. Nields has informed us
15 that Thursday and Friday of this week are Upsher-Smith
16 days.
17 We have arranged for five witnesses to come
18 from Upsher-Smith, and they will -- they will all
19 either -- they are all either here or will be arriving
20 here by tomorrow morning.
21 In addition, we would like ideally to call a
22 sixth witness, a nonparty witness, a lipidologist;
23 however, we have a constraint in that regard, and that
24 is the parties have an informal understanding of giving
25 72 hours notice before a witness may appear. We

1 arranged for this lipidologist late yesterday to come
2 to testify on Friday, and then last night we sent a
3 notice to complaint counsel that this witness we
4 anticipated to call on Friday.
5 Complaint counsel has raised an objection to
6 that witness testifying because they didn't have 72
7 hours notice. I wanted to raise that with you, Your
8 Honor, to explain why we may not have a complete, full
9 day on Friday, despite the fact that we have the
10 logistical ability to fill the day.
11 MR. SILBER: Your Honor, if I may respond.
12 First, I think the 72-hour provision on
13 notification of witnesses was your provision. The
14 parties, in addition, worked out a separate provision
15 regarding providing demonstratives, which also requires
16 72 hours notice. Last night, after 10:00 p.m., we
17 received a letter informing us that this witness would
18 be called on Friday.
19 In addition, last night, after 10:00 p.m., we
20 received eight demonstratives that are to be used with
21 this witness, I believe, and it puts us in quite a bind
22 to prepare for this witness that we had no notice of in
23 less than the time that the Court set for notice on
24 witnesses and less time than the parties had set on
25 demonstratives, and we think that we would be

1 prejudiced by having to cross examine this witness with
2 effectively just 48 hours notice.
3 While we would like to keep the trial moving,
4 the fact that Schering just informed Upsher that they
5 need to put on witnesses for two days, you know, is
6 really not our fault, and we feel we should have
7 adequate time to prepare to cross examine an expert
8 who's going to speak to issues concerning cholesterol
9 lowering and other technical issues.
10 JUDGE CHAPPELL: So, you think you need three
11 days?
12 MR. SILBER: Yes, we do, Your Honor.
13 JUDGE CHAPPELL: I mean, you knew who the
14 witness was.
15 MR. SILBER: Yes, we did, Your Honor.
16 JUDGE CHAPPELL: And you've probably deposed
17 the witness.
18 MR. SILBER: Yes, we have, Your Honor.
19 JUDGE CHAPPELL: And you don't want to take a
20 while and see if you can prepare; you just want to
21 object to it.
22 MR. SILBER: Your Honor, I've consulted with
23 the attorney who is going to prepare the cross
24 examination, and he has -- he's the individual who took
25 the deposition. He's the individual who is going to do

1 the cross examination, but he had not seriously started
2 preparing for this, because we did not anticipate this
3 to occur until sometime next week.
4 JUDGE CHAPPELL: So, we can do the direct
5 examination of the witness.
6 MR. SILBER: I have no problem with that, Your
7 Honor, if the cross is held over until Monday. We
8 certainly have no problem with that.
9 MR. CURRAN: Well, we don't have a personal
10 problem, but this is a doctor from across the country.
11 To ask him to come testify on Friday and then wait
12 until Monday to have his cross would be a problem. We
13 could do the cross on Saturday morning. That would
14 comply with the 72 hours notice.
15 Alternatively, if there is some specific aspect
16 of the demonstratives that create a burden in
17 preparation, we'll withdraw the demonstratives that
18 create the problem, and we'll put the witness on, and
19 he can testify without demonstratives.
20 JUDGE CHAPPELL: Do you want to consider that?
21 MR. SILBER: We could consider that, Your
22 Honor, but still I think the larger issue remains that
23 we did not have proper notice, and I think -- I mean,
24 the demonstratives make it a larger issue, but even
25 absent the demonstratives, we should have 72 hours to

1 prepare for a witness.

2 In addition, there are other witnesses that

3 have been -- that we have been given proper notice,

4 Schering witnesses and I believe Upsher witnesses.

5 These individuals could be called on Friday to fill

6 that time, individuals for whom we have been given

7 proper notice.

8 JUDGE CHAPPELL: So, why don't we just move

9 this witness, if he can only be here one day, until

10 Monday?

11 MR. CURRAN: We could, but we don't have

12 anybody else who can testify Friday afternoon. We've

13 got five witnesses, and my current expectation is that

14 that would leave time for an additional witness on

15 Friday afternoon.

16 JUDGE CHAPPELL: Well, I'm going to -- since

17 you're offering a few tweaks to it and they're

18 objecting to it, I'm going to give the parties a little

19 more time to negotiate this and then get back with me

20 end of the day or tomorrow morning, and if you can't

21 work it out, then I'll make a decision.

22 MR. CURRAN: Thank you very much, Your Honor.

23 JUDGE CHAPPELL: But it sounds like if you're

24 trying to work it out, maybe you can come to some

25 understanding.

1 MR. CURRAN: Okay, we will give it a try
2 perhaps over lunch today, Your Honor. Thanks very
3 much, and my thanks to Mr. Nields and the witness for
4 this brief interruption.
5 JUDGE CHAPPELL: Also, I wanted to inform the
6 parties regarding your post-trial briefs, proposed
7 findings and conclusions, I just wanted to direct your
8 attention to the FTC Rule 3.46. It has very express
9 requirements for your proposed findings and
10 conclusions. So, you need to read and heed 3.46, just
11 FYI. Thank you.
12 MR. CURRAN: Thank you, Your Honor.
13 JUDGE CHAPPELL: Mr. Nields, do we need to go
14 back into in camera session?
15 MR. NIELDS: Yes, we do, Your Honor.
16 JUDGE CHAPPELL: Okay, at this time, I'll have
17 to ask the public to leave the courtroom. I think they
18 already have, but just to be safe.
19 (The in camera testimony continued in Volume
20 19, Part 2, Pages 4485 through 4519, then resumed as
21 follows.)
22 MR. NIELDS: With the Court's permission, I'll
23 simply reask the question that I think I was halfway
24 into?
25 JUDGE CHAPPELL: Yes, or have the reporter read

1 it back.

2 MR. NIELDS: I think I was just halfway through

3 it, Your Honor.

4 JUDGE CHAPPELL: Okay, go ahead.

5 BY MR. NIELDS:

6 Q. Mr. Lauda, when Schering negotiates a license

7 deal, are there other bidders?

8 A. Sometimes there are and sometimes there aren't.

9 Q. And can you give us examples where there are

10 not any other license bidders?

11 A. Ribavirin had no other bidders, Centocor had no

12 bidders, and -- those two. There may have been others.

13 Q. And ribavirin is the ICN deal?

14 A. The ICN product.

15 Q. Now, if there are no other bidders, why would

16 Schering pay $23 million up front to ICN and $31

17 million up front to Centocor?

18 A. That's what it takes to make the deal. You

19 know, they're not going to just give away a drug. So,

20 that's what it took to get the deal done.

21 Q. Where there are other bidders, do you generally

22 know what they are bidding?

23 A. No.

24 Q. And how do you decide what to bid on a license

25 deal then?

1 A. We conduct our internal assessments of the
2 product, and from there we make a judgment as to what
3 we would be willing to pay for the drug and how we
4 would be willing to make -- how we would be willing to
5 pay it.
6 Q. And do you do that by doing assessments of the
7 sales projections and economic value and the other
8 factors?
9 A. Yes, we do, yes.
10 Q. And the way in which you did for Niacor-SR?
11 A. Yes.
12 Q. And in the final analysis, how was the price
13 actually determined?
14 A. It's a negotiated agreement between the
15 companies.
16 MR. NIELDS: May I have a moment, Your Honor?
17 JUDGE CHAPPELL: Yes.
18 (Counsel conferring.)
19 MR. NIELDS: Your Honor, I'm informed that
20 there may have been two items on the chart that I
21 neglected to ask the witness about, and the problem is
22 that to ask them, we would have to go back into in
23 camera, I'm afraid.
24 JUDGE CHAPPELL: Okay. Are you going to tell
25 that lady you're sorry?

1 MR. NIELDS: I am.
2 JUDGE CHAPPELL: At this time, we will have to
3 go back into in camera session. I have to ask the
4 public to leave.
5 (The in camera testimony continued in Volume
6 19, Part 2, Pages 4520 through 4521, then resumed as
7 follows.)
8 JUDGE CHAPPELL: Does Upsher have any direct
9 exam of this witness?
10 MR. CURRAN: No, Your Honor, thank you.
11 JUDGE CHAPPELL: Cross?
12 CROSS EXAMINATION
13 BY MR. EISENSTAT:
14 Q. Did you attend any of the -- oh, excuse me, it
15 is nice to see you again.
16 A. Oh, thank you. I'd like to say the same...
17 Q. Thank you.
18 Mr. Lauda, did you attend any of the
19 negotiating sessions between Schering and Upsher-Smith?
20 A. No.
21 Q. Do you have any idea what Upsher-Smith was
22 asking for in those negotiating sessions?
23 A. I only know the amount that Ray told me would
24 be needed to make the Niacor portion of the deal.
25 Q. He didn't tell you how they framed that?

1 A. He had just indicated to me that there were a
2 number of products.
3 Q. And did he indicate to you whether or not those
4 discussions involved settlement of a patent dispute?
5 A. We had no discussion on that.
6 Q. You said at some point you, Schering, decided
7 they were not going to go ahead by themselves with the
8 Niacor-SR project. Is that right?
9 A. That's correct.
10 Q. Do you recall approximately when that was?
11 A. Oh, I think there was some thought about it
12 for -- but it must have been in late -- mid -- let me
13 say third quarter '98, somewhere around there, but I
14 think we had some concerns that they just weren't
15 moving forward on the project.
16 Q. You saw that note from Mr. Audibert earlier
17 today. Was it -- would it be after that note about
18 the -- his conversation with Mr. Troup?
19 A. Well, I actually had a conversation with Jim
20 before that, and he suspected that things were not
21 going to -- that they were going to abandon the
22 program. So, I had asked him to have a direct session
23 with the Upsher people, along with Ray, to find out
24 where they were.
25 Q. Was the decision by Schering to discontinue the

1 product, though, made after that direct contact he and
2 Ray had with Mr. Troup?
3 A. Yes, but we were -- we were looking at it all
4 along. The decision was made after that.
5 Q. Was there any documentation of this decision?
6 A. There was a -- I think the only letter that I
7 can recall was that -- between Jim informing me where
8 Upsher was intending to not proceed forward, he had
9 indicated at that time that, you know, it looked bleak
10 for Schering-Plough but that we would further discuss
11 that, and I think we did further discuss that, and we
12 decided not to move forward.
13 Q. When Schering made its decision not to move
14 forward, did you create any paper record of that
15 decision?
16 A. I don't recall any.
17 Q. Do you recall if other people besides yourself
18 participated in that decision?
19 A. I think it was largely Jim, Jim Audibert and
20 myself and perhaps Ray. Ray may have -- I don't know
21 if he participated in the actual discussions, I don't
22 think he did there, but he was aware that we were not
23 going to move forward.
24 Q. Did you tell anybody above you in the corporate
25 organization that you were not going to go forward?

1 A. I don't recall a specific conversation. It --
2 it could have been. I don't recall a specific
3 conversation.
4 Q. Prior to the end of March in 1998 -- that would
5 be well before Mr. Audibert had his conversation with
6 Mr. Troup. Is that right?
7 A. That's correct.
8 Q. Prior to the end of March in 1998, did you tell
9 anybody from Upsher-Smith that Schering was abandoning
10 Niacor-SR?
11 A. I never had a discussion with anybody from
12 Upsher-Smith on any subject.
13 Q. So, you didn't tell them that.
14 A. I did not.
15 Q. Are you aware of anybody else from Schering who
16 prior to the end of March in 1998 told Upsher-Smith
17 that Schering was abandoning Niacor-SR?
18 A. I'm not aware of anybody who would have done
19 that.
20 Q. Okay. Before you started evaluating the
21 project, you got a phone call from Ray Kapur. Is that
22 correct?
23 A. That's right.
24 Q. And that was in June of 1997?
25 A. Yes.

1 Q. And Mr. Kapur told you in that phone
2 conversation that he had a packet of information to
3 give you about the product. Is that correct?
4 A. That's correct.
5 Q. And that packet of information was then sent
6 over to global marketing, you don't recall if it was
7 directly to yourself or to Mr. Audibert. Is that
8 correct?
9 A. That's correct.
10 Q. And before you got that packet of information,
11 you knew that Mr. Kapur was considering paying $60
12 million to Upsher-Smith. Is that correct?
13 A. He had mentioned it to me on the phone.
14 Q. And before you began your assessment of the
15 product, before you and Mr. Audibert began working on
16 the product, you had an understanding that Europe would
17 have to be the primary market for the Niacor-SR
18 product, correct?
19 A. I don't -- you mean did I discuss that with
20 Ray, is that what you're asking me?
21 Q. No, I'm asking if that was your understanding.
22 A. Yeah, that was -- that's generally our
23 understanding when we're looking at international
24 rights.
25 Q. Now, the Niacor-SR product, that was not a

1 generic product, was it?
2 A. I'm sorry?
3 Q. The Niacor-SR product, that was not a generic
4 product, was it?
5 A. No.
6 Q. Okay. And at the time you started working on
7 the product, you had a general understanding of the
8 risk factors in niacin?
9 A. Yes.
10 Q. Do you recall the date when you actually
11 received the information from Mr. Kapur and began
12 working on it?
13 A. I don't recall. I don't recall if it was me
14 who received it directly.
15 Q. But yourself and Mr. Audibert wouldn't have
16 begun working on the commercial assessment of Niacor-SR
17 until after you actually received that data from Mr.
18 Kapur?
19 A. I think Jim may have started on it. He doesn't
20 necessarily need the data to start the assessments.
21 There's marketing, pricing, there's a whole lot of
22 things to consider.
23 Q. But considering specifically the Niacor-SR, he
24 couldn't have started considering that until he
25 actually got the data.

1 A. I think he may have had a pretty good
2 understanding of what the product's expectations were.
3 I can't say when Jim actually started working on it,
4 but I would suspect that he could have started at any
5 time after my conversation.
6 Q. And you don't recall the date of your
7 conversation with Mr. Kapur?
8 A. It was immediately following the conversation
9 that I had with Ray Kapur.
10 Q. But you don't recall the date of your
11 conversation with Mr. Kapur?
12 A. I don't recall the exact date, but it was when
13 Ray informed me.
14 Q. Could you turn to CX 1042, which is in your
15 notebook.
16 A. Which one?
17 Q. CX 1042.
18 A. Binder 1?
19 Q. It's in binder 1.
20 A. CX -- did you say 10 --
21 Q. 1042.
22 A. I have it.
23 Q. If you turn to the second page, you can read
24 the facsimile transmission line at the top. Do you see
25 that document? Do you see that line up there?

1 A. Yes.
2 Q. And that reads, "June 12th, 1997"?
3 A. Yes.
4 Q. "Thursday, 1634"?
5 A. Yes.
6 Q. So, it's fairly clear that you didn't get this
7 until June 17th (sic) of 1997?
8 A. I presume this is the date it went to Warrick.
9 Q. Warrick is where Mr. Kapur --
10 A. Mr. Kapur, where he works.
11 Q. You say you don't recall if you were given the
12 deadline for the project?
13 A. You know, I didn't recall at the time. I think
14 as I went through all the depositions, it strikes me
15 that Ray may have mentioned it, but I don't have a
16 direct recollection that Ray said this was an urgent --
17 it must have been.
18 Q. Why do you say it must have been?
19 A. Well, because as I go back through all the
20 depositions, there was a rather quick turnaround on the
21 project.
22 Q. But while you don't recall specifically, you
23 have no recollection of what deadline he gave you if he
24 gave you one. Is that right?
25 A. I don't recall. I do not recall.

1 Q. Do you recall when you completed or when Mr.
2 Audibert completed his analysis?
3 A. Yeah, when he returned the documents to me,
4 which was I guess about two weeks later or something.
5 I don't recall the exact date.
6 Q. Let's turn again to the binder, binder 1, and
7 turn to Exhibit SPX 2.
8 A. SPX 2?
9 Q. SPX 2. It's a little further back in the
10 binder.
11 A. I've got it, yes.
12 Q. And is this a document you sent to Mr. Kapur?
13 A. Yes, it is.
14 Q. And what date is on this document?
15 A. It's the 17th.
16 Q. So that by the 17th, Mr. Audibert had completed
17 his assessment --
18 A. Right.
19 Q. -- you had gone over it with him, and then you
20 sent it to Mr. Kapur. Is that right?
21 A. That's correct.
22 Q. And that was, what, five days after the
23 information --
24 A. The document, right.
25 Q. And when you and Mr. Audibert did the

1 commercial assessment of Niacor-SR, you just assumed
2 that the Niacor-SR would get necessary regulatory
3 approvals in Europe for you to market it there. Is
4 that right?
5 A. Well, we looked at the clinical work. We knew
6 they had the clinical support for it. We knew the
7 product. I mean, this was -- again, I think -- you
8 know, this was a pretty straightforward project to work
9 on. So, we had, looking at the data and what we knew,
10 we had made the assumption that this product would get
11 registered.
12 Q. So, you assumed that it would be registered.
13 A. Oh, absolutely. Absolutely.
14 MR. NIELDS: Your Honor, I guess I should
15 object to the form of the question. It seemed to me
16 the witness did not say he assumed it. I think he said
17 he talked it through and concluded it. And then Mr.
18 Eisenstat again repeated the phrase, "You just assumed
19 it." I object to the form of that question.
20 JUDGE CHAPPELL: I'm going to overrule it,
21 because the witness responded, "Absolutely." I'm
22 assuming he understood it.
23 BY MR. EISENSTAT:
24 Q. And in addition to the Niacor-SR product,
25 Schering from time to time does license drugs from

1 other companies. Is that right?
2 A. Sure.
3 Q. And from time to time you're involved in those
4 licensing deals. Is that right?
5 A. That's correct.
6 Q. And the European division of Schering-Plough
7 does from time to time license drugs from other
8 companies. Is that correct?
9 A. That's correct.
10 Q. And when a Schering subsidiary within the
11 European division wants to license a product from
12 another country, one approach that can happen is a
13 country type approach, where, say, the Schering
14 subsidiary, say France, is in discussions with another
15 company, and they have evaluated the opportunity, and
16 they want to take a license, and that can happen. Is
17 that right?
18 A. That's right.
19 Q. And the Schering subsidiary in France, they
20 could take the proposal, and they could send it to the
21 president of the European division. Is that right?
22 A. They could.
23 Q. And if the president of the European division
24 wanted support from your group, he might send it to you
25 and ask you what you think of it. Is that right?

1 A. That's correct.
2 Q. Or if it's within his authority, the president
3 of the European division might just approve the license
4 himself. Is that right?
5 A. He could do that.
6 Q. But in all cases, that product has to have a
7 safety review by the Schering-Plough Research
8 Institute, correct?
9 A. That's correct.
10 Q. Was there a safety review of Niacor-SR by the
11 Schering-Plough Research Institute?
12 A. I think we made the judgment on the basis of
13 the marketed product.
14 MR. EISENSTAT: Could you repeat the question,
15 please?
16 THE WITNESS: We made the judgment -- oh.
17 (The record was read as follows:)
18 "QUESTION: Was there a safety review of
19 Niacor-SR by the Schering-Plough Research Institute?"
20 BY MR. EISENSTAT:
21 Q. Can you answer that question?
22 A. The answer is that we -- we had in our judgment
23 made a judgment that this product was safe, that this
24 product was going to get submitted to regulatory
25 authorities, and that -- so, we had made that judgment.

1 MR. EISENSTAT: Could you reread the question
2 again, please?
3 (The record was read as follows:)
4 "QUESTION: Was there a safety review of
5 Niacor-SR by the Schering-Plough Research Institute?"
6 BY MR. EISENSTAT:
7 Q. Can you answer that question yes or no?
8 A. The answer is I don't know. Jim, if he needed
9 it, would have gotten it. I don't think he needed it.
10 Q. So, you don't know whether or not there was
11 a --
12 A. I don't know if Jim actually had that done.
13 Q. So, you don't know whether there was one done.
14 A. That's correct. That's correct.
15 Q. Who was the sponsor of the Niacor-SR license?
16 A. The sponsor? What -- when you say "sponsor,"
17 what do you mean?
18 Q. Are you familiar with the term "sponsor" as
19 it's used in licensing at Schering-Plough?
20 A. I -- it could mean a lot of things. It could
21 mean who's making the deal. It could mean who's
22 driving a piece of the deal. It could mean who
23 initiated the deal. I mean, we don't use that
24 terminology, so -- that I'm aware of.
25 Q. Okay, but you're not aware of Schering-Plough

1 using that terminology?
2 A. Let me put it this way, I don't use it.
3 Q. And sometimes when Schering-Plough considers
4 licensing a product, that product has not gotten
5 regulatory approval, right?
6 A. That's correct.
7 Q. And in fact, it's more often than not the case
8 that a product that Schering's considering licensing
9 has not gotten regulatory approval, correct?
10 A. Generally speaking, yes.
11 Q. You recognize that there's risk in licensing a
12 product that does not yet have regulatory approval,
13 right?
14 A. That's right.
15 Q. Many research and development projects in the
16 pharmaceutical field have never resulted in an approved
17 pharmaceutical product. Is that right?
18 A. That's correct.
19 Q. Even some drug development projects that reach
20 phase III clinical trials never receive FDA approval.
21 Is that correct?
22 A. That's correct.
23 Q. And phase III clinical trials is the last stage
24 in the clinical trials for a drug to get an NDA at the
25 FDA?

1 A. That's correct.
2 Q. So, even some drug development projects that
3 reach the last stage in the clinical trials never
4 receive FDA approval, correct?
5 A. That's correct.
6 Q. And this is well understood in the drug
7 industry?
8 A. Yes, it is.
9 Q. And forecasting potential sales of a product
10 prior to its approval is not an exact science, correct?
11 A. No, it's not.
12 Q. And there is some degree of uncertainty in
13 attempting to forecast the sales potential of an
14 unapproved product, correct?
15 A. That's correct.
16 Q. And even if a drug receives FDA approval, not
17 all drugs that receive FDA approval live up to their
18 preapproval expectations in terms of their overall
19 sales. Is that right?
20 A. That's correct.
21 Q. And some drugs may fall well below those
22 expectations, correct?
23 A. Some may.
24 Q. Now, Schering agreed to pay Upsher-Smith a
25 total of $60 million in up-front payments under the

1 agreement by which they licensed Niacor-SR?
2 A. That's correct.
3 Q. And the $60 million in payments was not
4 contingent upon Niacor-SR getting approval in the
5 United States, correct?
6 A. That's correct.
7 Q. And the $60 million in payments was not
8 contingent upon Niacor-SR getting approval in any other
9 country, was it?
10 A. That's correct.
11 Q. And even if the Niacor-SR never received
12 approval in any country, Schering was obligated to make
13 those $60 million in payments. Is that correct?
14 A. That's correct.
15 Q. So, Schering assumed the risk that the
16 Niacor-SR would not get approval in any of these
17 countries. Isn't that right?
18 A. That's correct.
19 Q. Other than Schering's obligations to make
20 available to Schering clinical trial data and
21 intellectual property, Schering's $60 million payments
22 to Upsher were not contingent upon Upsher taking any
23 actions or satisfying any conditions concerning the
24 development of Niacor-SR. Is that correct?
25 MR. NIELDS: Objection. I think the question

1 has a mistake in it.
2 MR. EISENSTAT: Could you reread the question,
3 please?
4 (The record was read as follows:)
5 "QUESTION: Other than Schering's obligations
6 to make available --"
7 MR. EISENSTAT: The question clearly has a
8 mistake in it. Thank you, John. I had the companies
9 reversed, Your Honor. Let me try again.
10 BY MR. EISENSTAT:
11 Q. Other than Upsher-Smith's obligations to make
12 available to Schering clinical trial data and
13 intellectual property, Schering's $60 million payments
14 to Upsher-Smith were not contingent on Upsher-Smith
15 taking any actions or satisfying any conditions
16 concerning the development of Niacor-SR.
17 MR. CURRAN: Objection, Your Honor, calls for a
18 legal conclusion.
19 MR. EISENSTAT: The man has worked on lots of
20 license agreements, and I'm merely asking him what his
21 understanding of this license agreement was.
22 MR. NIELDS: Your Honor, on that I've got a
23 foundation objection, too, because I think he's
24 elicited from this witness that he didn't negotiate the
25 deal.

1 JUDGE CHAPPELL: I'll sustain both objections
2 as worded. If you want to make it clear you're asking
3 his understanding, I'll allow the question.
4 MR. EISENSTAT: Okay, very well, Your Honor.
5 BY MR. EISENSTAT:
6 Q. Is it your understanding that other than
7 Upsher-Smith's obligations to make available to
8 Schering clinical trial data and intellectual property,
9 Schering's $60 million payments to Upsher-Smith were
10 not contingent on Upsher-Smith taking any actions or
11 satisfying any conditions concerning the development of
12 Niacor-SR?
13 A. I read the agreement once at your request, and
14 from my reading of the agreement, they were required to
15 provide us with all intellectual property and all
16 know-how that we would have needed to make our own
17 filing. So, that $60 million entitled us to have
18 access to all data, all know-how that we needed to make
19 a filing in the European and other markets around the
20 world.
21 Q. Other than giving you all that data and all
22 that know-how, is it your understanding, then, that
23 Schering's $60 million payments to Upsher-Smith were
24 not contingent upon Upsher-Smith taking any other
25 actions or satisfying any other conditions concerning

1 the development of Niacor-SR?
2 A. I was not aware of anything -- any other
3 requirements.
4 Q. In other words, so long as Upsher-Smith turned
5 over to you the data and the intellectual property, if
6 Upsher-Smith otherwise simply abandoned development
7 work on Niacor-SR, Schering was still obligated to make
8 the $60 million in payments?
9 MR. CURRAN: Objection, Your Honor, unless
10 that's asking for this witness' understanding of that
11 legal document.
12 MR. EISENSTAT: Again, Your Honor, along the
13 same lines, I'm simply asking for the witness'
14 understanding.
15 JUDGE CHAPPELL: Well, with that I assume the
16 objection is withdrawn.
17 MR. CURRAN: If the question is modified in
18 that regard, the objection is withdrawn.
19 JUDGE CHAPPELL: Okay, do you want to restate
20 it?
21 MR. EISENSTAT: Very well, Your Honor.
22 BY MR. EISENSTAT:
23 Q. Is it your understanding of the agreement that
24 as long as Upsher-Smith gave you the data and the
25 intellectual property, that Upsher-Smith could simply

1 abandon development of Niacor-SR and Schering would
2 still be obligated to make the $60 million in payments?
3 A. Let me preface it by saying, you know, that we
4 both had an interest in this product. They had an
5 interest in the U.S., and we had an interest in the
6 international business. So, our interests were
7 aligned.
8 At the time that we were proctoring through the
9 deal that we made the assessments, I didn't have an
10 understanding of the contractual terms that we had with
11 Upsher-Smith. Are you asking me given today what I
12 know, is that my understanding?
13 Q. Yes, given today.
14 A. Today, what my understanding is is that Upsher
15 was obligated to give us all the data we needed and all
16 the know-how, and that was what we paid the $60 million
17 for.
18 MR. EISENSTAT: At this point, Your Honor, I'm
19 going to be going through some of the tables that the
20 respondents have used this morning, and the tables all
21 reference the in camera documents.
22 JUDGE CHAPPELL: Okay, do you have the in
23 camera portion of your cross in one spot?
24 MR. EISENSTAT: I think from now on it's almost
25 all going to be in camera, Your Honor.

1 JUDGE CHAPPELL: Okay, then --
2 MR. EISENSTAT: Because we are going to be
3 going through these various documents and the charts
4 that were prepared from them.
5 JUDGE CHAPPELL: Once again, I will have to ask
6 the public to leave the courtroom, and we will be
7 entering an in camera session.
8 (The in camera testimony continued in Volume
9 19, Part 2, Pages 4522 through 4541, then resumed as
10 follows.)
11 JUDGE CHAPPELL: Okay, let's adjourn for lunch.
12 We will reconvene at 2:30.
13 (Whereupon, at 1:30 p.m., a lunch recess was
14 taken.)
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1 AFTERNOON SESSION

2 (2:30 p.m.)

3 JUDGE CHAPPELL: We are currently in public

4 session.

5 MR. CURRAN: Your Honor, if we can perhaps

6 close the loop on the scheduling matter I discussed

7 earlier?

8 JUDGE CHAPPELL: Okay.

9 MR. CURRAN: I think we have reached an

10 agreement here and I would just like to memorialize

11 that we do have an agreement.

12 I think there's an agreement that Dr. Knopp,

13 the witness in question, may appear and testify on

14 Friday. We commit that he will be our last witness of

15 the day on Friday. Complaint counsel has agreed to

16 review the demonstratives supplied in connection with

17 that testimony. If any of them strike them -- strike

18 complaint counsel as surprising or burdensome, we will

19 withdraw them.

20 JUDGE CHAPPELL: Okay.

21 MR. CURRAN: Have I stated that accurately?

22 MR. SILBER: Quite accurately.

23 JUDGE CHAPPELL: What about cross exam of the

24 witness?

25 MR. CURRAN: That will go forward on Friday

1 afternoon.

2 JUDGE CHAPPELL: Okay, and this witness is only

3 available Friday?

4 MR. CURRAN: No, he is not available only

5 Friday. If necessary, if Your Honor were to conclude

6 he under these circumstances should not appear Friday,

7 we think we could get him here next week. The hang-up

8 on our part is it's a doctor who lives in Seattle,

9 Washington. So, if he's going to testify on Friday,

10 he's got to get on a plane pretty darn quickly.

11 JUDGE CHAPPELL: Fact or expert?

12 MR. CURRAN: He's an expert witness.

13 JUDGE CHAPPELL: I guess what I'm inquiring

14 about is whether this is a situation where we're --

15 once we start, then we're forced to go Friday night

16 until we're finished with this witness.

17 MR. CURRAN: Your Honor, I -- while this is an

18 expert witness, he has testimony of limited scope. I

19 believe we'll still be over by normal business hours or

20 earlier, 5:00, Friday afternoon.

21 JUDGE CHAPPELL: So, possibly before -- whereby

22 I could invoke the Friday afternoon rule?

23 MR. CURRAN: I would not dare to knock out that

24 possibility, Your Honor.

25 JUDGE CHAPPELL: Okay.

1 MR. SILBER: We are in agreement.
2 JUDGE CHAPPELL: See, that wasn't hard, was it?
3 MR. SILBER: Not at all.
4 JUDGE CHAPPELL: Okay.
5 MR. CURRAN: Thanks to everyone. Thank you.
6 JUDGE CHAPPELL: Mr. Eisenstat, you have some
7 in camera questions still, right?
8 MR. EISENSTAT: I am going to do some -- since
9 we are not in camera now, continue with some material
10 first that's not in camera, and then I will go back to
11 my in camera documents.
12 JUDGE CHAPPELL: Okay. Does Mr. Silber know
13 that? I just didn't know if he was going to turn the
14 sign around.
15 Would someone mind changing the sign to public
16 session?
17 (Discussion off the record.)
18 JUDGE CHAPPELL: You may proceed.
19 MR. EISENSTAT: If I may approach the witness,
20 Your Honor?
21 JUDGE CHAPPELL: Yes.
22 BY MR. EISENSTAT:
23 Q. Mr. Lauda, let me hand you what's been marked
24 CX 689. That's a document from the files of
25 Schering-Plough Corporation. It's entitled at the top

1 Schering-Plough Finance Manual.
2 Are you familiar with the Schering-Plough
3 Finance Manual?
4 A. I am.
5 Q. If you look at the purpose of this section --
6 excuse me, Your Honor, I made a technical faux pas and
7 turned off the computer.
8 Do you see where the purpose of this document
9 is to establish a policy for the financial review and
10 management approval of product, product line, company
11 acquisitions and divestitures, joint venture proposals
12 and licensing proposals prior to the commitment of
13 company resources? Do you see that?
14 A. Yes.
15 Q. And we -- down below, do you see the section
16 that's called Application? Do you see that section?
17 A. Yes, yes.
18 Q. And the second paragraph reads, "Applies to all
19 Acquisitions and Divestitures, except when the
20 acquisition of a company is proposed for the primary
21 purpose of acquiring their facilities in lieu of
22 Schering-Plough constructing its own facilities (For
23 those types of acquisitions, refer to Policy Number
24 3300 - Capital Investment Guidelines) and to all Joint
25 Ventures and Licensing Proposals."

1 Do you see that?
2 A. Yes.
3 Q. So, this application would include the
4 Niacor-SR license. Is that correct?
5 A. It could.
6 Q. And let's turn to the next page. At the top it
7 says, "Licensing Agreement," under the definitions.
8 Do you see that?
9 A. Yep.
10 Q. And licensing agreement is defined as, "An
11 agreement entered into by a Schering-Plough legal
12 entity and an outside party whereby the owner or holder
13 (licensor) of a patent, technology, trademark, other
14 intellectual property grants to another party
15 (licensee), the option or right to manufacture, use
16 and/or sell the licensed subject matter or products
17 utilizing or incorporating the licensed subject matter.
18 This arrangement may also be referred to as a
19 franchise."
20 Do you see that?
21 A. Yes.
22 Q. And would Niacor-SR be such a license
23 agreement?
24 A. Could be.
25 Q. What do you mean when you say "could be"?

1 A. I'm not sure I really have thought deeply about
2 it, but it seems to be.
3 Q. Seems to be. And do you see under there a
4 proposal, there's a definition of proposal?
5 A. Yes.
6 Q. And it says, "A formal submission to corporate
7 management proposing an Acquisition, Divestiture, Joint
8 Venture or License Agreement which details the
9 information necessary to satisfy the data requirements
10 and guidelines set forth in this policy."
11 Do you see that?
12 A. Um-hum.
13 Q. Is that a yes?
14 A. Yes.
15 Q. And was there a proposal on Niacor-SR that was
16 written?
17 A. I didn't make a proposal.
18 Q. You didn't make a proposal?
19 A. I didn't make a proposal.
20 Q. Down below, under Policy, the first paragraph
21 reads, "The sponsoring unit has final responsibility
22 for the preparation and submission of the Proposal for
23 any Transaction."
24 Do you see that?
25 A. Um-hum.

1 Q. Is that a yes?
2 A. Yes.
3 Q. And my question to you then is, do you know who
4 the sponsoring unit was for the Niacor-SR license?
5 A. You know, I -- again, it's being used in a
6 generic way. It's not a capitalized term, so, you
7 know, they're assigning -- I would say it's the person
8 proposing the deal.
9 Q. And do you know who that was?
10 A. I assume it's Ray Kapur.
11 Q. Ray Kapur was the sponsoring person?
12 A. Yeah, I presume. Again, you're using -- that's
13 a generic term to me. It's not a capitalized term.
14 It's not something I deal with day to day, who sponsors
15 a project.
16 Q. But you did not have final responsibility for
17 the --
18 A. I did not sponsor the project or submit a
19 proposal.
20 Q. Let me finish my question, please.
21 You did not have final responsibility for the
22 preparation and submission of the proposal for the
23 Niacor-SR transaction.
24 A. No.
25 Q. And I presume, therefore, then, Mr. Audibert

1 did not either.
2 A. No.
3 Q. Going back to that time in June when you found
4 out about the -- this deal with a call from Ray Kapur,
5 you said you called Jim into your office and you talked
6 to him. Do you remember that?
7 A. Yes.
8 Q. Do you recall what your instructions were to
9 him?
10 A. I had indicated to him that we were asked to
11 make an assessment of the Niacor sustained release. I
12 told him that there would be a package coming. I also
13 told him that Ray Kapur was available for him to
14 consult with, if he needed anything, he should go
15 directly to Ray, and pretty much that was it.
16 Q. Did you give him any instructions regarding
17 contacting anybody else within Schering-Plough?
18 A. No.
19 Q. You didn't tell him that he was or was not to
20 contact SPRI?
21 A. I asked Jim for an assessment. He would make
22 that judgment.
23 Q. But you didn't give him any instructions one
24 way or another?
25 A. I gave no instructions on it.

1 MR. EISENSTAT: Your Honor, I am going to go
2 back to the documents now, and we will be going through
3 the in camera documents for a considerable time.
4 JUDGE CHAPPELL: Okay, at this time I'll have
5 to ask the parties to leave the courtroom as we are
6 going into in camera session.
7 (The in camera testimony continued in Volume
8 19, Part 2, Pages 4542 through 4580, then resumed as
9 follows.)
10 BY MR. EISENSTAT:
11 Q. Mr. Lauda, besides the $60 million in payments
12 to Upsher-Smith, Schering would have had some
13 additional expenses, would it not, in getting the
14 dossiers ready and filing them?
15 A. Minimal, minimal additional costs. It would
16 have been internal people just converting -- and what
17 we were to receive was an NDA. We would have had to
18 have been made some minimal additional costs in terms
19 of converting it and an expert's report, but
20 fundamentally, the bulk of the data is in the NDA.
21 Q. Do you have any estimate today of what the cost
22 would have been to convert the information from the
23 form that Upsher-Smith -- you expected to get it from
24 Upsher-Smith into forms to file in Europe?
25 A. I don't have those figures, but it's an

1 insignificant amount.
2 Q. When Upsher-Smith stopped working on Niacor-SR,
3 you were still free to go and get the data from them if
4 you wanted it. Is that right?
5 A. That's right.
6 Q. But the data wasn't in the finished form that
7 you expected it. Is that right?
8 A. I don't know.
9 Q. Did you make any assessment at that time of
10 what the cost would be to gather up the data and do the
11 filings in Europe?
12 A. No, we didn't.
13 Q. In 1999, you looked at the -- was it Geltex
14 deal?
15 A. Geltex Company.
16 Q. And that was for a cholesterol-lowering
17 product. Is that right?
18 A. That's correct.
19 Q. And that product was -- what was that product?
20 We're both drawing a blank on it.
21 A. I can't recall at the moment. It will come
22 back to me. Geltex was the company --
23 Q. Cholestagel?
24 A. Cholestagel.
25 Q. Cholestagel?

1 A. Cholestagel.
2 Q. Okay, was the product. When you did that
3 analysis, you never made a deal with Geltex. Is that
4 right?
5 A. No.
6 Q. And at that time, 1999, you still owned rights
7 to the Niacor-SR information in Europe. Is that right?
8 A. That's correct.
9 Q. Did you do any evaluation at that time of
10 whether it was worthwhile to gather up the data and
11 make another try in Europe?
12 A. It wasn't a question of the data. That's not
13 why we decided not to pursue the project. The question
14 was we didn't believe the product was going to go over
15 in the marketplace, and so we would have been investing
16 good money, commercial money, after a project that we
17 didn't think was going to give us a return. So --
18 Q. And you know that -- and your concern about
19 going over in the marketplace, that's based upon Kos'
20 experience?
21 A. Kos' experience, right, and the understanding
22 that it just wasn't being picked up by the doctors.
23 Q. Do you know what Kos' sales were last year of
24 Niaspan?
25 A. Yeah, they're closing in, if I remember right,

1 in the $100 million range somewhere, after five -- four
2 years of pushing it, five years.
3 Q. Would $100 million be enough to induce you to
4 try the Niacor-SR product in Europe?
5 A. It well -- it might have. It might have, you
6 know, but that's a four-year effort to get there. We
7 were expecting that to be a little bit faster uptake.
8 There's some other considerations that we were
9 looking at, too, you know, at the time. We have now
10 entered a deal with Merck, which is a
11 co-marketing/co-promotion/co-development of our
12 ezetimibe product, which is a -- that is the major
13 product. That's one of the major strategic drivers
14 here.
15 So, now that we have that deal, and we were in
16 heavy discussions with them over the last several
17 years, it -- it somewhat alleviates the need to really
18 leverage another agent in the marketplace, because
19 we're going in with the world's leader in cholesterol
20 management, Merck.
21 Q. Now, the Merck-Schering deal, that's only for
22 the United States?
23 A. No, it's Europe, too.
24 Q. That is for Europe, too?
25 A. Oh, yeah.

1 Q. And did you have that deal in place when you
2 were discussing the Geltex deal?
3 A. It wasn't in place, but there were discussions
4 ongoing that looked pretty good to us. We had, in
5 fact, at an early stage reached a contractual agreement
6 which later fell apart, but we ultimately put the deal
7 together for both parts -- all parts of the world,
8 actually, except Japan.
9 Q. So, when you were looking at Geltex, you had
10 already started working on your --
11 A. We were -- we were in negotiations, in
12 discussions with Merck. They started in -- actually in
13 around '96, but they heated up later on.
14 Q. Do you have any idea why nobody else is selling
15 a sustained release niacin product on a prescription
16 basis in Europe today?
17 A. I think it's probably for the same reason that
18 we're not interested. There's just not a market there
19 for sustained release. There's just not a market
20 that's significant enough to put the time and resources
21 in that we would need to put.
22 Q. And $100 million in sales would not be
23 significant?
24 A. Well, I'm not saying there's a hundred million
25 dollars sales in Europe. You're saying that. You

1 know, Europe's a different marketplace. Pricing is
2 different, everything's different than it is in the
3 United States. I don't think that that's doable.
4 Q. Without regard to Kos' success here?
5 A. It's the U.S. market. Prices are different,
6 physician attitudes are different. It's a different
7 ball game in Europe.
8 Q. When you were looking at the Niacor-SR product,
9 do you recall if you did a preliminary evaluation to
10 see if you were interested in the product?
11 A. Niacor? I don't think we did a preliminary
12 evaluation.
13 Q. And I think we've already talked about safety
14 review. As far as you know, there was no safety review
15 done?
16 A. Yeah, but you know, remember, a safety review
17 in the context that you put it is a safety review
18 before you enter the marketplace. We hadn't entered
19 the marketplace yet with the product. So, you know,
20 that review would have been done when the file was
21 reviewed.
22 Q. Was the safety review done on the COR agreement
23 before or after you signed the deal?
24 A. The COR agreement, again, I told you, the
25 safety review was done as part of the overall process

1 of reviewing the clinical data. So, since we had
2 elected to go and review their clinical data in that
3 level of detail, that encompassed the safety review.
4 In the case of niacin, we -- Niacor, we did not
5 look at the details, you know, we looked at the overall
6 summaries that they provided us, but in the preparation
7 of an NDA or a filing, you go through a safety review.
8 That's reviewed not only by us but it's also reviewed
9 by regulatory authorities.
10 So, when you talked about in Europe, that they
11 needed a safety review before they launch a product,
12 that's absolutely true. Do they need a safety review
13 to go out and talk to somebody or start negotiating a
14 deal? That is not necessarily true.
15 Q. In the COR deal, the safety review was done
16 before you sent the papers forward.
17 A. It was done in the overall review of the data.
18 Q. How about in the Neurogen deal?
19 A. Same thing.
20 Q. How about in the ICN ribavirin deal?
21 A. Let me remind you of something. A safety
22 review can never be complete until you complete the
23 clinical trials. So, you know, when I -- when you say
24 there was a safety review, there was a review of safety
25 on the basis of the data that was given, but there was

1 no safety sign-off on a drug that had not gone through
2 phase III trials, phase II trials. So, you know, I
3 mean you need to get the concept. Before we launch a
4 drug, we give it a safety sign-off. Before we file an
5 NDA or a regulatory, it's got the safety sign-offs.
6 Q. So, SPRI gave the COR deal a safety sign-off
7 before you went forward and sent them --
8 A. Again, it didn't give a safety sign-off,
9 because they didn't have clinical trials. They
10 reviewed the data that was there for the safety, and we
11 had concerns about the -- but there's no, that's it,
12 check the box and it's done. Until you have all the
13 clinical data and not until you make the filing, you
14 don't have the final safety sign-off, because I think
15 what you're looking at, it's one thing to say I got the
16 data and I looked at it for safety. That was done.
17 Another thing is to sign it off and say we're ready to
18 launch this in the marketplace. That only happens when
19 all clinical work is done and a dossier is ready for
20 filing.
21 Q. Would it be correct to say that SPRI did a
22 safety review of the data that they had in the COR
23 deal?
24 A. That would be correct.
25 Q. Before the document -- before the deal was

1 signed?
2 A. They did a safety review of the data they had
3 in their possession.
4 Q. Before the deal was signed?
5 A. That's true.
6 Q. And SPRI did a review, a safety review, of the
7 data that Schering had in the Neurogen deal before the
8 license was signed.
9 A. As a course of reviewing the data.
10 Q. And SPRI did a safety review of the data they
11 had in ICN in the ribavirin deal before the license was
12 signed.
13 A. In the course of reviewing data.
14 Q. That's a yes?
15 A. In the course of reviewing data.
16 Q. Yes, in the course of reviewing the data,
17 right.
18 And in the Zonagen deal, did SPRI do a
19 review -- a safety review of the data they had?
20 A. Yes, they did.
21 Q. Before the license was signed?
22 A. Of the data they had, yes.
23 Q. And did SPRI do a safety review of the data
24 they had before the Chugai license was signed?
25 A. Yes, they did.

1 Q. And did SPRI do a safety review of the data
2 they had before the Centocor deal was signed?
3 A. Yes, they did.
4 Q. Did SPRI do a safety review of the data they
5 had before the British Biotech deal was signed?
6 A. Yes, they did.
7 Q. And did SPRI do a safety review of the
8 AtheroGenics data that they had before the license was
9 signed?
10 A. Yes.
11 Q. We've been talking about pharmacokinetic
12 studies today. Is that right?
13 A. We've discussed it, yeah.
14 Q. Could you just for the record explain what a
15 pharmacokinetic study is?
16 A. Yeah, it's -- when you administer the drug, you
17 measure the blood levels -- a simple explanation, I'm
18 not a scientist -- you measure blood levels to see what
19 the level of the drug is in the blood.
20 Q. And a pharmacokinetic study, a successful
21 pharmacokinetic study, is a necessary condition to
22 filing an NDA. Is that right?
23 A. Yes.
24 Q. One other thought just occurred to me, going
25 back a minute, we were talking about Europe. Before

1 you filed under your original plan, when you were going
2 to take the data that you got from Upsher in the form
3 where they had it ready for the NDA and convert it to a
4 health registration dossier for Europe and file that in
5 Europe, would you have had to do any additional
6 clinical work in Europe?
7 A. I don't think so. We were not anticipating to
8 do any.
9 Q. Okay, let's go back to the PK study.
10 May I approach the witness?
11 JUDGE CHAPPELL: Yes.
12 THE WITNESS: Thank you.
13 BY MR. EISENSTAT:
14 Q. Mr. Lauda, I've handed you what's been marked
15 previously as CX 1379. This is a document from the
16 files of Upsher-Smith.
17 You've never seen this document before, have
18 you?
19 A. No.
20 Q. This is a fax from the Center for Drug
21 Evaluation and Research at the FDA to Cindy Farner at
22 Upsher-Smith Laboratories. Do you see that?
23 A. Yes.
24 Q. Do you know if there's anything unusual about
25 the FDA sending faxes to companies that are working to

1 get drugs approved?
2 A. I don't know that there's anything particularly
3 unusual.
4 Q. You don't know or --
5 A. I don't know.
6 Q. Let's turn to the second page of the document.
7 It says page 1 in the upper right-hand corner.
8 A. Um-hum.
9 Q. And do you see at the very top it says, "IND
10 37-984 Niacor-SR Tablets"?
11 A. Yes.
12 Q. So, this is about Niacor-SR, and I would like
13 to go on to the biopharm review comments, number 1. Do
14 you see that?
15 A. Yes.
16 Q. It says, "We have good reason to believe that
17 your inability to detect niacin and niacin metabolites
18 in plasma is due to inadequate study design of Protocol
19 901455."
20 Do you see that?
21 A. Yes.
22 Q. Do you know what protocol 901455 is?
23 A. I don't know, I don't recall.
24 Q. Do you know what metabolites are?
25 A. Yes.

1 Q. And what are they?
2 A. It's the active ingredients in a drug,
3 contained within a drug. It breaks down into
4 metabolites to provide the active component of the
5 drug.
6 Q. Would it be important that Upsher-Smith had not
7 been able to detect niacin and niacin metabolites in
8 plasma?
9 A. Would it be important?
10 Q. Would it have been important, yeah.
11 A. I guess so.
12 Q. And going down the page under paragraph 3, it
13 says, "The following studies will need to be performed
14 to support the Human Pharmacokinetics and
15 Bioavailability Section of a future NDA submission for
16 this product."
17 Do you see that?
18 A. Where are you reading? I'm sorry.
19 Q. Number 3, paragraph number 3.
20 A. Number 3, okay.
21 Q. Do you see that?
22 A. Yes.
23 Q. And just -- I might not have mentioned this,
24 going back to the first page, this is dated January
25 13th, 1997 on the first page. Is that right?

1 A. Yes.
2 Q. So, this document would have been in existence
3 when you did your license deal with Upsher-Smith. Is
4 that correct?
5 A. That's right.
6 Q. Then it lists on that second page a series of
7 studies, a single-dose randomized crossover
8 bioavailability/dosage form equivalence study, a
9 single-dose randomized crossover food-effect study, a
10 multiple-dose, randomized, cross-over study, and the
11 possibility under D of a fourth study.
12 Do you see that?
13 A. Yes.
14 Q. Would you have wanted to know that the FDA had
15 inquired of Upsher-Smith about these studies before you
16 signed the license deal for Niacor-SR or before you did
17 your commercial assessment of Niacor-SR?
18 A. This is a pharmacokinetic study, which is a --
19 generally a relatively easy study to do. I mean, would
20 I have wanted to know it? Yes. Would it have made a
21 difference in the overall scheme of the deal? No.
22 Q. Well, you at least would have wanted to know
23 about the issue.
24 A. It would have been nice to know, yes. It's not
25 a major issue.

1 MR. EISENSTAT: May I approach the witness,
2 Your Honor?
3 JUDGE CHAPPELL: Yes, you may.
4 BY MR. EISENSTAT:
5 Q. Mr. Lauda, I'm handing you what's been
6 previously marked as CX 1382, again a document from the
7 files of Upsher-Smith, and the first two pages are a
8 letter from Mark B. Halvorsen of Upsher-Smith to
9 Solomon Sobel.
10 Do you see that?
11 A. Yes.
12 Q. You've never seen this document before?
13 A. No, I have not.
14 Q. And this document's dated February 24th, 1997?
15 A. Yes, it is.
16 Q. And again, that was before you did your
17 commercial assessment of Niacor-SR. Is that right?
18 A. That's correct.
19 Q. Do you know who Solomon Sobel is?
20 A. I think he's the head of the -- and director of
21 the division.
22 Q. At the FDA?
23 A. At the FDA.
24 Q. And the second paragraph of the letter on the
25 first page says, "Enclosed is a copy of the

1 Upsher-Smith February 5, 1997 Meeting Minutes for your
2 review (see Attachment 1)."
3 Do you see that?
4 A. Yes.
5 Q. Let's turn to Attachment 1. It starts on the
6 page numbered 107433. Do you have that in front of
7 you?
8 A. I do.
9 Q. The first paragraph reads, "On February 5,
10 1997, Upsher-Smith Laboratories, Inc. representatives
11 met with FDA representatives from the Division of
12 Pharmaceutical Evaluation II and the Division of
13 Metabolism and Endocrine Drug Products to discuss
14 pharmacokinetic issues regarding Niacor-SR."
15 Do you see that?
16 A. Yes.
17 Q. And then below that we have listed
18 representatives of the FDA and representatives of
19 Upsher-Smith who attended the meeting.
20 A. Yes.
21 Q. And one of the FDA representatives is Mike
22 Fossler, Ph.D., and another is John Hunt, deputy
23 director of Pharmaceutical Evaluation II.
24 Do you see that?
25 A. Yes.

1 Q. Let's turn to the next page. The second full
2 paragraph there reads, "Dr. Fossler explained that the
3 issue is qualifying the product for a sustained-release
4 or extended-release claim. The efficacy and
5 bioavailability conditions are probably met and the
6 application is probably fileable with existing data
7 without an extended-release claim. In order to obtain
8 an extended-release claim, metabolite levels need to be
9 detectable showing the differences between an
10 immediate-release and the extended-release dosage form.
11 Mr. Hunt supported Dr. Fossler's explanation,
12 indicating that Upsher-Smith does not have adequate
13 data to meet the regulatory requirements for an
14 extended-release product."
15 Was it important in evaluating Niacor-SR that
16 it was an extended release product as opposed to the
17 immediately release niacins that were then on the
18 market?
19 A. Yes, it was.
20 Q. So, this was an important issue?
21 A. This is an issue indicating that they need to
22 do a pharmacokinetic study. A pharmacokinetic study is
23 a routine study in our industry. It's not an issue
24 that would cause me to blink. I'd simply put it on
25 a -- and ask Upsher to finish the study. It's not an

1 issue that would cause me to blink in terms of how I
2 looked at the project.
3 Q. If you knew about this before you did your
4 commercial assessment, would you have picked up the
5 phone and asked Upsher when they were going to get
6 their act together and do the study?
7 A. I would have just -- I would have just assumed
8 it was going to be done. It's not a costly endeavor
9 and it's not a lengthy endeavor from a time standpoint.
10 So, it would have not really caused a blip on the
11 radar. It would have just been one item to further
12 follow up on.
13 Q. Let's turn to the next page of the document,
14 page number 107435.
15 A. 435?
16 Q. Yeah, 435.
17 A. Yes.
18 Q. And the first full paragraph on that page says,
19 "Dr. Fossler summarized that a crossover study between
20 immediate-release and sustained-release products,
21 evaluating for all the urinary metabolites, would be
22 acceptable. Mr. Hunt commented that a lack of dose
23 dumping would need to be demonstrated, as well.
24 Considerable discussion followed regarding whether the
25 already performed single dose study, although

1 inadequate in design, may adequately demonstrate a lack
2 of dose dumping under fed and fasted conditions. It
3 was noted that the product will be labeled to take with
4 meals."
5 Would it be of any concern to you at all, this
6 issue of showing that there was a lack of dose dumping
7 on the product?
8 A. No.
9 Q. Again, that's something that --
10 A. It would have just come through in the trial.
11 You have to remember, we have seen full clinical data
12 here, so we knew that there was, in effect, a reduction
13 over immediate release of some of the side effects. We
14 knew that. So, it wasn't -- the pharmacokinetic study
15 was a matter of mechanics, of getting it done. We had
16 no concern that -- I would have no concern that I
17 wouldn't be able to complete a trial successfully in
18 pharmacokinetics to show the adequate blood levels.
19 Q. Let's turn to the next page, which bears the
20 number 107435.
21 A. 435? That's the one I'm on.
22 Q. 436, excuse me.
23 A. Yes.
24 Q. The bottom paragraph there reads, "Dr. Robbins
25 asked if the NDA would be fileable with the existing

1 data and subsequently amending the application with the
2 results of the new study. There was considerable
3 discussion regarding this proposal. Dr. Orloff
4 concluded that under user fee regulations, the NDA
5 should be approvable at the time of filing. Due to the
6 known pharmacokinetic issues outstanding for Niacor-SR,
7 the FDA should not file the NDA without the requested
8 pharmacokinetic study results."
9 Would that be of any concern to you?
10 A. No, that's standard, standard practice.
11 Q. They need the study, but you'd expect them to
12 be able to do it?
13 A. They want a full file, a complete file within
14 the FDA. It's not unusual.
15 Q. Before we leave the document, let's turn to the
16 next page, 107437, and just quickly look at what Upsher
17 and the FDA agreed to.
18 "In summary, Upsher-Smith and the FDA agreed to
19 the following conclusions:
20 "A 3-way crossover study will be performed,
21 with one 1000 mg immediate-release niacin fasted arm,
22 and two 1000 mg sustained-release arms -- one fed and
23 one fasted. There will be approximately 10 to 15
24 subjects per arm with urine collection at preclose,
25 0-1, 1-2, 2-4, 4-6, 6-8, 8-12, and 12-24 hours post

1 dose. Urinary excretion of niacin and its metabolites
2 will be analyzed. Standardized meals will be
3 administered throughout the study. No aspirin will be
4 used due to its affects (sic) on the metabolism of
5 niacin. Upsher-Smith dissolution data to be provided
6 will be evaluated to determine if a 250 mg arm, either
7 fed or fasted, is necessary."
8 So, again, this is just the standard kind of
9 thing that you would --
10 A. This is -- I mean, they were developing a
11 dossier. They would have done this, because it was a
12 standard low-cost, small patient, you know, 15 patients
13 in each arm. This is not a major undertaking.
14 JUDGE CHAPPELL: Mr. Eisenstat, how much more
15 do you estimate you have?
16 MR. EISENSTAT: Excuse me?
17 JUDGE CHAPPELL: How much more cross do you
18 have?
19 MR. EISENSTAT: Probably less than a half hour.
20 JUDGE CHAPPELL: Let's go ahead and take a
21 short break. We will recess until 4:20.
22 (A brief recess was taken.)
23 JUDGE CHAPPELL: You may proceed, Mr.
24 Eisenstat.
25 MR. EISENSTAT: May I approach the witness,

1 Your Honor? May I approach the witness, Your Honor?
2 JUDGE CHAPPELL: Yes.
3 BY MR. EISENSTAT:
4 Q. Mr. Lauda, I'm handing you what's been marked
5 as CX 1383, and that's also a document from the files
6 of Upsher-Smith, and it's -- again, it's a fax dated
7 March 26th, '97 from the Center for Drug Evaluation and
8 Research at the FDA to Upsher-Smith.
9 Now, you've never seen this document before?
10 A. No.
11 Q. Could you turn to the second page of the
12 document, and again, you can see at the top it says,
13 "Controlled release niacin, Niacor-SR," this just
14 continues the communications we've been looking at.
15 A. Um-hum.
16 Q. And I direct your attention to the first
17 numbered paragraph, which says, "Upon review of the
18 comparative dissolution data, it appears that the 250
19 and 500 mg differ sufficiently such that a waiver of
20 the requirement for pharmacokinetic data for the 250 mg
21 tablet can not be granted. Therefore, the proposed
22 study design should be amended to include a fourth
23 treatment arm administering 4 X 250 mg tablets under
24 fed conditions."
25 Would this just be a normal type of

1 communication from the FDA specifying exactly what they
2 want from a study?
3 A. Sure, another arm.
4 Q. And that's no cause for alarm, is it?
5 A. No.
6 Q. And paragraph 2 reads, "We continue to believe
7 that the recommendations as faxed to Upsher-Smith on
8 1/13/97 represent the ideal manner in which to study
9 the controlled-release characteristics of Niacor-SR.
10 However, as discussed in the 2/5/97 meeting between
11 your firm and the Agency, if Upsher-Smith feels that
12 single doses of niacin above 1000 mg represent a
13 significant safety concern when given to normal
14 volunteers, then the design as outlined in your
15 submission dated 2/24/97 will be sufficient for filing,
16 provided that a 250 mg treatment arm is added to the
17 study. It is emphasized that approval of Niacor-SR as
18 a controlled-release product is dependent on the
19 results of the submitted study, and not merely on its
20 completion."
21 Is there anything troubling in that paragraph?
22 A. No.
23 Q. You would expect them to tell them that they
24 have to have successful results of the study and not
25 merely complete it?

1 A. Sure.
2 Q. Do you know if Upsher-Smith ever did their PK
3 study?
4 A. I don't know.
5 Q. Do you know of any reason why they wouldn't
6 complete their PK study?
7 A. The only reason I would imagine is because they
8 were not planning to go forward and commercialize the
9 product.
10 Q. And that wouldn't be a reason not to do the PK
11 study, say, in the summer of '97?
12 A. No.
13 MR. EISENSTAT: May I approach the witness,
14 Your Honor?
15 JUDGE CHAPPELL: Yes, you may.
16 BY MR. EISENSTAT:
17 Q. I'd like to hand you what's been marked, again,
18 as CX 1111, another document from the files of
19 Upsher-Smith, and this is a letter dated October 6th,
20 1998 to Mr. Ray Kapur, president of Warrick
21 Pharmaceuticals, from Paul Kralovec, chief finance
22 officer at Upsher-Smith Laboratories. Do you see that?
23 A. Yes.
24 Q. Have you ever seen this document before?
25 A. Can I read it? I may have. I don't know.

1 Q. Sure, I'm sorry, take your time.
2 A. (Document review.) I can't recall if I've seen
3 the letter. It seems to me I have, but I'm aware of
4 the contents.
5 Q. Excuse me, you are aware of the contents?
6 A. Yeah.
7 Q. And the first paragraph of the letter reads,
8 "Per your request to Ian Troup last week, I am writing
9 to confirm that Upsher-Smith Laboratories, Inc. has
10 suspended all research on Niacor-SR. There were
11 multiple reasons for this decision. First and
12 foremost, an additional multiple-dose pharmacokinetic
13 study was required prior to submitting an NDA. In
14 light of Niaspan's FDA approval, Upsher-Smith's NDA
15 would have been two to three years behind the launch of
16 Niaspan."
17 Do you see that paragraph?
18 A. Yeah.
19 Q. Do you know any reason why they wouldn't have
20 done a pharmacokinetic study by this date if they were
21 serious about bringing Niacor-SR to the market?
22 A. Again, I think that the study itself was not a
23 major troubling issue. I don't think the study is the
24 driving reason.
25 Q. Do you know of any reason why they wouldn't do

1 the study if they were serious about bringing the
2 product to market?
3 A. I don't know what their thinking was.
4 MR. EISENSTAT: At this point, Your Honor, I am
5 going to have to go back to in camera for the last few
6 documents.
7 JUDGE CHAPPELL: Okay, we are going to need the
8 public to leave the courtroom, please, for an in camera
9 session.
10 (The in camera testimony continued in Volume
11 19, Part 2, Pages 4581 through 4593, then resumed as
12 follows.)
13 JUDGE CHAPPELL: Thank you.
14 Go ahead.
15 BY MR. EISENSTAT:
16 Q. The Schering license agreement with
17 Upsher-Smith, if that had been structured so that some
18 portion of the money was dependent upon Upsher-Smith
19 providing the ISS and ISE data to Schering, whatever
20 portion was made conditional on that would never have
21 had to be paid. Is that right?
22 A. That's correct.
23 Q. And if some portion of the money that Schering
24 promised to pay Upsher had been conditional on Upsher
25 completing its pharmacokinetic studies for the FDA,

1 that portion of the money never would have had to be
2 paid. Is that right?
3 A. You're assuming that that would have been
4 accepted in the negotiation, right? I mean, we're
5 assuming that the other party would have accepted that.
6 That typically isn't what happens.
7 Q. No, but assuming that the deal had been
8 structured that way, that Upsher -- then Schering would
9 never have had to pay for whatever portion was
10 contingent on completion of the pharmacokinetic
11 studies. Is that right?
12 A. And if I said give me a completed approved
13 product and I'll give you a dollar, I don't think we
14 would have made a deal. I think that's the point I'm
15 trying to make.
16 Q. But that wasn't my question, Mr. Lauda. My
17 question was, if you made a portion of the payment to
18 Upsher conditional on completion -- successful
19 completion of a PK study, Schering never would have had
20 to make that portion of the payment. Is that correct?
21 MR. CURRAN: Objection, Your Honor, lacks
22 foundation. I think the record's clear Upsher-Smith
23 did complete certain PK studies.
24 JUDGE CHAPPELL: Any response?
25 MR. EISENSTAT: No, we have just been through

1 the documents where the last document has the letter
2 dated October 1998 from Upsher saying they still have
3 to do a PK study.
4 MR. CURRAN: Your Honor, I don't object if he's
5 talking about a PK study that, in fact, was not done.
6 So, there may be a way that the question can be
7 modified to avoid the issue.
8 JUDGE CHAPPELL: Do you want to restate?
9 MR. EISENSTAT: I'll try, Your Honor. Just
10 give me a second to compose my thoughts.
11 JUDGE CHAPPELL: Okay.
12 BY MR. EISENSTAT:
13 Q. If some portion of the payment from Schering to
14 Upsher-Smith was made contingent upon the completion of
15 all PK studies required by the FDA for filing of the
16 Niacor-SR NDA, then that portion of the payment would
17 never have had to be made by Schering. Is that right?
18 A. If we had conditioned the payment upon receipt
19 of all of those, that would be right, if we conditioned
20 the payment that way.
21 MR. EISENSTAT: No further questions, Your
22 Honor.
23 JUDGE CHAPPELL: Redirect?
24 MR. NIELDS: Yes, Your Honor, and I'm afraid
25 briefly I'm going to have to go into in camera at the

1 very front end, and then that will be the end of --
2 JUDGE CHAPPELL: Okay, once again, I am going
3 to have to ask the public to leave the courtroom.
4 (The in camera testimony continued in Volume
5 19, Part 2, Pages 4594 through 4602, then resumed as
6 follows.)
7 BY MR. NIELDS:
8 Q. You were asked some questions by Mr. --
9 May I proceed, Your Honor? May I proceed?
10 JUDGE CHAPPELL: Yes, you may.
11 MR. NIELDS: Thank you.
12 BY MR. NIELDS:
13 Q. You were asked some questions by Mr. Eisenstat
14 about how Kos was doing at various points in time. On
15 June -- in June 1997 when you did the Niacor-SR
16 assessment, did you know how Kos was going to do then?
17 A. We thought they would do pretty well.
18 Q. And in September of 1998 when you and Mr.
19 Audibert I think you testified were trying to decide
20 whether to go forward with -- did you know how Kos was
21 doing then?
22 A. Yes, we did. It was widely touted in the
23 industry, and they were doing very poorly, and the
24 analysts were picking up on it.
25 Q. Now, back in June, when you said you believed

1 Kos would do very well, did you and Mr. Audibert
2 project sales in Europe in the $100 million range and
3 above?
4 A. Yes, we did.
5 Q. And then in September, when you -- of 1998,
6 when Kos was doing poorly and you decided to abandon
7 the project, what was your sense then of the likely
8 sales in Europe?
9 A. We just didn't believe it would do well at all.
10 We didn't think the physicians were going to buy in.
11 In Europe, we thought maybe price would get us there,
12 but they weren't buying the concept of the sustained
13 release niacin.
14 Q. And that was based on how Kos was doing in the
15 U.S.?
16 A. That was based on how Kos was doing.
17 Q. And Mr. Eisenstat pointed out that Kos is now
18 looking like it's selling almost $100 million a year or
19 maybe over $100 million a year U.S. If back in 1998
20 Kos had been selling $100 million, what kind of
21 decision do you make in September '98 then?
22 A. We'd continue to watch it, but, you know, $100
23 million is not a hugely successful product in the
24 United States.
25 Q. Now, Mr. Eisenstat showed you some documents

1 from Upsher-Smith's files. Do you recall seeing those?
2 A. Excuse me?
3 Q. From Upsher-Smith's files.
4 A. Yes.
5 Q. Some documents, correspondence with the FDA and
6 things like that.
7 A. Yes.
8 Q. Do you remember seeing that?
9 A. Just now.
10 Q. Yes. Did he show you anything from Upsher's
11 files such that if you had known it in June of 1997, it
12 would have affected your decision?
13 A. It would have made no difference, John.
14 MR. NIELDS: I have nothing further, Your
15 Honor.
16 JUDGE CHAPPELL: Recross?
17 MR. EISENSTAT: None, Your Honor.
18 JUDGE CHAPPELL: Anything further for this
19 witness?
20 MR. NIELDS: Nothing further from this witness.
21 JUDGE CHAPPELL: Thank you, sir. You're
22 excused.
23 THE WITNESS: Thank you.
24 JUDGE CHAPPELL: Mr. Nields, who's your next
25 witness?

1 MR. NIELDS: Your Honor, our next witness is
2 likely to last a while. It's Dr. Banker, and we
3 actually had only had him ready in case. We are
4 reluctant to put him on now at five past 5:00, because
5 Upsher has six witnesses that it wants to get on and
6 off in the next two days, and we believe if we start
7 him, we'll be using up a reasonable portion of
8 tomorrow.
9 JUDGE CHAPPELL: Okay. Did I understand you to
10 say he will be the first witness tomorrow or Upsher
11 will have some --
12 MR. NIELDS: No, Upsher will -- he will then
13 come back next week, which was as we had originally
14 scheduled it actually.
15 JUDGE CHAPPELL: Okay, why don't we -- let's go
16 ahead and adjourn. Anything else today?
17 MR. NIELDS: Not from us, Your Honor.
18 MR. EISENSTAT: No, Your Honor.
19 MR. CURRAN: We will be ready with the witness
20 at 9:30 or whenever Your Honor would like tomorrow
21 morning.
22 JUDGE CHAPPELL: Okay, then we will adjourn
23 until 9:30 in the morning.
24 (Whereupon, at 5:06 p.m., the hearing was
25 adjourned.)

1 C E R T I F I C A T I O N O F R E P O R T E R
2 DOCKET/FILE NUMBER: 9297
3 CASE TITLE: SCHERING-PLOUGH/UPSHER-SMITH
4 DATE: FEBRUARY 20, 2002
5
6 I HEREBY CERTIFY that the transcript contained
7 herein is a full and accurate transcript of the notes
8 taken by me at the hearing on the above cause before
9 the FEDERAL TRADE COMMISSION to the best of my
10 knowledge and belief.
11
12 DATED: 2/21/02
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14
15
16 SUSANNE BERGLING, RMR
17
18 C E R T I F I C A T I O N O F P R O O F R E A D E R
19
20 I HEREBY CERTIFY that I proofread the
21 transcript for accuracy in spelling, hyphenation,
22 punctuation and format.
23
24
25 DIANE QUADE