UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION



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| In the Matter of<br><br>Schering-Plough Corporation,<br>a corporation,<br><br>Upsher-Smith Laboratories,<br>a corporation,<br><br>and<br><br>American Home Products Corporation,<br>a corporation. | ) | Docket No. 9297 |

**RESPONDENTS' JOINT MOTION TO EXCLUDE THE EXPERT TESTIMONY OF DR. NELSON L. LEVY**

Respondents Schering-Plough Corporation ("Schering") and Upsher-Smith Laboratories, Inc. ("Upsher-Smith") respectfully submit this motion to exclude the expert testimony of Nelson L. Levy. Complaint counsel offers Dr. Levy as a proposed expert witness in support of complaint counsel's allegation that the license payments from Schering to Upsher-Smith for Niacor-SR and other pharmaceutical products were in fact disguised payments to keep Upsher-Smith from entering the market with a generic version of Schering's K-Dur.

Dr. Levy's experience does not qualify him to give the testimony complaint counsel has requested, however. Dr. Levy is not a cardiologist and is plainly not knowledgeable about cholesterol-reducing drugs. He has little or no experience in marketing and no experience in the valuation of pharmaceutical products. He has meager experience in in-licensing pharmaceutical products at large companies (since 1983 he has worked at only one for fourteen months in the early 1990s), he has no regulatory expertise, and no experience in marketing drugs overseas. Moreover, his conclusion

rests, in large part, on his determination that the fact witnesses in this case are lying. Dr. Levy may not opine on the credibility of witnesses or Schering's intent, however, and his opinion in this regard must be excluded.

For these reasons, as set forth in the accompanying joint memorandum, Respondents respectfully request that the Court grant this motion, and exclude the testimony of Dr. Levy.

Respectfully submitted,

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Dated: January 3, 2002

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| In the Matter of<br><br>Schering-Plough Corporation,<br>a corporation,<br><br>Upsher-Smith Laboratories,<br>a corporation,<br><br>and<br><br>American Home Products Corporation,<br>a corporation. | ) | Docket No. 9297<br><br>**NON-PUBLIC VERSION** |

**MEMORANDUM IN SUPPORT OF RESPONDENTS' MOTION TO EXCLUDE THE EXPERT TESTIMONY OF DR. NELSON L. LEVY**

Respondents Schering-Plough Corporation ("Schering") and Upsher-Smith Laboratories ("Upsher-Smith") submit this memorandum in support of their motion to exclude the expert testimony of Nelson L. Levy.

## I. INTRODUCTION

Complaint counsel contends that the $60 million (made in three payments over two years) Schering paid Upsher-Smith for the license rights to market Niacor-SR, a sustained-release niacin product to treat elevated cholesterol, and three other pharmaceutical products in Europe cannot reasonably be considered to have been a licensing fee. Complaint counsel contends that the payments were instead disguised payments to Upsher-Smith to refrain from entering the market with its generic version of Schering's K-Dur.

Complaint counsel has no direct evidence to support this claim. The Niacor-SR product was evaluated in writing by a uniquely well-credentialed official at Schering—an

official who knew nothing about the patent case or its settlement. And every witness who knew about the license has testified that it was a *bona fide* transaction. Schering will call these witnesses live at trial.

Complaint counsel plans to prove its contention through the opinion testimony of an expert witness, Dr. Nelson Levy. Dr. Levy will testify that in his opinion, and contrary to the testimony of every fact witness in the case, that: (1) the licensing fee was "grossly excessive for the value received;" (2) data from Upsher-Smith's clinical trials made FDA approval of Niacor-SR questionable; and (3) the "due diligence" Schering performed was inadequate and that the $60 million payment must have been intended for something other than the licenses.

As set forth more fully below, Dr. Levy's experience does not qualify him to give expert testimony on these subjects. Dr. Levy is medically trained and spent three years in the Research and Development department of Abbott Laboratories--a large pharmaceutical manufacturer—in the early 1980s. However, Dr. Levy is not a cardiologist and is plainly not knowledgeable about cholesterol-reducing drugs. He has little or no experience in marketing, and virtually none in the valuation of pharmaceutical products. He has meager experience in in-licensing pharmaceutical products at large companies (in the seventeen years since 1983 he has worked at only one such company for fourteen months in the early 1990s), he has no regulatory expertise, and no experience in marketing drugs overseas.

Dr. Levy betrayed his lack of experience related to cholesterol-reducing drugs in his deposition. He testified that liver toxicity, a frequently encountered side effect of cholesterol-reducing drugs, is measured by persistent elevations at 1.5 times the upper limit of normal (ULN). He was unaware that FDA and all experts in the field, including complaint counsel's rebuttal expert, Dr. Pitt, agree that the relevant benchmark is 3 times ULN. As a result, Dr. Levy drew wild conclusions about the liver toxicity results of the Niacor-SR clinical trials. Further, Dr. Levy thought that Schering should be faulted for

not looking at data from animal studies on Niacor-SR, when no such studies were required or conducted. And he believed Schering should have rounded up the subjects of Upsher-Smith's clinical trials, re-dosed them with higher doses of Niacor-SR, and taken biopsies from their livers before entering into an agreement. Biopsies involve inserting a large needle through the skin and flesh into the liver and extracting a plug of the liver itself. Not surprisingly, Dr. Levy's astonishing testimony on this subject drew no agreement from complaint counsel's other expert. *See* Pitt Dep. (attached as Exhibit 1 to Memorandum in Support of Respondents' Motion to Limit the Rebuttal Tesimony of Dr. Bertram Pitt Regarding Conversations with FDA Officials) at 47-49.

Because Dr. Levy's clinical research experience does not include any experience with cholesterol-reducing drugs or with the FDA approval process, he has nothing to offer in the way of expertise on the prospects for FDA approval. And because he has no experience in marketing or in-licensing drugs for sale outside North America, he is uniquely ill-suited to second-guess Schering's sales projections and Schering's valuation of the rights to Niacor-SR. Finally, his four years of work at pharmaceutical companies, most of which occurred almost twenty years ago, does not begin to qualify him to testify to what due diligence "standards" exist in the industry today.

Finally, Dr. Levy's opinion that the licensing fee was "grossly excessive" and cannot "reasonably be considered to be a licensing fee" is squarely at odds with the sworn testimony of the witnesses involved in the transaction. His opinion thus rests heavily on his conclusion that these witnesses, none of whom he has ever laid eyes on, are not telling the truth. (Deposition of Nelson Levy ("Levy Dep." at 244) (attached as Exhibit 1 hereto) ("I think to the extent that they maintain this was a license fee for Niacor-SR, they are being untruthful"). And, believing that his experience qualifies him to opine on Schering's motivations, he also intends to opine that Schering, in paying $60 million, was motivated by something other a desire to obtain the rights to market the licensed products. *See* Levy Dep. at 117 ("I do not see that consideration being

anywhere near provided by the licensed products, and so either Schering was in a very charitable mood or it got something else for it"). Under dispositive case law, an expert witness may not opine on the credibility of fact witnesses or on a party's intent, and Dr. Levy's opinions in this regard are inadmissible.

## II. DISCUSSION

### A. Principles Governing the Qualifications of Experts

#### 1. The Expert's Area of Expertise Must Match the Subject Matter of His Testimony

Courts have "broad discretion" to exclude expert testimony. *In re Natural Organics, Inc.*, 2001 FTC Lexis 25 *9 (Feb. 26, 2001). A purported expert witness must have expertise on each of the particular matters upon which he intends to render an opinion:

> Even where a witness has special knowledge or experience, ***qualification to testify as an expert also requires that the area of the witness's competence matches the subject matter of the witness's testimony***. Thus, the courts have frequently precluded a witness from testifying as an expert where the witness has specialized knowledge on one subject but offers to testify on a different subject.

29 C. Wright & V. Gold, *Federal Practice & Procedure*, § 6265 at 255-56 (1997) (emphasis added). *See also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 157 (1999) ("The trial court had to decide whether this particular expert had sufficient specialized knowledge to assist the jurors 'in deciding the particular issues in the case.'"). When an expert lacks the requisite credentials, it is not simply a matter of according less weight to his testimony—the proper remedy is to exclude the testimony. *See In re Air Crash Disaster at New Orleans*, 795 F.2d 1230, 1233 (5th Cir. 1986) ("[W]e recognize the temptation to answer objections to receipt of expert testimony with the shorthand remark that the jury will 'give it the weight it deserves.'. . . . [but] [t]rial judges must be sensitive to the qualifications of persons claiming to be experts.").

The law is also clear that the testimony of an expert who is not experienced in the specific field at issue, but is instead experienced in a more generalized field, or in a related one, should be excluded for lack of the requisite qualifications. *See Coal Resources, Inc. v. Gulf & Western Indus., Inc.*, 954 F.2d 1263, 1268 (6th Cir. 1992) (CEO of coal company with expertise on development of mining rights not qualified as expert on costs and appropriateness of coal preparation plants); *United States v. Chang*, 207 F.3d 1169, 1173 (9th Cir. 2000) (expert in international finance cannot opine whether international securities were counterfeit); *McDonald v. Federal Labs, Inc.*, 724 F.2d 243, 248 (1st Cir. 1984) (expert on chemistry of mace cannot opine on mace canister design); *Wilson v. Woods*, 163 F.3d 935, 937 (5th Cir. 1999) (expert with 25 years' experience consulting on fire reconstruction and teaching mechanical and industrial engineering cannot opine on auto accident reconstruction where he never taught, conducted studies or published in that field); *Barrett v. Atlantic Richfield Co.*, 95 F.3d 375, 382 (5th Cir. 1996)(expert on animal studies not qualified to testify on correlation between animal results and human results).[1] Courts particularly adhere to this rule to exclude medical experts where they attempt to provide an expert opinion beyond their particular fields of medicine in which they possess expertise. *See Edmonds v. Illinois Central Gulf R. Co.*, 910 F.2d 1284, 1287 (5th Cir. 1990) (clinical psychologist not qualified as expert on whether stress worsened coronary disease).[2]

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[1] *See also United States v. Kladouris*, 964 F.2d 658, 669 (7th Cir. 1992) (witness with general knowledge of hydrocarbons not qualified as an expert on chemistry of fire causation); *Firemen's Fund Ins. Co. v. Videfreeze Corp.*, 540 F.2d 1171, 1180 (3d Cir. 1976) (geologist not an expert on seismology); *Jones v. Lincoln Elec. Co.*, 188 F.3d 709, 724 (7th Cir. 1999) (abuse of discretion not to exclude metallurgist from testifying on health effects of manganese); *City of Hobbs v. Hartford Fire Ins. Co.*, 162 F.3d 576, 587 (10th Cir. 1998) (expert with 30 years experience in handling and adjusting third-party claims not qualified to opine on first-party claims); *McCullock v. H.B. Fuller Co.*, 981 F.2d 656, 657 (2d Cir. 1992)(electrical and industrial engineer not qualified to opine on adequacy of warning label).

[2] *See also Watkins v. Schriver*, 52 F.3d 769, 771 (8th Cir. 1995) (neurologist not qualified to opine on accident reconstruction in case involving paralyzing neck injury); *Gates v. United States*, 707 F.2d 1141, 1145 (10th Cir. 1983) (professor of immunology not qualified to review particular patient's medical records).

This rule has also been specifically applied to experts who wish to opine on issues of valuation. Courts regularly exclude purported experts who have merely demonstrated some general experience or expertise, but who lack the specific expertise necessary to perform the valuation of the asset in question. *See Suitum v. Tahoe Regional Planning Agency*, 80 F.3d 359, 363 (9th Cir. 1996) (vacated on other grounds) (excluding expert on development rights transfers as not qualified to opine on market valuation of development rights.

Further, it is well established that where geographic distinctions matter, even a witness with great experience in one geographic area is not qualified to render expert opinions on other regions. *See Taylor v. Ouachita Parish School Bd.*, 648 F.2d 959, 970 (5th Cir. 1981) (affirming exclusion of "able sociologist with a fine academic record" who had studied segregation in 16 cities but not the city at issue).[3] Thus, an expert on the value of real estate in California would not be qualified to opine on the value of a piece of real estate in Massachusetts.

Finally, supervision of others while in an executive position at a company does not itself qualify a person as an expert on the matter supervised. *See Coal Resources, Inc.* 954 F.2d at 1268 (rejecting plaintiff's assertion that CEO's approval and review of all coal preparation plant construction and modification during his tenure qualified him as expert on the costs and appropriateness of such plans; holding "review of plans and budgets prepared by others differ substantially from the preparation and design of the plans" himself).

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[3] *See also United States v. Hirschberg*, 988 F.2d 1509, 1514 (7th Cir. 1993) ("knowledge of police practices in Chicago does not qualify Illinois police detective as expert on practices in Miami"); *Koch v. Gorilla*, 552 F.2d 1170, 1173 (6th Cir. 1977) (expert on medical standards in Duluth cannot testify on standards in community located 100 miles away).

### 2. An Expert May Not Testify on the Credibility or Motivation of Witnesses

It is fundamental that assessments of credibility belong to the trier of fact, and are not a proper subject for expert testimony. *See Wright & Gold*, § 6262 at 178 (Rule 702 "seeks to preserve the trier of fact's traditional powers to decide the meaning of evidence and the credibility of witnesses"). *See, e.g., United States v. Awkard*, 597 F.2d 667, 671 (9th Cir. 1979) (error to allow expert to testify on witness' ability to recall incident: "opinion testimony on credibility is limited to character; all other opinions on credibility are for the jurors themselves to form"); *United States v. Benson*, 941 F.2d 598, 604 (7th Cir. 1991) ("credibility is not a proper subject for expert testimony").

It is equally improper for an expert to testify about a party's intent or motivation. *See, e.g., Aerotech Resources, Inc. v. Dodson Aviation, Inc.*, 2001 U.S. Dist. LEXIS 5646, *6-*7 (D. Kan. Apr. 4, 2001) (improper for expert to testify about intended effect of agreement, as that was province of factfinder); *In re Diet Drugs Products Liability Litigation*, 2001 U.S. Dist. LEXIS 1174, *7 (E.D. Pa. 2001) ("any proffered expert testimony concerning the intent of AHP or any other entity (such as the FDA) shall be excluded on the basis that the question of intent is to be determined by the jury, not experts").

## B. Dr. Levy is Not Qualified to Render an Opinion on Whether the Rights to Market Niacor-SR Outside North America Were Worth $60 Million

### 1. Factual Background

**a. The licensed product.** Niacor-SR, a sustained release niacin formulation being developed by Upsher-Smith was the principal product involved in the licensing transaction at issue. Niacin (vitamin B-3) is a well-known compound, which Dr. Levy admits has valuable cholesterol-lowering properties. (Report of Nelson Levy ("Levy Rep."), attached hereto as Exhibit 2, at 4-5). Well before 1997, niacin was recognized (as it is now) as a good complement to statins (such as Mevacor and now

Lipitor) for use in combination therapy in the management of cholesterol and lipid levels. However, as of 1997, the use of niacin was limited because the then-available immediate-release niacin products frequently produced unpleasant side effects. Niacor-SR, however, utilized a novel sustained-release technology, which, by introducing niacin into a patient's system more gradually, offered the promise of fewer side effects. Because Upsher-Smith planned to market Niacor-SR in North America on its own, Schering and Upsher-Smith negotiated a license giving Schering the rights to market Niacor-SR outside North America. Thus, the principal targets for Schering were Europe and Asia's multi-billion dollar markets for cholesterol-lowering drugs.

Shortly before negotiating with Upsher-Smith for the rights to market Niacor-SR outside North America, Schering had negotiated with a company called Kos Pharmaceuticals, Inc. ("Kos"), for the rights to co-market its sustained-release niacin product, known as Niaspan. Schering did detailed sales projections for Niaspan in the United States, and concluded that its sales would exceed $100 million per year and that the profits had a net present value of over $250 million. Market analysts predicted even greater sales for Niaspan of over $250 million per year, and Kos (then a one-product company) raised $60 million from the public in an initial public offering in exchange for less than 30 percent of Kos' stock. Partly because of the fact that Kos' expectations for Niaspan exceeded Schering's, no transaction with Kos was ever consummated.

When the opportunity arose to acquire the rights to market Niacor-SR outside North America in June 1997, Schering once again prepared sales and profit projections. The Schering official who performed these projections, James Audibert, was uniquely qualified to do so. He is scientifically trained and had spent several years in Research and Development inside a pharmaceutical company. He was extraordinarily knowledgeable about cholesterol-reducing drugs, having made them a special focus of his study and work during the previous six months. He had extensive experience in sustained-release technology and in bringing sustained-release formulations of old drugs

to market. He was in 1997 a member of Schering's Global Marketing division, and had experience in markets outside the United States.

Mr. Audibert reviewed the results of the Niacor-SR clinical trials provided by Upsher-Smith. He projected annual sales for Niacor-SR of over $100 million after its third year on the market—sales which would yield a profit to Schering with a net present value of $225-265 million.

**b. Dr. Levy's opinion.** Dr. Levy does not question that in 1997 Schering had the experience and acumen to evaluate and market a drug such as Niacor-SR on a successful basis. But he nonetheless renders the opinions that (1) Schering paid too much for the rights to Niacor-SR, (2) approval by regulators was questionable, and (3) Schering's due diligence was unusually cursory, and Schering must have intended the $60 million as payment for something other than the rights to the licensed products. Based on these opinions Dr. Levy cavalierly concludes that the payments for the license reflect either "charity", "idiocy" or dishonesty on Schering's part. (*Id.* 118-19).

**c. Dr. Levy's Credentials.** After completing his medical education in the 1967 and obtaining a Ph.D. in immunology 1973, Dr. Levy spent eight years at Duke University doing academic research and teaching on cancer immunology, neurology, multiple sclerosis and brain control of the immune system. (Levy Rpt. 1). He does not report having done any research in the field of cardiology. He is board certified in allergy and immunology. He is not board certified in cardiology.

Starting in 1981, he spent three years at a pharmaceutical company, Abbott Laboratories, overseeing drug research on HIV, infections, hypertension and prostatic hypertrophy. (*Id.*). During the course of his deposition he could not identify any instance in which he oversaw or did any research on any niacin products, any of the statins, or any other cholesterol reducing agent. *See generally* Levy Dep.

For nearly all of the 17 years since he left Abbott, Dr. Levy has worked out of his home, running a small consulting firm with two other professionals advising start-up

companies and investors, quite unlike Schering, principally on product development. (*Id.*; Levy Dep. 99). In response to questions regarding his qualifications and experience, the one product that he proffered as an example of a product that CoreTechs, his consulting operation, was working on was a so-called "Lox Box," a device for converting salmon into lox. (Levy Dep. 167-76).

Finally, more than seven years ago Dr. Levy briefly headed the U.S. operations of a Japanese pharmaceutical company, Fujisawa, with no claim that any of the drugs with which he dealt treated cholesterol or were similar to Niacor-SR in terms of pharmacology or market prospects. (Levy Rpt. 1). After just 14 months at that job he was asked to leave the company. (Levy Dep. 79-80). Levy has not been employed by a pharmaceutical company in any capacity since 1993. (*Id.* at 77).

Unlike Mr. Audibert, Dr. Levy has no expertise in cholesterol-reducing drugs, no expertise in sustained-release technology, no marketing or valuation experience, and absolutely no experience marketing or licensing drugs outside North America. Given his credentials, it is surprising that Dr. Levy believes he is qualified to second-guess Mr. Audibert's evaluation of Niacor-SR, and astonishing that he purports to render an opinion that Schering did not intend the $60 million as a *bona fide* payment for the licensing rights.

### 2. Dr. Levy Is Not An Expert On Valuing A License For The Sale Of Pharmaceuticals Anywhere – Let Alone In European Market

#### a. Dr. Levy is Not Qualified to Value the Niacor-SR License

Dr. Levy has no experience, education or training that qualifies him to appraise the value of the Niacor-SR license. First, Dr. Levy's educational and teaching background through 1981 does not qualify him to evaluate the value of a pharmaceutical products license. He never attended business school, he has not written any articles on

the topic of valuation of pharmaceutical licenses, and he never took or taught any courses on the subject. Moreover, Dr. Levy himself admits that when he left academia: "I would not characterize myself in 1981 as an expert on the in-licensing or out-licensing of pharmaceuticals" and that he "knew very little about the general area of finance." (Levy Dep. 144). Thus, any claim to expertise necessarily depends on his subsequent work experience. And little or none of it involves marketing or valuation of pharmaceuticals.

Dr. Levy's brief tenure at two pharmaceutical corporations many years ago, where he supervised research in therapeutic areas unrelated to cardiology and cholesterol and presided briefly over the American subsidiary of a Japanese company, does not provide him with the relevant expertise. His experience overseeing R&D at Abbott is inapposite – experience in scientific research does not make one an expert in other aspects of the business, such as valuation and marketing. *See, e.g., Chang*, 207 F.3d at 1173 (international finance expert cannot opine on whether international securities were counterfeit). Likewise, Dr. Levy's ill-starred 14 months at Fujisawa, where he merely supervised others, does not qualify him as an expert. *See, e.g., Coal Resources*, 954 F.2d at 1268 (CEO's oversight of coal plant construction did not qualify him as an expert on construction budgets and plans prepared by others).

Dr. Levy's own description of his work history confirms that he is unqualified to opine regarding pharmaceutical license valuations generally:

- He admits that most of his corporate pharmaceutical experience was overseeing pharmaceutical research departments. (*Id.* 144).
- He admits that in his roughly three years at Abbott and his 14 months at Fujisawa – his only corporate pharmaceutical work – he never worked in market research at all, let alone for markets outside of the US. (Levy Dep. 169).
- He admits that while at Fujisawa he never negotiated licensing deals because he "had business development people who had responsibility for negotiating the deals . . ." (*Id.* at 238).

- He admits that during his corporate experience any valuation, licensing, or marketing work was outside his area of responsibility and incidental to his primary research responsibilities at Abbott. (*Id.* at 97-98).

- His CV indicates that he has in-licensed only two major drugs in his lifetime (*id.* 81) and, although in his deposition he claimed to have been involved with four, he admits none of these in-licensed drugs treated cholesterol. (Levy Depo. 83-84).

For these reasons alone his opinions on the valuation of Niacor-SR do not meet the requirements of *Daubert* and *Kumho* and Rule 3.43(b).

**b. Dr. Levy Lacks Experience in Cholesterol-Reducing Drugs**

Dr. Levy, as he admits, is not an expert on lipidology and cholesterol, which is at the very heart of Niacor-SR's technology:

> Q: Sir, is it generally accepted in the scientific community that the effects of niacin on blood lipids reduce the incidence of coronary artery disease?
>
> A: I can't say what's generally accepted. ***As I said, the state of knowledge about blood lipids and coronary vascular disease ... changes as we learn more, and I really can't speak to what the current state of knowledge is in this area.*** I think maybe you ought to consult a guy like Joe Goldstein who might be able to give you more up-to-date information about that.
>
> * * *
>
> I don't represent the scientific community that focuses on cholesterol metabolism.

(Levy Dep. 191-92 (emphasis added)). He could not name the five drugs, either by brand or generic name, that comprise the immensely successful statin class of cholesterol-reducing drugs.

The only knowledge Dr. Levy may possess regarding cholesterol is based on his medical school days of 34 years ago. (*Id.*). This knowledge is plainly outdated and an insufficient a basis for an expert opinion on new drugs or the current regulatory environment and market conditions. *See Posado v. Deters*, 5 F.3d 119, 124 (5th Cir.

1993) (excluding expert who had not worked in relevant field in almost 20 years and had not taken any refresher courses). For example, during the course of his deposition he recanted a statement in his report regarding current research on niacin's effect on cholesterol (*id.* 186) and conceded that he was unfamiliar with "newer" medical terminology.[4] Obviously, a new drug's prospects for FDA approval depend on the current state of the art. (*Id.*). Dr. Levy's research after medical school did not involve cholesterol-lowering drugs. (*Id.* 84, 91, 192). He also has no professional experience with sustained release drugs or drugs using a new delivery mechanism for a known compound. (*Id.* 89, 91).

**c. Dr. Levy is Not Qualified to Opine on European Market Potential**

Dr. Levy also has no expertise in marketing or licensing drugs outside North America. The prospects for drugs differ among various geographical markets due to differences in drug pricing, regulatory structures, prescribing patterns, and insurance coverage, among others factors. Dr. Levy does not disagree. *See* Levy Rep. at 16.[5] This is striking because not only is Dr. Levy's general experience with valuing pharmaceutical drugs marginal at best, but by his own admission he has virtually no experience in the European market. In his deposition he admitted that:

- He has no sales or marketing experience for pharmaceuticals outside North America. (Levy Dep. 87).
- He has never been substantially involved in filing a new drug application in any European country. (*Id.* 251-253).

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[4] Dr Levy was unfamiliar with several common acronyms for the liver enzymes at issue used by lipidologists and cardiologists, such as ALT and AST. "AST is a term I must admit is a newer term from when I went to medical school, so I don't use that term very fluently." (Levy Dep. at 11). "ALT is the newer term, and its an analogous comment to AST." (*Id.* at 12).

[5] Indeed, one of Dr. Levy's criticisms is that one member of Schering's internal review team, Raman Kapur, was the head of Schering's U.S. generic pharmaceutical business, rather than a European expert. (Levy Rep. at 14).

- He has never done a licensing deal or sought a licensing partner for a pharmaceutical product to be sold in the European market. (*Id.* 238).

- He has not even consulted with anyone having European market expertise regarding this case. (*Id.* 125).

- He is unfamiliar with the European drug approval testing requirements (*id.* 253) or the acronym for European drug applications. (*Id.* 98).

- He believes that niacin products are available over the counter in Europe, (Levy Rpt. 18), but was unable to name any such products. (Levy Dep. 127).

- His knowledge about the availability of niacin in Europe in 1997 is "based solely on the deposition testimony he has read in this case." (*Id.* at 128).

In fact, it is apparent from these admissions that Dr. Levy's knowledge regarding niacin in Europe and European markets and licensing generally is based on what he has learned from reading depositions in this case. Knowledge gained through work as a witness, however, does not count toward an expert's credentials. 29 *Wright & Gold*, § 6265 at 248. Indeed, courts routinely exclude expert testimony where the expert is merely interpreting the deposition testimony of the witnesses. For example, one court excluded an expert who relied "almost exclusively on his interpretation of deposition testimony" to reach his conclusions because in so doing the witness "does not serve as an expert, but seeks to supplant the role of counsel in making argument at the trial and the role of the jury interpreting the evidence." *Primavera Familienstifung v. Askin*, 130 F.Supp. 2d 450, 528 (S.D.N.Y. 2001).

In sum, Dr. Levy simply lacks the expertise to evaluate cholesterol-reducing drugs or to value any drug for marketing either here or in Europe. He plainly lacks expertise to opine, as he does, that Schering personnel must have been "flaming idiots" or "blithering idiots" (Levy Dep. 119, 242) to value Niacor-SR's European potential as they did. Without knowing the range of reasonable values for a license for Niacor-SR in Europe, Dr. Levy's conclusions regarding the license agreement are unsupportable.

### 3. Dr. Levy Is Not Qualified To Render an Opinion Regarding the Likelihood of FDA or European Regulatory Approval For Niacor-SR

Dr. Levy is similarly unqualified to opine regarding the likelihood of regulatory approval of Niacor-SR in 1997. His lack of expertise is demonstrated not only by his lack of qualifications regarding U.S. approval of cholesterol-fighting drugs, but also by the jarring fundamental errors in his description of Niacor-SR and the applicable FDA standards. Further, in his deposition he effectively admitted he was uninformed as to basic European regulatory approval matters. Accordingly, his opinion that Schering should have concluded that the side effects of Niacor-SR raised questions regarding FDA or European approval is neither correct nor admissible.

At no point in his brief corporate pharmaceutical career did Dr. Levy ever have substantial involvement with issues related to regulatory approval. His three years as a laboratory researcher did not involve interactions with any agency responsible for drug approvals. Levy Dep. at 251. And his consulting work out of his home over the past 17 years has not focused on FDA drug approval issues. *See id.* at 99-105, 159-61. Dr. Levy never worked for the FDA or a regulatory agency in any European country, and does not claim to have shepherded any cholesterol-fighting drug remotely similar to Niacor-SR, or, indeed, any other drug, through the FDA approval process. *Id.* at 251.

Dr. Levy revealed his ignorance of European regulatory approval procedures during his deposition. He was unable to identify any instance in which he had substantial personal involvement in the filing of an NDA in the European Union on any product, much less a sustained-release product. (*Id.* 251-52). Although he made much of the pharmacokinetic testing required for Niacor-SR by the FDA his report, in his deposition he admitted and that he was unfamiliar what pharmacokinetic study or data European regulators would have required in 1997. (*Id.* 253). In fact, he was even unfamiliar the acronym commonly used in referring to European drug applications ("HRD"). (*Id.* at

98). Plainly, Dr. Levy is not qualified to opine on the likelihood and timing of approval of Niacor-SR by European regulators.

Moreover, Dr. Levy's opinion regarding the likelihood of regulatory approval of Niacor-SR depended on his views on the drug's potential liver toxicity. That opinion rests primarily on data received by Schering showing that as part of its clinical studies Upsher-Smith already had tested Niacor-SR for liver toxicity and found that some patients exhibited elevated liver enzymes at the level of 1.5 times the upper limit of normal ("ULN"). According to Dr. Levy, this would have precluded FDA approval and would have caused the FDA to require further tests.

Not only does Dr. Levy lack any professional basis to opine that FDA would reject a drug at the low 1.5 ULN threshold, the evidence is clear that he could not be more wrong. Liver enzyme levels of 1.5 times ULN cause no concern at FDA at all. Indeed, the subjects in cholesterol drug clinical trials, such as those conducted by Upsher-Smith on Niacor-SR, can and do *begin* the trials with liver enzyme levels of up to 1.5 times ULN. FDA told Upsher-Smith the relevant standard was 3 times ULN and this is the standard the FDA used in evaluating all the other major cholesterol reducing agents (including the blockbuster statins).[6] *See* June 29, 1993 record of telephone communication between FDA and Upsher-Smith (Upsher-Smith-FTC 095036-7). Moreover, other experts in this case who opine on this issue, including Complaint Counsel's rebuttal witness Dr. Pitt, confirm that the relevant standard is 3 times ULN. *See, e.g.*, Pitt Rep. 5; Horowitz Rep. 14-15; McVey Rep. 11. In light of this record and the total absence of evidence that "other experts in the industry" (or the FDA) uses Dr. Levy's 1.5 times ULN standard, his opinion regarding the FDA approval (and therefore the reasonableness of the license agreement) should be excluded. *Kumho*, 526 U.S. at 157.

[6] Cholesterol drugs which cause liver enzyme levels to exceed 3 times ULN in some percentage of patients may nonetheless be approved. Davidson Dep. at 89-92. FDA recommends liver enzyme monitoring for such drugs. Horovitz Dep. at 190-93.

Indeed, Dr. Levy made several other strikingly erroneous assertions regarding FDA approval. Based on his incorrect assumption that 1.5 times ULN is the relevant standard, he assumes that Upsher-Smith should have conducted invasive liver biopsies of the test patients (Levy Rep. at 8) as well as further testing at twice the previous dosing. (Levy Dep. at 44-45). These speculations on his part are again at odds with standard practice and the opinions of the other medical experts in this matter, including Dr. Pitt. (Pitt Dep. at 12). Moreover, through questioning it became clear that his basis for these conclusions was not any experience with the FDA, but that he was simply extrapolating from what he as a "general practitioner"[7] would do for a patient with elevated liver enzymes. (*Id.* at 36). Finally, Dr. Levy even asserted that Schering should have reviewed the animal toxicology results for Niacor-SR because such tests are required by the FDA and would be informative. In fact, however, such tests are not required for known compounds (such as niacin) and no such studies had been conducted. Thus, the basis for his conclusions is not properly tethered to reality and, as the Supreme Court cautioned, "nothing...requires a district court to admit evidence that is connected to existing data only by the *ipse dixit* of the expert." *General Electric Co. v. Joiner*, 522 U.S. 136, 146 (1997).

For these reasons, Dr. Levy's conclusions regarding the approvability of Niacor-SR are fatally flawed, and thus his conclusions regarding the reasonableness of the license agreement is without foundation and should be excluded.

### C. Dr. Levy Failed to Use Reliable Methods and Principles in Reaching His Conclusion as to Valuation of Niacor-SR and the Other Licensed Products

Even if Dr. Levy's credentials were sufficient to qualify him on the valuation of pharmaceutical licenses, his methods and conclusions fail to meet the standard of

[7] It does not appear that Dr. Levy has been a general practitioner for at least two decades.

reliability *Daubert, Kumho*, and Rule 3.43(b) require. Indeed, although Dr. Levy purports to opine on the reasonableness of the license agreement negotiated by Schering and Upsher-Smith, he rejects the standard measure of asset valuation used in the pharmaceutical industry and finance generally, i.e., discounted cash flows (net present value). Having done this, however, he fails to perform any quantitative valuation of Niacor-SR, let alone the other pharmaceutical products Schering licensed.

As part of its internal process for approving the Niacor-SR license, Schering performed a detailed financial analysis of the value of the drug to Schering. As part of that analysis, Mr. Audibert concluded in a June 17, 1997 memorandum that Niacor-SR would produce profits fo $345 million in its first five years of sales. (SP 1600035-36). Mr. Audibert's documents have been produced, and he has stood by his valuation throughout both of his depositions.

Dr. Levy nonetheless opines that the license fees "cannot reasonably be considered to have been a license fee (Rep. at 3), or, as he stated in his deposition, "there is no way in hell that $60 million was a license fee." Levy Dep. at 116. Yet nowhere in his report, or, for that matter, anywhere else, does Dr. Levy provide a calculation of what he believes the Niacor-SR license was worth.

The use of net present values (NPVs) to determine the value of a license is a long-established practice in the pharmaceutical industr. See Deposition of James Egan (former Searle executive) at 12 -13 (describing use of discounted cash flow model to determine whether NPV of product made it a good candidate for in-licensing). Indeed, every economic expert in the case agrees on this point.

Dr. Levy's explanation for why he did not perform an NPV evaluation here, however, is contrary to the accepted practice in the pharmaceutical industry: "I find classical financial analyses — let's just be more specific, net present value calculations — to be very unhelpful in almost every situation, and particularly in a situation where the product itself is not on the market or is not yet marketable." Levy Dep. at 179. Although

acknowledging that NPVs are widely used and requested, Dr. Levy flat out rejects using NPV analysis; he even states that in advising clients with start-up or new products, his company, CoreTechs, does not "present to ourselves or to potential investors any valuation numbers." *Id.* at 177. Tellingly, Dr. Levy also concedes (perhaps because he is aware he is far outside of the industry standard) that not preparing valuation numbers "may sound strange . . . and . . . it's somewhat unusual in this industry . . . ." *Id.*

Where an expert's opinion deviates from the majority view, he is obligated to show that the alternative method he suggests is employed by at least a recognized minority of within the field. *See Daubert v. Merell Dow Pharms., Inc.*, 43 F.3d 1311, 1318 (9th Cir. 1995) (scientific experts might be permitted to testify if they could show that the methods they used were also employed by "(at least) a recognized minority of scientists in their field."). Moreover, where an expert claims to be applying principles and methods in accordance with standards in the field, but reaches a conclusion that other valuation experts would not reach (here, that NPV is useless), the trial court should be skeptical. Fed. R. Evid. 702, Committee Note (2000 Amendment) ("[W]hen an expert purports to apply principles and methods in accordance with professional standards, and yet reaches a conclusion that other experts in the field would not reach, the trial court may fairly suspect that the principles and methods have not been faithfully applied.") (citing *Lust v. Merrell Dow Pharms., Inc.*, 89 F.3d 594, 598 (9th Cir. 1996).

Dr. Levy's report cannot meet this requirement of Rule 702. He simply does not propose his own method of evaluating the value of the license agreement, let alone provide a quantitative valuation of the license agreement. Instead, his opinion is exactly that – his ***personal*** opinion. Even a cursory review of his report reveals that his is not relying on any objective or industry standard, but rather his own gut feelings:

- The due diligence would "fall immeasurably below that ***I have ever encountered . . .***" (Levy Rep. 3).

- "It is ***inconceivable to me*** that any pharmaceutical company would spend anything approaching $60 million . . . " (*Id.* 3).
- "Summary of My Perception of Niacor-SR . . ." (*Id.* 13).
- "It is ***my opinion*** that Mr. Audibert was quite junior to handle by himself the due-diligence . . . " (*Id.* 14).
- It was "***strange to me***" that David Poorvin wasn't involved in this license. (*Id.* 14).
- "***In my experience***" it is "almost unheard of" for a pharma company to pay "$60 million in non-contingent payments." (*Id.* 25).

These statements in his report articulating a personal rather than industry standard, combined with Dr. Levy's resort in his deposition to unsupported and often inflammatory rhetoric, rather than reasoned analysis,[8] only further demonstrates his unfamiliarity with the standards prevailing in the industry at the time the licensing agreement Schering and Upsher-Smith in June 1997.

Dr. Levy's reliance on inexact conclusory statements, which are based on his personal reactions, and his failure to perform the analysis that is standard in the industry is simply another reason Dr. Levy's opinion should be excluded. *See Navarro v. Fuji Heavy Indus., Ltd.*, 925 F. Supp. 1323, 1329 (N.D Ill. 1996) (finding an expert witness's affidavit inadmissible as it "includes nothing defining the 'reasonable standard of care' in the industry, much less any information showing that Fuji failed to conform to such a standard."). As he does not offer an alternative industry standard for valuation, Dr. Levy's testimony "supplies nothing but a bottom line [and] supplies nothing of value to the judicial process . . . ." *Id.* at 1329 (internal citations and quotations omitted). Because Dr. Levy's opinion is not based on any reliable principles or methods but rather

[8] During his deposition, in the guise of analysis, Levy offered a variety of epithets and pejorative conclusions about the license agreement and the work of the pharmaceutical employees of Schering-Plough. *See* Levy Dep. at 119 (opining one possibility is "they're just flaming idiots", referring to Schering employees); *id.* at 242 ("blithering idiots" as a potential view of Schering employees); *id.* at 223 ($60 million was an "absurd" payment); *id.* at 246 ("$60 million was so absurd as to defy belief"); *id.* at 116 ("there is no way in hell that that $60 million was a license fee"); *id.* at 115-16 ("This behavior [the transaction] was so out of the norm for anything I had ever experienced, I had ever heard of, and I could ever conceive of occurring that the picture to me seemed utterly and totally inexplicably ridiculous.").

unsupported and conclusory opinions which do not assist the Court, his expert report should be excluded.

### D. Dr. Levy Is Not Qualified To Render An Opinion On The Credibility Of Schering Witnesses Or Schering's Intentions In Entering Into The License Agreement

Dr. Levy concludes that Schering witnesses, "to the extent that they maintain that this was a license fee for Niacor-SR, they are being untruthful." (Levy Dep. 244). *See also id.* at 246 ("there's dishonesty somewhere"); *id.* at 247 ("they have been untruthful in their testimony throughout this matter); *id.* (Q: "Well, you said you've reached the conclusion that there was dishonesty, correct?" A: "Yes."); *id.* at 249 ("I don't know how this plot emerged and how this process emerged. What I know is it doesn't begin to meet a basic smell test, and where the errancy has its root, I am not able to testify.")

Expert opinion does not assist the trier of fact "if it draws inferences or reaches conclusions within the jury's competence or within an exclusive function of the jury." *Nichols v. American National Insurance co.*, 154 F.3d 875, 883 (8th Cir. 1998). In *Nichols*, a psychiatric expert testified as to the "psychological credibility" of the plaintiff in a sexual harassment case. The expert testified that "recall bias, secondary gain and malingering" influenced the plaintiff's testimony. *Id.* The Court held that the expert "used these terms to indicate that [the plaintiff's] version of the facts was inconsistent and changed over time and that it was tainted by bias and desire for financial gain." *Id.* at 884. Because these were "inferences" that the jury was required to draw, the Court excluded the expert's opinion on the grounds that it "impermissibly instructed the jury on how to weigh . . . evidence." *Id.*

Similarly, in *Securities and Exchange Commission v. Lipson*, an accounting expert offered an opinion that the defendant would not have traded stocks on the basis of his company's internal reports because the defendant believed that those reports were unreliable. The court refused to admit this testimony because "all of [the expert's] years

of training and experience as an accountant . . . do not specially equip him to divine what Defendant truly believed about the reliability of the reports." 46 F. Supp. 2d at 763. The court characterized the experts' opinions as "at worst, rank speculation" and "at best, . . . credibility choices that are within the province of the jury, not [the expert], to make." *Id.* *Cf. In re Diet Drugs*, 2000 U.S. Dist. LEXIS 9037, * 22 ("testimony of an expert that constitutes mere personal belief as to the weight of the evidence invades the province of the jury"); *DeJager Construction, Inc. v. Larry Schleninger*, 938 F.Supp. 446, 449 (W.D. Mich. 1996) (expert's opinion excluded where expert selected portions of record supporting client's position and then opined on credibility of witness statements).

Nothing in Dr. Levy's background qualifies him to give "expert" testimony to the effect that Schering witnesses lied in their depositions. To the extent his opinion is based on his belief that Schering's due diligence fell below some "standard" in the pharmaceutical industry, it is inadmissible: Dr. Levy has been out of the industry for far too long to render an expert opinion on this subject.

To the extent Dr. Levy's opinion is based on his belief about their credibility, he must not be permitted to render it at the hearing. The question whether Schering witnesses are telling the truth is one for this Court to decide for itself. Dr. Levy is equally unqualified to opine on Schering's motivations in entering into the license agreement. In his deposition, he testified that, based on his belief that Schering grossly overpaid for the rights to market the licensed products, Schering must have been motivated by something else. Levy Dep. at 117. When asked what qualifications he possessed that would render him an expert on Schering's motivations, he cited his experience in the pharmaceutical industry. *Id.*

Dr. Levy's beliefs about Schering's motivations must be excluded. The intent or motivation of a party is a matter for the trier of fact, not experts. In *Aerotech*, for example, an aviation consulting expert proposed to testify that the parties' contract negotiations demonstrated an intent to establish an exclusive brokerage agreement rather

than the sale of an aircraft. The district court excluded this testimony, on the ground that it "would speak to the effect that the parties intended their agreement to have. This is a task more properly performed by a fact finder." *Id.*; *see also Salas*, 980 F.2d at 305 ("conclusory assertions regarding [a defendant's] state of mind would not be helpful to a jury, [and are] not admissible."). Dr, Levy should be similarly precluded from testifying about the intentions of Schering and Upsher-Smith and entering the license agreement.

## III. CONCLUSION

Because Dr. Levy has no specialized knowledge that will assist the Court in understanding the evidence or determining the disputed factual issues, his testimony should be excluded.

Respectfully submitted,

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Dated: January 3, 2002

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

| | | |
|---|---|---|
| In the Matter of<br><br>Schering-Plough Corporation,<br>a corporation,<br><br>Upsher-Smith Laboratories,<br>a corporation,<br><br>and<br><br>American Home Products Corporation,<br>a corporation | ) | Docket No. 9297 |

**ORDER GRANTING RESPONDENTS' JOINT MOTION TO EXCLUDE THE TESTIMONY OF DR. NELSON L. LEVY**

The Court finds that the background and experience of complaint counsel's proposed expert, Dr. Nelson L. Levy, do not qualify him to offer his proposed testimony in this matter.

Accordingly, IT IS HEREBY ORDERED that Respondents' joint motion to exclude the testimony of Dr. Levy is hereby GRANTED, and Dr. Levy shall not be permitted to testify in this matter.

D. Michael Chappell
Administrative Law Judge

Dated: January _____, 2002

**In The Matter Of:**

*SCHERING-PLOUGH & UPSHER-SMITH*
*MATTER NO. D09297*

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*NELSON L. LEVY, Ph.D, M.D.*
*November 20, 2001*

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FEDERAL TRADE COMMISSION

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FEDERAL TRADE COMMISSION

In the Matter of: )
SCHERING-PLOUGH CORPORATION, )
a corporation, )
and )
UPSHER-SMITH LABORATORIES, ) File No. D09297
a corporation, )

Tuesday, November 20, 2001

Federal Trade Commission
601 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

The above-entitled matter came on for deposition, pursuant to notice, at 8:17 a.m.



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ALSO PRESENT:
Richard DiCicco



PROCEEDINGS

Whereupon—

NELSON L. LEVY, PhD, MD

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

EXAMINATION

BY MS. SHORES:

Q: Please state your name for the record.

A: Nelson L. Levy.

Q: And what is your home address?

A: 1391 Concord Drive, Lake Forest, Illinois 60045.

(Levy Deposition Exhibit Number 1, Expert Report of Nelson Levy, was marked for identification.)

BY MS. SHORES:

Q: Dr. Levy, I'm showing you what's been marked as Levy Exhibit 1 for identification. I see you have another copy of what appears to be the same document in front of you. Is that correct?

A: Yes.

Q: Does the copy of the report in front of you contain any handwritten annotations?

A: I don't recall. I have circled a few things, that's all.



MS. SHORES: Seth, I don't know what you want to do here. If he wants to refer things that he's written on, I guess I need copies of that.

MR. SILBER: That's fine. Do you want us to have copies made now or —

BY MS. SHORES:

Q: If we could try this, Dr. Levy, if you could refer to the one that we've marked, and then if you find that you need to look at the one that you've written on, maybe you could defer that issue.

A: Fine.

Q: Okay, if you could turn to page 8 of your report. Dr. Levy, does page 8 of the report that you have in front of you, your version of it, contain any handwritten annotations?

A: Yes, it does.

Q: And do you feel you're going to need to refer to those to answer questions about page 8?

A: I don't know what the questions will be. What those handwritten notes are are simply the page numbers in the Schering documents from which these various pieces of data came from. It just was — would expedite my going back to your documents to —

Q: Do you mind if I take a look at page 8?

A: No. Is it —



MR. SILBER: No, that's perfectly fine.

THE WITNESS: That's probably the most marked up of the pages.

MS. SHORES: I guess I would like to have a copy made of this.

MR. SILBER: Okay.

MR. CURRAN: Likewise.

MR. SILBER: Do you want us to just run a copy of the whole thing?

MS. SHORES: We might as well since we may run into this issue more than once, if we could just go off the record.

(A brief recess was taken.)

(Levy Deposition Exhibit Number 2, Expert Report of Nelson Levy with handwritten annotations, was marked for identification.)

BY MS. SHORES:

Q: Dr. Levy, I've now marked as Exhibit 2 to your deposition the annotated version of your report, which I think will help us enormously.

Looking at the left-land — the note that appears in the middle of the page on the left-hand side, can you read that for the record?

A: "Also headache at least one —" hmm, I honestly can't read my own writing — "at least one something at

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all doses —" oh, "at least one AE," that is adverse event, "at all doses in 80 percent."

Q: Dr. Levy, is that a page number reference?

A: No, that 80 refers to 80 percent.

Q: Okay. So, when you said before that there was nothing on this page but page number references, that wasn't true, right?

A: I'm a little uncomfortable saying it wasn't true. It was certainly not meant to be misleading.

Q: Well, are there — I'm sorry, it might have been misleading, is that what you said?

A: I said that I would not characterize it as being untrue. I think that's a bit of a pejorative perspective. It was — there are annotations on the — most of the annotations on the page refer to page numbers, and that is the exception.

Q: Well, let's look at the right-hand margin also in about the middle of the page. Are those page number references?

A: Yes.

Q: So, where it says, "Abnormal, greater than 1.5." that's a page number reference?

A: No, that refers to the standard of abnormality that was applied to that column.

Q: And underneath that, what does it say?

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A: "Pts used 92."

Q: Is that a page number reference?

A: Yes, it is.

Q: Okay. In your report on this page or just generally, you point to a number of concerns you say existed regarding the safety of Niacor-SR. Is that correct?

MR. SILBER: Misstates his report, objection.

THE WITNESS: It's correct that — it's correct that I refer to a number of adverse problems with Niacor-SR.

BY MS. SHORES:

Q: And do those include safety issues?

A: They include some safety issues.

Q: It says right at the top of this page that there are a number of concerns regarding the safety of Niacor-SR, does it not?

A: That's correct.

Q: You say in — where it's bolded in letter (a) about the middle of the page that most significant was the increased incidence of the elevation of liver enzymes in the blood of patients taking Niacor-SR. Is that correct?

A: You're reading correctly.

Q: Well, is that your opinion?

Page

A: My opinion is as stated in my report.

Q: Well, do you agree with this statement?

A: Of course I agree with it. I wrote it.

Q: Okay. There's a table that appears above that. Which lines in this table reflect the increased incidence of the elevation of liver enzymes?

A: The lines — well, there are several actually. Directly, the second and third lines from the bottom refer to that, but also lines one, two and three were heavily concerned with the hepatic enzyme elevations.

Q: Okay. Referring to the second and third lines from the bottom, what is SGOT?

A: That's one of the transaminases, which is an enzyme that's found in hepatic cells.

Q: Do you know what SGOT stands for?

A: Serum glutamic-oxaloacetic transaminase, I believe.

Q: What about AST, do you know what that stands for?

A: AST is a term that I must admit is a newer term from when I went to medical school, and so I don't really use that term very fluently.

Q: So, you don't know what those letters stand for?

A: I — I actually don't.

Page

Q: Okay. What about SGPT?

A: That's another — another transaminase enzyme found in liver cells.

Q: And can you —

A: And there, it's pyruvic. The P is pyruvic, and it's serum — I presume that's glutamic-pyruvic transaminase, but I'm not certain of that. It's embarrassing, actually having used these — this acronym for 40 years, never really to have thought about what it specifically stands for.

Q: And what about ALT?

A: ALT is the newer term, and it's an analogous comment to AST.

Q: Okay. Which of these, whether you refer to them as SGOT — why don't we go with the terms you're more familiar with — which of these is considered more indicative of liver toxicity?

A: I can't intelligently respond to that. I have never considered one of those enzyme elevations to be more important than the other.

Q: Is a patient's age a factor in liver function test results?

A: Yes, in my experience, there are — there are myriad factors that can lead to the — to enzyme elevations, and these tests are meant as screening

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tests. They're associated with hepatic toxicity but are found in — oh, for instance, trauma to the liver, trauma to the musculature. In some older patients there are wasting conditions, for instance, that can lead to release of enzymes not from the liver but from musculature particularly, since we have such a predominant mass of musculature in our bodies.

Q: So, is that a question, that age is a factor in liver function test results or it can be?

A: My answer is there are a myriad of things, and I don't think age, per se, is — is as important as some of the conditions that may be associated with age.

Q: Okay. How about a person's race?

A: I don't know the answer to that question.

Q: Okay. How about a person's body weight?

A: I don't know the answer to that question either.

Q: How about a person's gender?

A: I don't know the answer to that either.

Q: How about a person's consumption of alcohol, say the night before they get tested?

A: That most definitely can lead to enzyme elevations.

Q: Okay. How about if a person exercises or works out prior to being tested?

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A: That is — that is somewhat controversial. When I went to medical school and even when I was a professor, it was generally accepted that heavy — heavy work and heavy exercise could lead to enzyme elevations. As I understand it now, there are people who don't feel as comfortable with that assumption.

Q: Okay. How about if the person was taking some sort of pain medication?

A: That's a rather ambiguous question, because there are — there are certain pain medications that are associated with hepatic enzyme elevations, and it's not necessarily related to their analgesic activity. It's — it's — it is related to their having an effect on the liver. I mean, the most commonly recognized example of that is Tylenol or acetaminophen.

Q: Okay. Well, let me ask the question this way: If you were designing, you know, a study and you wanted to control for the effect of medications or at least keep a record of what the patients had taken to — so as to know whether the enzyme elevations that you're seeing are the result of what you're studying or something else, are there particular medications that you would want to control for?

A: Yes, there are medications that are known to — I mean, such as acetaminophen.

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Q: Okay.

A: I think that in general, when conducting particularly a short-term study, the most prudent thing to do is to exclude all medications since there are — there are myriad drug interactions that could occur, and many of these have not been fully characterized, because each drug is not studied in concert with every other drug, and so the safest thing, if one can do the trial this way, is to exclude all medications.

Q: Okay. And other than Tylenol and acetaminophen — those are the same thing, is that correct, or are they different?

A: Johnson & Johnson might think otherwise, but —

Q: Fair enough.

A: — if one assumes that the generic acetaminophens are manufactured to the same standard as Tylenol is, they are the same thing.

Q: Okay. But other than those, can you name any particular ones that are known to have some effect on liver enzymes?

A: Yes, toradol is an enzyme — is an analgesic that does that. The opiates in general are not to my knowledge associated with any form of hepatotoxicity, and so that excludes, you know, a large number of the analgesics.

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Q: Can you tell me where the data came from that appears in, again, those same two lines of your report, the ones entitled Elevation of Liver Enzyme?

A: Yes, all of the data in that chart I believe came from the — an exhibit that was attached to several of the depositions, and I believe it was — among other things, it was Exhibit 2 to the Audibert deposition. It's this document entitled Upsher-Smith Laboratories, Inc.

Q: And that's your personal copy of that document that you have before you?

A: I'm not sure I understand the word "personal." It is my copy of that document.

Q: And does that contain your handwritten notes?

A: I wrote a — just a couple of things on the cover. I don't believe there are any other notes in it.

MR. SILBER: Laura, we're obviously willing to let you look at the documents. If you want to check what notes are in there, you can do it yourself.

MR. CURRAN: I definitely want to check any documents that may have underlinings or annotations or other forms of the witness' notes.

MS. SHORES: Well, perhaps at a — when we take a break, we can check it and make a copy of it if it's

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necessary, but for now, I'm going to mark a clean copy of the document Levy Exhibit 3.

(Levy Deposition Exhibit Number 3, Upsher-Smith Innovative Pharmaceuticals Since 1919, was marked for identification.)

BY MS. SHORES:

Q: Can you tell me where in Levy Exhibit 3, which I believe is the data package that Upsher-Smith gave to Schering prior to the Niacor license, the data in the — in your chart that reflect elevated liver enzymes came from?

A: Yes, it was SP 160091.

Q: Okay. And what level of liver enzyme elevations do these data reflect? Again, the ones that appear in the two lines of your table on page 8 referring to elevated liver enzymes.

A: I don't understand your question.

Q: I'm trying to understand what level of liver enzyme elevations these numbers refer to.

A: These numbers refer to an elevation of 1.5 times the upper limit of normal.

Q: Okay. Is there a reason why you focus on 1.5 times the upper limit of normal?

A: Yes, I view the SGOT and SGPT tests as screening tests. If you will, we can personalize this

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for a moment. If you or I were to go for our physical examination where they do a chemistry battery, 15-20 tests, and if you were to have an SGOT or an SGPT at all above the upper limit of normal, it would be flagged, and what that would mean, depending on the magnitude of the elevation, is that if it were a relatively minor elevation, it would signal the physician to repeat the test. If it were a greater elevation, he would most likely still repeat the test, but it would signal to him to look further, perhaps to do a liver biopsy or some other exploratory action on you or me in the course of your physical examination, and I view this as the same thing.

Unfortunately, we were presented very little data in this package from Upsher-Smith. I can't say whether this represents a multitude of tests on the same patient. It most likely represents a single test on those patients. And so, I think that one in using a screening test, as this is, should use a fairly sensitive indicator.

Q: Can you tell me how many categories there are of lipid-lowering drugs?

A: I would say there are four major categories.

Q: And what are they?

A: HMG-CoA reductase inhibitors or the statins,

Page

the bile acid sequestrants, a class of drugs that are referred to as fibrates, and then the nicotinic acid-related drugs.

Q: Can you name — how many reductase inhibitors are there on the market now?

A: Many. I don't know the exact number.

Q: Can you name any of them?

A: Sure. Atorvastatin, you know, is probably the most commonly used one.

Q: Does that have a brand name?

A: Lipitor.

Q: Can you name any others?

A: Yeah, pravastatin.

Q: Does that have a brand name?

A: Yes, it does, and I — I don't usually refer to drugs by their brand name, I'm embarrassed to say in front of the branded pharmaceutical companies here, so I don't know.

Q: Okay. Any others?

A: There are several others. Mevacor.

Q: Does that have a generic name?

A: That is — actually, I believe that that is its brand name, and I believe its generic name is probably mevastatin. I don't know.

Q: Any others?

Page

A: There are many others. I just don't — you know, off the top of my head, I don't recall the names.

Q: Okay. How about bile acid sequestrants?

A: The —

MR. SILBER: What's the question?

MS. SHORES: The question is, can he name them?

THE WITNESS: The only one that I can name in that category is cholestyramine, which has many — it's a generic drug, and it has many brand names now, and I really don't know all the brand names.

BY MS. SHORES:

Q: Do you know which — what the name of the pioneer drug was?

A: I've just forgotten.

Q: And can you think of any other bile acid sequestrants other than cholestyramine?

A: I cannot, no.

Q: Okay. How about fibrates, can you name what drugs fall in that category?

A: Clofibrate is I think the one which at least to me is most — is most prominently known, and I won't venture a guess on the others.

Q: Okay. And is —

A: There are others, though.

Q: And is clofibrate the generic name or the brand

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name?
A: I believe that is the generic name.
Q: What are — I want to ask you about the side effects of each of these classes. Let's start with the reductase inhibitors or the statins. Can you tell me what the side effects are associated with statins?
A: The statins have been recognized as pretty clean drugs that have relatively few side effects. They are — they have been studied for a long time in many patients, and, of course, they're taken chronically, and I don't think there are any prominent side effects that appear frequently with these drugs. I believe that they have been reported to cause headache, and then when one looks at the PDR, there are — there's a whole litany of things that have been associated with them, but I don't think that any of those are prominent and frequent side effects of these drugs.
Q: Among the litany of things that have been associated with the statins, is hepatotoxicity one of them?
A: Hepatotoxicity, per se, is not what I would characterize as having been associated with the statins. The statins have been associated in a very small number of patients, a dose-related elevation of

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hepatic enzymes, and these elevations have — well, for instance, with Lipitor, where I have more recently looked at the data, at the — at the 10-milligram dose, for instance, the incidence was merely 0.2 percent. It was 0.2 percent at the 20-milligram dose. It went up to 0.6 percent at the 40-milligram dose, and at the highest dose, it was approximately 2 percent. And this refers to liver enzyme elevations, and all of these elevations were — were transient and were reversible. So, I don't look at that as hepatotoxicity.
Q: And when you say — you gave me a couple of different percentages, 0.2 percent at 20 milligrams, I think you said, 0.6 percent at 40 milligrams and 2 percent at the highest dose.
A: Um-hum.
Q: What do those percentages refer to, what level of liver enzyme elevation?
A: The fraction of patients in the clinical studies that showed these enzyme elevations.
Q: And do you know what level of enzyme elevations those percentages refer to? In other words, how many times the upper limit of normal?
A: I don't recall that number.
Q: Well, you say the data that's reflected in the data package showing the enzyme elevations at 1.5 the

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upper limit of normal is a problem for Niacor. Is that correct?
A: I didn't use those words.
Q: Well, what words did you use?
A: I said that those data raised a heightened sensitivity in me as I looked at those data and prompted me to have concern —
Q: Well, I think you said —
A: — that these drugs may be hepatotoxic and would definitely have prompted me to seek more information.
Q: I think you said, referring back to page 8 of your report, that, in your opinion, "such enzyme elevations in patients taking Niacor-SR would have alerted any person familiar with drug toxicity issues to the strong possibility that Niacor-SR was a hepatotoxic (i.e., toxic to the liver) drug."
Is that true?
A: I'm very comfortable with that statement.
Q: Okay. And in that sentence you're referring to the data showing enzyme elevations at 1.5 times the upper limit of normal. Is that correct?
A: It's correct that that statement refers to those data and the overall picture that was seen with this drug that is reflected in the table. It's not

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just the enzyme elevations. It's that these enzyme elevations were among the elements that were associated with the patients having to either drop the dose of the drug during the clinical trials or to remove themselves from the trial altogether.
In other words, these enzyme elevations were perceived by the patients and/or the physicians as significant enough to alter the course of the patient's participation in the trial.
Q: But the — from your point of view, the clinically significant information with respect to liver enzyme elevations is the data that shows 1.5 times the upper limit of normal?
MR. SILBER: Objection, misstates his testimony.
THE WITNESS: Yeah, I — that's not what I said, so I mean if you would like to — to give your own testimony, you're more than welcome to do that. That's not what I said.
BY MS. SHORES:
Q: I'm just asking you a question. You can correct me if I've misstated your testimony.
MR. SILBER: He just restated his testimony and the basis for his testimony.
THE WITNESS: I think that counsel has spoken

for me in that regard.

BY MS. SHORES:

Q: Well, that's not exactly the way things are supposed to go.

Is there any other line in your table on page 8 that has any other level of enzyme elevation other than 1.5 times the upper limit of normal?

A: In this table, there is no other information reflected.

Q: Is there anywhere else in your report where there's any other level of liver enzyme elevation other than 1.5 times the upper limit of normal?

A: I don't recall in my — in my report referring to any other data specifically on that — on that matter.

Q: Okay. But you're not backing away from your statement that those data gave you concern. Is that right?

A: It's correct that I felt when I wrote the report and I feel, as I sit here today, that the incidence of enzyme elevations reflected in this table cause me considerable concern and still do.

Q: Do you know what the data for some of the other lipid-lowering drugs — let's take the statins. Do you know what the data for the statins show with respect to



how many incidences patients experienced in the clinical trials of liver enzyme elevation at 1.5 times the upper limit of normal? I'm trying to get at what you compared this data to.

A: Well, now you're asking me two questions. If you're asking me directly what — to what I compared these data and what led to my conclusion, I think I responded to it earlier. In my opinion, as a physician, as a scientist, as a person who's conducted clinical trials, as a person who's reviewed many, many, many clinical trials, these liver enzymes to me are a mere screening test, and if they are elevated at all above the upper limit of normal in any significant fraction of patients, they absolutely alert me to a potential concern and a grave concern about the possibility of there being liver toxicity.

They don't by themselves speak to the presence of liver toxicity. They alert any cogent physician in my opinion to the possibility that liver toxicity exists and should mandate to that clinical researcher or physician further investigation.

Q: Okay. Do you know what the comparable data are for the statins?

A: As I testified earlier, I know the data that I related to you, and I don't recall what standard was



used in arriving at that percentage of patients in the clinical trial.

Q: Okay. So, you don't know what multiplier of upper limit of normal those percentages that you gave me earlier reflect?

A: I would repeat what I just said.

Q: Well, I'm asking you to answer the question. I'm just trying to understand your testimony.

A: I do not recall what standard was used to arrive at the percentages of patients taking Lipitor that had elevations of their hepatic enzymes.

Q: Okay. So, when you said that Lipitor showed, for example, 2 percent of patients experiencing liver enzyme elevations at the highest dose, you can't tell me whether 2 percent of the patients experienced liver enzyme elevations at 1.5 times the upper limit of normal or two times the upper limit of normal or three times the upper limit of normal. Is that right?

MR. SILBER: Objection, misstates his testimony.

THE WITNESS: What I'd say to you is what I said before, is that candidly, I don't care. I'm looking — I spent my time looking at these data, not comparing them to another situation, another drug.

In my opinion — and I will repeat this — that



the enzyme elevations at the level of 1.5 percent the upper limit of normal is significant enough to me that I would not have failed to insist that further information be gathered on this matter.

BY MS. SHORES:

Q: Do you know what the exclusion criteria were for Upsher's clinical trials for Niacor on the issue of liver enzyme elevations?

A: Yes, I believe that at least in one of the clinical trials, the — I don't recall seeing the inclusion criteria for both of their pivotal trials, but I do recall seeing that at least with one of those clinical trials, they purposefully excluded patients that had enzyme elevations greater than 1.5 times the upper limit of normal.

Q: So, does that mean that there could have been patients in the trial who even before they took Niacor had liver enzyme elevations of 1.4 times the upper limit of normal?

A: I would — I would repeat that they excluded patients with enzyme elevations greater than 1.5 times the upper limit of normal. What degree of flexibility they used in applying that standard I can't — I can't say. I don't know what they would have done with someone with a 1.4 times the upper limit of normal.

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One can assume that all the physicians followed the protocol, but I can't know that.

Q: Well, let's assume they followed that standard strictly and that they excluded people with 1.5 times the upper limit of normal and greater and included people who didn't have enzyme elevations at that level. Would that mean that patients at 1.4 times the upper limit of normal would have been included in the study?

MR. SILBER: Objection, incomplete hypothetical.

THE WITNESS: By your hypothetical, if you're assuming that the protocol was adhered to strictly, patients could have been included in this study with enzyme elevations 1.4 times the upper limit of normal; however, the distribution of those patients would have been random and would have been in both the placebo or control groups as well as all the various dosage groups, and therefore, one would not have expected to see a dose-related increase in the percentage of those elevations in patients taking Niacor-SR.

BY MS. SHORES:

Q: Can you explain why if 1.5 times the upper limit of normal is in your view evidence that strongly suggests liver damage why the studies would include people up to 1.5?

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MR. SILBER: Objection, misstates his testimony.

THE WITNESS: Yes, I — you seem particularly interested in mischaracterizing what I've said, and that's — if you enjoy doing it, I'll be happy to —

BY MS. SHORES:

Q: Well, please correct me. I don't mean to mischaracterize it.

A: No, I did not say that an enzyme elevation of 1.5 times the upper limit of normal definitely connotes liver toxicity. I've said, and I'll say it again, that this test is a screening test. It alerts me and it should alert anybody else looking at these data for the possibility of there being hepatotoxicity associated with this drug.

Q: A strong possibility. Is that correct?

A: If you — a strong possibility I'm not uncomfortable with.

Q: Well, you said it in your report.

A: As I say, I'm not uncomfortable with that at all.

Q: Good. So, 1.5 times the upper limit of normal, in your view that's indicative of a strong possibility that there's liver damage, correct?

MR. SILBER: Objection, misstates his testimony.

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MS. SHORES: I'm just asking a question.

THE WITNESS: That's not correct. There is a strong possibility that an elevation of liver enzymes associated with 1.5 times — an enzyme elevation 1.5 times the upper limit of normal could be associated with liver toxicity.

BY MS. SHORES:

Q: Okay. Do you think you're in the minority of experts who consider 1.5 times the upper limit of normal to be the relevant benchmark?

A: I think that I am in the distinct majority since virtually every physician in America, certainly those that went to the medical schools and residence trainings that I attended, would use an SGOT or SGPT elevation exactly as I said, that if it were elevated at all above the upper limit of normal, it would be flagged. It would suggest to the physician that at a minimum he or she repeat the test, and if it were still elevated, even minimally elevated, and consistently so after repeat tests, would prompt that physician to look for an explanation.

Q: Would it surprise you to learn that the FDA told Upsher-Smith that it considered liver function tests at three times the upper limit of normal, at

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successive elevations of that, to be clinically significant?

A: You're asking me a very different question now.

Q: Yep.

A: And if you're asking me did it surprise me that the FDA set a standard of three times the upper limit of normal to connote the presence of liver toxicity, I am — no, it doesn't surprise me. They're using the test differently from the way I am using it in this regard.

Q: In what way are —

A: I said I am using it as a screening test. What I tried to do in reviewing these data is to put myself in the position that Mr. Audibert was in when he first saw these data and tried to speculate as to what I would have done in that position, and that is a very different position from that that the FDA faces when it sees a compilation of data and has to make a decision on those data.

To me, when I saw those data, and hence, when I wrote this report, it said to me that without question, without one iota of question, having seen those data, I would have demanded more information and a more extensive elucidation of those elevations before I would have considered moving forward in any way, shape

or form with this compound.
Q: If Mr. Audibert had considered the relevant benchmark to be successive elevations at three times the upper limit of normal as opposed to what you considered to be a red flag at 1.5, would he just be wrong?
A: In my opinion, he would be wrong.
Q: Are you familiar with Dr. Bertram Pitt?
A: Yes, I am.
Q: Would it surprise you to learn that he considers successive elevations at three times the upper limit of normal to be clinically significant?
A: No, I've read his report, and I would repeat to you that I view these enzyme tests as a sensitive screen that should be pursued if they're abnormal. If Dr. Pitt or Mr. Audibert chooses a less sensitive indicator in this kind of screening modality, then I would ask you to have them defend that. I would choose a different standard.
Q: Okay. Well, you said Mr. Audibert would have been wrong if he had chosen a different standard.
A: If he —
MR. SILBER: Misstates his testimony.
THE WITNESS: — if he were to choose the standard of three times the upper limit of normal as



the screening threshold that would have led him to seek additional information on this matter, I would consider him wrong.

BY MS. SHORES:

Q: And what about Dr. Pitt?
A: I would say the same for Dr. Pitt. If he were to have used the standard as three times the upper limit of normal to alert himself to the possibility of there being liver toxicity present and to prompt him to look for additional information, were he in that context to have used the standard of 3X times the upper limit of normal, I would think he is being — I would think he as being incorrect.
Q: And the FDA would have been incorrect, too, if they had focused on two or three times — successive elevations at two or three times the upper limit of normal, they would be wrong?
A: No, the FDA is using it in a different manner. The FDA has to make the judgment as to whether the drug is hepatotoxic, and they can't go back and — they can mandate additional studies being done, but they can't go back and simply do those studies, and they have chosen a standard that is at 3X to connote hepatotoxicity, and that's a different matter from choosing a standard that would suggest the possibility



of hepatotoxicity.
Q: Well, the FDA is charged with determining whether or not a drug is safe. Is that correct?
A: Yes, they are.
Q: Okay. And are you saying they're not being conservative enough if they focus on three times the upper limit of normal?
MR. SILBER: Objection, misstates his testimony.
MS. SHORES: I'm just asking a question.
THE WITNESS: That's not what I said.

BY MS. SHORES:

Q: I'm just asking to try to understand where you're coming from here.
A: The FDA is faced with a data set and must make the — must draw the conclusion as to whether a drug is or is not hepatotoxic, and they have chosen that standard. That is a more conservative standard than the one that I would choose that's one and a half times the upper limit of normal, because I have the luxury, as a person who is going to make the decision to license a drug or not license a drug, to ask for additional information. I don't have to license that drug. I don't have to take the chance that that drug would be hepatotoxic.



Q: Does the FDA —
A: I can ask the sponsor of the study for more information, and I would choose to do that were I to be faced with those data, just as I would and as any physician in America would were he faced with an enzyme elevation one and a half times the upper limit of normal. Were you to go in for your physical examination or I and to have an SGOT or SGPT elevation of the magnitude that I'm defending, that is, one and a half times the upper limit of normal, your physician or mine would seek that test to be repeated, and if it — if it consistently was elevated, he would or she would seek a cause and an explanation of that elevation, and I would expect no less in my review or anyone else's review of a potential in-licensing candidate.
Q: Going back to the FDA, did you — you might have misspoken or I might have misheard you, I thought you said their standard was more conservative than yours.
A: Their standard was more conservative in terms of identifying a compound as being hepatotoxic. I mean, they are not willing to label a compound as hepatotoxic unless it has this elevation of 3X upper limit of normal. They are being conservative vis-a-vis the wishes of the industry. They may be being — they

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would be being less conservative if one looks at it from the other context of identifying potentially hepatotoxic agents.

Q: So, do you think the FDA is less conservative than you are in their concern for identifying potentially hepatotoxic agents?

A: That's not what I said. There it's not a question of the FDA's concern or lack of concern. It's a question that the FDA has a different charge from what I would have in making the decision to in-license a compound, and the other parameter that you are not considering in any of this discussion is the frequency with which these kind of elevations appear.

Q: I just haven't gotten there yet.

Still on page 8 of your report, it says — and I'm reading from the bottom of the paragraph labeled (a), "Such data would have mandated a detailed examination of the effects of Niacor-SR on the liver prior to any consideration of in-licensing the drug. Such detailed examination in my opinion would have included, at the least," and then there's a little (i), "Examination of liver biopsies in patients treated with Niacor-SR."

What does a liver biopsy entail?

A: It entails — the most frequent liver biopsies

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are needle biopsies, and it would entail placing a small needle or trocar in the liver and withdrawing a piece of tissue and examining it under the microscope.

Q: How does it — can you just describe the procedure? I mean, how does it work? How does the needle get to the liver?

A: The patient is given local anesthetic. The area is surgically prepped, it's cleansed, and a needle — usually I used an 18-gauge needle when I did this, and people use larger ones, but 18-gauge is about the size needle that's used to give an intramuscular injection, and it has a metal plunger that goes down through the bore of the needle. This is injected — this is pushed through the skin into the liver, and then the plunger is withdrawn, and it pulls a small piece of tissue with it.

Q: So, the needle actually, it goes through your flesh to your — I mean, through your skin, through your flesh, and then takes out a little piece of your liver?

A: That's correct.

Q: Is the patient awake for the procedure?

A: Yes.

Q: Now, how is it that you would expect someone who was considering an in-license of Niacor-SR to do

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these liver biopsies?

A: I would expect to see some additional clinical data generated on patients who were dosed with Niacor-SR and liver biopsies obtained. Ideally, I'd like to go back to those patients that had had the enzyme elevations and examine the course that they had following the study and also seek to dose them again and biopsy them again, biopsy them.

Q: So, again, how would you expect someone who was considering an in-license to accomplish that? Would they demand that of in this case Upsher, that they go and perform these liver biopsies?

A: Yes, it would be quite reasonable to ask the licensor to do these kind of studies. This class of drugs, sustained-release niacin compounds, have been associated with quite significant liver toxicity, not just enzyme elevations. Likewise, nicotinic acid itself has been associated with fulminate, serious hepatotoxicity, and knowing that, one would have been and should have been very careful with the in-licensing decision on another member of this very class, and it is in that context that I would insist upon the assiduousness that I've described in this report.

Q: Would you expect that the FDA would have required Upsher to perform liver biopsies of the

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patients in this clinical trial?

A: It's my opinion that the FDA would have rejected this drug based on the data that it had before it and wouldn't have required them to do anything further, just simply would have rejected the drug and insisted that they go back and perform more pivotal trials.

Q: Let's assume that the FDA differed with you on what these data show and that they wouldn't have rejected the drug based on the data that you examined. Let's just assume that.

A: Um-hum.

Q: Would you expect that the FDA, before approving the drug, assuming that that didn't knock it out by itself, would ask Upsher to conduct liver biopsies?

MR. SILBER: Objection, incomplete hypothetical.

THE WITNESS: I would say — let me understand what — what your hypothetical is.

BY MS. SHORES:

Q: Okay.

A: Am I correct in assuming that you're asking me whether — were the FDA to have been unconcerned about the elevations in liver enzymes, then had asked the sponsor to conduct liver biopsies?

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Q: Um-hum, before approving the drug, yeah.
A: I would say that that is to me a bizarre hypothetical, because certainly if the FDA had no concerns about the liver enzyme elevations —
Q: I — I —
A: — I don't think that they would require a party to do a liver biopsy.
Q: Maybe I misspoke. I don't think I asked you to assume they had no concerns. I asked you to assume that they disagreed with you and your view that these data alone were sufficient grounds to reject the drug, but let's say it gave them some concern. If they were concerned but not concerned enough to reject it out of hand, would you expect the FDA to ask Upsher to conduct liver biopsies?
MR. SILBER: Objection, misstates his testimony, incomplete hypothetical.
THE WITNESS: Would you mind repeating that hypothetical again?
BY MS. SHORES:
Q: Sure, sure, absolutely. I'm asking you to — you said, I think, that in your opinion, the FDA would not have approved Niacor-SR based on these data.
A: Let me respond to that.

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Q: Okay, I thought that's what you said. We can —
A: That is what I said. When I say "these data," there are other data that were provided, and there were data provided at the higher standard as well. There were data provided for the 115 study, I believe it was, on all three doses plus the immediate release at the higher standard that you alluded to before, and that is three times the upper limit of normal.
Q: Um-hum.
A: And even at that standard, the incidence of liver toxicity was in my opinion considerably too high for the FDA to have considered approving this drug.
Q: Okay, and I'm asking you to go with me a little bit here and assume that you're wrong about that, okay, assume that those data were not sufficient in and of itself for the FDA to reject the drug. They still were interested in it. Had concerns, but didn't reject it out of hand.
A: Um-hum.
Q: Would you then expect, before approving the drug, that the FDA would require Upsher to conduct liver biopsies?
MR. SILBER: Objection, incomplete hypothetical.

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THE WITNESS: If the FDA were to have looked at the data that I saw, that is, all these enzyme elevations, the — the high incidence of withdrawal from the study and dose reductions, you know, in the pivotal trials, if they were to look at that whole picture and were still, to paraphrase you, I believe, on the fence about this drug, that is, uncertain which way to go, there are many directions that they could have taken.
In my opinion, the FDA looks at this drug — would look at this drug and looks at any other drug before it with a risk-benefit analysis, and they would not look at this liver toxicity information in isolation. They would look at the benefit that this drug offers to the patient community and then try to make an assessment as to whether the adversity produced by the drug or potential adversity produced by the drug is worth the risk.
I think when they looked at the whole panoply before them concerning this drug, they would have come to the conclusion that this drug is simply not worth subjecting the populace to the risk of hepatotoxicity.
BY MS. SHORES:
Q: And now I'm just asking you to assume that they didn't form that conclusion based on these data, but

Page

there were sufficient concerns indicated by the data to make them want to, as you put it, seek further information. Would that include asking Upsher to conduct liver biopsies?
A: There are — if your hypothetical were, indeed, to have been operative, that is, if they were to have been, if you will, on the fence about this drug vis-a-vis the enzyme elevation data and other data, there were various paths that they could have taken.
One of those would have been to mandate that the sponsor conduct an additional trial that would include dosing patients and performing liver biopsies. There are other paths as well. They could have and probably would have strongly considered mandating that the sponsor perform additional pivotal trials.
For instance, taking — dosing patients at higher — at higher levels of the drug, recognizing that this was a dose-related effect and that the behavior of the patient population is often to take more of the drug than is supported by the labeling, and so to afford themselves a margin of safety, a simple thing that they would have done or could have done would be to have mandated an additional pivotal trial, this time dosing the patients at, say, 3000 or 4000 milligrams per day as opposed to the upper limit that

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they used of 2000.
There are various things that the FDA could do. I am quite confident that they would have — that doing nothing is not one of their alternatives. They absolutely would have had their sensitivity raised because of these data, and they would have mandated that the sponsor do something. Whether liver biopsies would have been one of the things that they would have mandated is possible.
Q: Would you expect that liver biopsies were done in the clinical trials for statins?
A: I don't know the answer to that question.
Q: Would it surprise you to learn that there was never a liver biopsy done of any patient in any clinical trial for a statin?
A: It wouldn't surprise me at all that liver biopsies were not performed in patients with statins.
Q: Okay.
A: For a variety of reasons.
Q: Why is that?
A: First of all, the incidence of elevated enzymes in these patients was considerably less. Secondly, this was a class of drugs that was perceived as a break-through in the treatment of hyperlipidemia. And again, on the risk-benefit continuum that I spoke of

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earlier, the statins would have — would not have elicited the level of adverse effect sensitivity that a drug of lesser import would.
Q: I think earlier you referred to — and I'm going to get in trouble for mischaracterizing your testimony, so please correct me — you said something along the lines of given the past history of this drug, these data would have — and the niacin now I'm talking about — these data would have caused you concern. What past history are you referring to?
A: I didn't say the past —
MR. SILBER: Objection, mischaracterize his testimony.
THE WITNESS: — history of this drug.
BY MS. SHORES:
Q: I told you I was going to get it wrong.
A: I said the past history of that class drug, the sustained-release nicotinic acid.
Q: And what past history was there for the sustained-release nicotinic acid?
A: There were various attempts to produce a sustained-release-nicotinic acid preparation that are alluded to in the literature.
Q: Were those over-the-counter products or prescription products?

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A: I don't think they made it that far, but I don't know the answer to that.
Q: Okay. Do you want to take a short break?
MR. SILBER: Sure.
(A brief recess was taken.)
BY MS. SHORES:
Q: Dr. Levy, can you identify all of the materials that you have spread out before you?
A: Yes. I'm confusing myself here. These are both copies — I believe identical copies of the data package that was given to Mr. Audibert when he was evaluating the Niacor opportunity, and this one is the one that I brought with me, and this is the one that I believe is a clean copy that was provided to me.
Q: Okay, and just for the record, you're referring to what's been marked as Levy Exhibits — I believe that's —
A: This is the — the clean copy is marked as Levy Exhibit 3.
Q: Levy Exhibit 3.
A: And this one is marked as Audibert Exhibit 2. This was not — this is not an exhibit to my deposition as far as I understand it.
Q: Okay, okay.

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A: I'm getting confused with these documents.
Q: And just so I'm clear, the one that you're — in your right hand here, that is a copy of, again, the Upsher-Smith data package that contains at least some handwritten notes of you. Is that right?
A: Yes, ma'am.
Q: Okay.
A: Let's see, this is a copy of my comment on the expert report of Walter Bratic, and it contains no handwritten marks except for the fact that on the last page I circled the words "company's historical licensing practices."
Q: Okay.
A: Let's see, this is a copy of Dr. Bertram Pitt's rebuttal report, and it contains on the table — the only additional markings that I placed were the page numbers referred to for each of the numbers in his table.
Q: Okay.
A: This is a printout of the front page of the subscriber version of the Recombinant Database that Mr. Bratic referred to in his expert report, where he used the free version that doesn't have this detail. So, I thought that if that line of questioning were to have emerged, I could have shown you how those databases

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differ. There's no markings on that.
Q: Okay.
A: This is a table of the Schering agreements that were alluded to in Mr. Bratic's report and contain various markings highlighting some of the elements of those agreements.
This is a printout that we derived from the subscriber version of the Recap Database referring to Genome Therapeutics, which was one of the licensing deals, where I simply wanted to identify and characterize the various types of past payments that were made.
Q: And that contains some notes, right?
A: That contains some notes.
Q: Yep.
A: This is the same printout from that same database regarding another agreement. This was the Myriad Genetics.
Q: And some notes on that document, as well?
A: There are some notes on that.
Q: Um-hum.
A: This is a table, again, listing the 23 other agreements — or non-Schering agreements that were alluded to in Mr. Bratic's report. There are no marks on that table.

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Q: Okay.
A: This is Exhibit 1 from Mr. Audibert's second deposition, and it is the material on Niaspan. There are no marks of any sort in this.
Q: Okay.
A: This is a printout from the pages of Goodman and Gillman's Textbook of Pharmacology that relate to nicotinic acid.
Q: Okay.
A: This is a rather unusable copy of the Physicians' Desk Reference entry regarding Niaspan, unusable because it's — the xerox didn't pick up part of the page, and so I can't read it.
Q: Okay.
A: But that's what it is.
Let's see, and finally, this is the transcript from Audibert's second definition —
MR. SILBER: Deposition. You said "definition."
THE WITNESS: Oh, I'm sorry.
BY MS. SHORES:
Q: That's all right.
A: Audibert's second deposition, and the only notes that it contains are on the front page where I summarize some of the — my comments and recollections from that deposition.
I believe that's everything.
Q: Okay. And are there any other materials that you brought with you today that you feel like you may need to refer to?
A: No.
MS. SHORES: I think based on that we are entitled to copies of those. I don't need to interrupt the deposition now to have them made, but —
MR. SILBER: As I stated off the record, the position that I'm setting forth is that if he needs to refer to one of these documents today in response to your question, we will provide that, and my position in part — and someone else may be helpful to clarify this — is I understand that at the deposition of Greg Brown, who was on the Upsher fact list, there was some dispute about some notes that he had at his deposition that were not provided to counsel, and —
MS. BIERI: They were provided to counsel.
MR. SILBER: They were provided to counsel?
MS. BIERI: Yes.
MR. WASSERMAN: Yes.
MR. SILBER: At the deposition?
MS. BIERI: Yes. There was a disagreement over whether they should be, and they were, in fact, provided to counsel. He wasn't relying on them, they were just in front of him.
MR. CURRAN: And he's a nonparty fact witness.
MR. SILBER: Okay, and doesn't have an attorney-client relationship in the same way that Dr. Levy does, and that was the reason I was raising that and that was the basis for my position. If that's incorrect, I don't have a problem providing these materials.
MS. SHORES: Okay, well —
MR. CURRAN: Your colleague did get the materials. He also got an oral comment, but —
MR. SILBER: I know, I know, I certainly heard about that, but you tell me how you want to proceed. I can have someone now while we continue make copies of these documents.
MS. SHORES: That would be terrific, and then if I ask a question that — I hope I don't do this — that you need to refer to something that's out being copied, we will just put it off and pick it up when they come back.
MR. SILBER: Okay.
MS. SHORES: Okay?
MR. SILBER: That's appropriate.
(Witness confers with counsel.)

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THE WITNESS: This is more consistent with your current line of questioning, so —

BY MS. SHORES:

Q: Okay, right, and I think I can predict that we are going to be on that for a little bit.

Again, I am going to get in trouble again for mischaracterizing something you said, but I thought you said something about the data for statins, that the liver enzyme elevations were shown in the case of statins to be reversible. Is that right?

MR. SILBER: Objection, misstates his testimony.

THE WITNESS: I don't think I said that. As I understand the liver enzyme elevations on the statins, from my readings in the Physicians' Desk Reference and another analogous publication, as well as the textbooks of pharmacology, the elevations — the hepatic enzyme elevations seen with the statins are seen very infrequently and are reversible when the — when the drug is stopped, and actually in many cases even when the drug is continued, the enzyme elevations remit.

BY MS. SHORES:

Q: Okay. And why is reversibility important in your opinion?

A: Reversibility, per se, I think has to be

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qualified. Reversibility can mean that there was hepatic damage being caused, and this hepatic damage, upon stopping the drug, was repaired, the liver having the capacity — I guess it's one of the very few organs in the body that has the capacity for self-repair.

It also can mean something even less significant than that, and that's that the enzyme elevations themselves were unrelated to any sort of hepatotoxic event and went away for a variety of reasons.

Q: Okay. Are there cases in which the FDA has approved drugs — well, let me strike that, I'll start that over.

Are there cases in which you can prescribe and use a drug and monitor the liver enzymes of the patient and then simply remove the patient from the drug when you see that occurring?

A: It's very frequent that the FDA will mandate in the labeling that patients be periodically followed with hepatic enzymes and for the purpose of identifying in the screening modality to which I alluded before the possibility of there being hepatotoxicity and thereby alerting the physician to stopping the drug or reducing the dose of the drug in the course of the patients being treated with that drug.

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Q: How about any lipid-lowering drugs, do any of those fall in that category other than the niacins?

A: I believe that the — there's recommendation that the statins — the patients on the statins be periodically examined for elevations of liver enzymes, and the fibrates as well. I don't — I don't think that the bile acid sequestrants have that recommendation.

Q: Okay. And in the case of the statins, do you know whether the labeling or the PDR, what level of liver enzyme elevation they refer to there?

A: I don't recall and I don't have in front of me the printout for any of the statins from the PDR, and I don't recall what standards of enzyme elevation they use.

Q: Would it surprise you that if, in the case of the statins, the level of liver enzyme elevation that the labeling and the PDR indicate is three times the upper limit of normal?

A: If you're asking me whether it would surprise me, I don't think it would surprise me.

Q: Okay. So, it wouldn't surprise you that according to the FDA, the relevant standard is three times the upper limit of normal, not 1.5 times the upper limit of normal in the case of drugs where you

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might want to remove them from the drug if they show —

A: I think, again, you know, if I may say, I think you're mischaracterizing what I'm saying.

Q: I'm just asking you a new question, that's all I'm trying to do.

A: I don't think that I said that this would — would you mind repeating what you just said?

Q: Sure, I'll try, and I believe it was just a poorly phrased question and maybe I'll improve on it.

I think you said that there are some drugs where the labeling or the PDR indicates that you should monitor them for increased liver enzyme activity and remove them from the drug, and my question was, would it surprise you that in the case of statins, what the PDR says is you should do so when the patient experiences successive elevations at three time the upper limit of normal as opposed to some lower multiplier?

MR. SILBER: Objection, misstates his testimony.

THE WITNESS: I don't understand what you mean by —

MS. SHORES: I didn't refer to his testimony.

THE WITNESS: — by "would do so." What do you mean by "would do so"?

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MS. SHORES: Can you read the question back?
(The record was read as follows:)
"QUESTION: I think you said that there are some drugs where the labeling or the PDR indicates that you should monitor them for increased liver enzyme activity and remove them from the drug, and my question was, would it surprise you that in the case of statins, what the PDR says is you should do so when the patient experiences successive elevations at three time the upper limit of normal as opposed to some lower multiplier?"

BY MS. SHORES:

Q: By "doing so," I meant remove the patient from the drug.

A: Would it surprise me that the FDA has suggested that patients be removed from the drug when they have a persistent elevation of the hepatic enzymes at a level greater than three time the upper limit of normal? I would say that that doesn't surprise me if that's the entry, because removing the patient from the drug, particularly a drug that is a primary mode of therapy for a very serious condition, removal of the patient from the drug is a fairly significant medical decision, and so the — the FDA has said — the FDA has looked at this in a — again, a risk-benefit fashion, saying that

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a person with an elevated cholesterol, with a hyperlipidemic condition, who's on a statin, is at greater risk being removed from the statin and suffering the hyperlipidemic condition than he or she may be from less significant elevations of liver enzymes.

Implied is that this patient would continue to be monitored, say the patient with an elevation of liver enzymes but at a lesser degree than the three times upper limit of normal. The patient, under I believe prudent medical care, would be monitored and perhaps monitored more frequently, and the course of the patient's hepatic function would be followed by this physician.

For instance, the elevation of liver enzymes, as I've said many times this morning, is the screening tool. One would look at the patient for clinical signs of any hepatic aberrancy. For instance, is there the presence of jaundice or some of the other symptoms of heparotoxiciry apparent? There are myriad things that, again, a physician can and should do in the face of hepatic enzyme elevations that fall short of simply removing the patient from a drug that the patient needs.

Q: Okay. Would you expect, then, in the PDR or

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the labeling for statins that there is some guidance about what to do if the patient shows elevated liver enzymes on the level of 1.5 times the upper limit of normal?

A: Excuse me.

Q: Sure.

A: I need my Claritin.

I'm sorry, would you please repeat that?

Q: Sure. My question was, would you expect, then, in the PDR or the labeling for a statin that there would be some guidance as to what a physician should d if a patient on the drug experienced elevated liver enzymes on the order of 1.5 times the upper limit of normal?

A: I don't — the PDR is not a textbook of medicine. The PDR doesn't offer guidelines for physicians in the proper practice of every facet of medicine, and I — I think that by suggesting that liver enzymes be monitored on patients taking these medications, the assumption is made that physicians will use those data in a prudent manner and would use any abnormal laboratory finding as one of the parameters in the evaluation of this patient's well-being.

Q: You said in your report that one of the things

Page

somebody or anybody considering a license of Niacor would have done is to look at the reversibility and the persistence of the enzyme elevations.

A: Yes, I believe I said that.

Q: Is that right? Okay.

And you fault Schering for not having done that. Is that right?

A: No, I don't believe I fault Schering for not having done that. There was provided some information in this data set from Upsher regarding the reversibility, and I think that that information in my opinion should have been more thoroughly examined, and it — as I believe would have been required by the FDA and to me would have been required were I to have licensed the drug, additional pivotal trials should have looked very carefully at the reversibility or lack thereof of these enzymes — of these enzyme elevations.

Q: What did the information in the data that Schering was given show on the issue of reversibility?

MR. SILBER: Feel free to look at the document if you need to.

THE WITNESS: Yes, please, if I may refer to that.

BY MS. SHORES:

Q: Sure, please.

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A: There is a table in here. (Document review.)
Q: If I can help, you might look at pages 92 to 93.
A: Thank you. (Further document review.) Yes, I believe on page 93 — yes, on page 93, there were data referring to this issue.
Q: And did it show whether the enzyme elevations were reversible?
A: These data were actually of some concern to me. The answer to your question is I don't think one can really talk about the reversibility from — from these data. This is the sort of incompleteness to which I was referring in my report.
Q: Okay. Is —
A: What — what the — if one simply looks at the figure on the — the lower of the two figures on that page, it says that 48 patients returned to within laboratory normal range. One normalized on a full dose and completed the study. Forty-eight normalized after the study medication was discontinued —
MR. SILBER: I think it says 44.
THE WITNESS: I'm sorry, 44 normalized after the study medication was discontinued prematurely or due to study completion. Three normalized on a reduced dose and completed the study.

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What I would have preferred to see and what concerns me is recognizing that Niacor-SR is a chronic medication that must be given for the life of the patient, in contrast, for instance, to an acute medication, like an antibiotic. An antibiotic, if given for, say, a two or three-week period causes a transient elevation of liver enzymes, and then those liver enzyme elevations go away after the drug is withdrawn, it's of no real consequence, because the patient only needs this medication for three weeks.
This medication must be given for the life of the patient, and so it doesn't solve anything to have to withdraw the patient from the medication for the liver enzyme elevations to remit. What I would have preferred to see is the normalization of the liver enzyme elevations while the patient continues on the drug, and this happens with other types of medications.

BY MS. SHORES:

Q: So, in your report where you say that someone considering a license should have examined whether the enzyme elevations disappear after the drug is stopped, you now think that's not important?
A: I didn't say —
MR. SILBER: Are you clear to where she's pointing to?

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MS. SHORES: It's at the bottom of page 8.
THE WITNESS: I didn't say that that's not important. I want to look at the whole panoply of hepatic effects of this drug when the drug is used as it will be used or would be used in the clinical setting.

BY MS. SHORES:

Q: Okay, but that's what's referred to in the remainder of that sentence, right?
A: Well, you're taking out of context that — a part of that sentence.
Q: I am?
A: What that whole sentence says is, "Examination of the reversibility and persistence of the enzyme elevations, i.e., do the enzyme elevations disappear after the drug is stopped and do the enzyme — do the elevations persist with prolonged administration of the drug?" And the second half of that sentence, that is, "do the elevations persist with prolonged administration of the drug," is that to which I was alluding earlier and which would be important to me in a patient who is going to need this drug for the duration of his life.
Q: And that would have been more important to you to show than the issue of whether they disappear after

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the drug is stopped?
MR. SILBER: Objection, misstates his testimony.
THE WITNESS: I didn't make any value judgment on —

BY MS. SHORES:

Q: I'm asking you now.
A: — on what is more important. I think that it's one incomplete piece of the puzzle that the enzyme elevations do or don't normalize when the drug is stopped. Another piece of the puzzle is whether they do or don't normalize when the drug is continually dosed.
Q: And the piece of the puzzle with respect to whether the enzyme elevations disappear after the drug is stopped, that piece was in the data package Schering had, right?
A: Would you repeat that, please?
Q: Yeah. The piece of the puzzle showing whether the enzyme elevations disappeared after the drug is stopped, that information was in the data Schering had, correct?
A: Yes, those data would be the least demanding standard to apply to these enzyme elevations.
Q: Okay.

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A: And to me, of far less significance for the reasons I said before, because this drug is going to be chronically used.

Q: I tried to ask you that question, and I got an objection.

Okay, if you would turn to the top of page 9 of your report. You say that anybody considering an in-license of Niacor-SR would necessarily have had to conduct a detailed examination of the histopathology results from animal toxicology studies done prior to the clinical trials.

Do you see that at the top of page 9 of your report?

A: Yes, I do.

Q: What additional information would that have given somebody considering an in-license on Niacor-SR?

A: As I — as I think I've tried to indicate, the enzyme elevations in a class of drugs that have been associated with significant liver toxicity alert me to the need for all the additional information I can get. Among the body of additional information realistically available to me are those data alluded to in this detailed examination of the histopathology results from animal toxicology studies done prior to the clinical trials.

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Q: Okay. And I guess I'm trying to get an understanding of what the animal toxicology tests might have shown, if you could just give me an example of the — what you have been looking to see in that data.

A: Well, there are any number of things that it could have shown. If the animal toxicology studies were entirely clean, if the animal toxicology studies had shown no enzyme elevations, if the examination of the histopathology in the rats and dogs in which these studies presumably were done showed no effect on the liver, it would have been encouraging.

Q: Okay.

A: If, on the other hand, it had shown the opposite, if there had been the same sort of enzyme elevations or more seen in the animals and if the histologic examination of tissues from these animals had shown actual hepatic necroses or other aspects of hepatotoxicity, it would have been a very — a very negative finding, you know, for these drugs.

Q: Okay. What do the histopathology results from the animal toxicology studies on Niacor-SR show?

A: I have no idea. Those data were never provided either to me or to Audibert as far as I know.

Q: So, you don't know whether the data therein would have been encouraging or discouraging?

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A: I have absolutely no idea.

Q: Would it surprise you to learn that there weren't any animal toxicology studies performed?

A: I'm going to be flippant in this answer. The conduct of research by Upsher-Smith was so abysmal th nothing would surprise me.

Q: So, it's your expert opinion that in order to get — well, let me just ask you. Is it your expert opinion that in order to get approval of Niacor-SR, Upsher would have had to do animal toxicology studies?

A: It is my experience that in order to file an investigational new drug application, an IND, in order to commence clinical trials in humans, one would have to provide histopathologic data in that IND, and hence, those type of studies would have been requisite.

Q: And that's true even for known compounds like niacin?

A: This was not a known compound. This was a new dosage form of a new delivery system, and it was being filed as an NDA, a new drug application, and that means that it is considered a new — a new compound and I don't think would be excused from these toxicologic requirements.

Q: So, it's your expert testimony here today that the FDA would have required animal toxicology studies

Page

or data from them before approving Niacor-SR?

A: I would have been surprised if the FDA would not have sought preclinical toxicology studies for this kind of product.

Q: Okay. In your report you also point to what you characterize as the high incidence of flushing as something that would have discouraged a potential licensor. Is that right?

A: Are you — are you referring to some —

Q: Yeah, page 9, letter (c), middle of the page.

A: Yes, I see it.

Q: Based on the information that Schering had at the time, what was the incidence of flushing associated with Niacor-SR?

A: I believe I cite that in my report, if I may refer to it.

Q: Sure.

A: The overall incidence of flushing was 87, 81 and 87 percent respectively for the 1000, 1500 and 2000-milligram doses of Niacor-SR —

Q: And you're referring to your report there when you —

A: I'm referring to my report, yes.

Q: What page, sir?

A: That's the table on page 8. And those data, in

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turn, were derived from the data set provided to Audibert and to me alluded to before, I believe it's at Exhibit — Levy Exhibit 3 —.

Q: Three I believe, yes.

A: — and it's page 00088 of that.

Q: Okay. And on page 00088, you're referring to the top line in the table that appears at the top of the page?

A: I'm referring to the upper of the two tables and the top line of that table that is listed as — under the Severity column, overall. I also have in my table in my report, on page 8 of my report, another line dealing with flushing that's entitled Flushing (Severe), and those numbers also are derived from this table, and the numbers were 62, 53 and 63 for the three doses of Niacor-SR.

Q: Okay. You're familiar I take it with Kos' Niaspan?

A: "Familiar" is a — is a term that I —

Q: I don't want to trap you into —

A: — wouldn't be —

Q: — saying something that you don't want to commit to. You have heard of it?

A: I have heard of Niaspan, and I have looked at some information on Niaspan.

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Q: Okay. In fact, you say in your report that it had distinct safety and performance advantages over Niacor-SR.

A: Yes, I believe I said that in my report and still feel that.

Q: Okay. Do you know what its overall incidence of flushing was reported to be in 1997?

A: I believe that the overall incidence of flushing was about the same as that cited in my table, about 88 percent.

Q: Do you know —

A: I don't recall what dose of Niaspan that number came from. It was probably the clinical dose of Niaspan, which is 2000 milligrams per day.

Q: Okay. In any event, you recall that the overall incidence of flushing of Niaspan was similar to that reported for Niacor?

A: The overall incidence of flushing for Niaspan and Niacor I believe were similar.

Q: Okay. Are you aware that Kos raised some money in an IPO, in an initial public offering?

A: I am peripherally aware of Kos' having done that.

Q: Do you know how much money it raised in its IPO?

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A: I don't know how much money it raised.

Q: Okay. Assume that it sold about 20 percent of its stock and raised $60 million in its IPO, okay?

A: Um-hum.

Q: How much would that make the whole company worth?

A: That's a — a strange calculation.

Q: It is?

A: Because selling part of the company in an IPO does not mean that the whole company would have sold for five times that.

Q: Well, okay. Do you know how much money that the marketplace was — or analysts were estimating that Kos was worth in this time frame?

A: The — the answer to that is no, I don't — I have not read any analysts' reports on Kos.

Q: Okay. Would it surprise you to learn that people were estimating that Kos was worth about a quarter of a million dollars?

A: I once again don't want to appear unduly flippant, but I am fairly familiar with the machinations of the investment banking community vis-a-vis IPOs, and I really don't care one lick what valuation they assign to a company whose IPO they are hawking.

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Q: Do you know — well, was Niaspan the main product in Kos' portfolio at the time?

A: Niaspan was one of Kos' products, as I understand it, and I don't want to try to leave the impression that I have done much, if any, reading on Niaspan or Kos. Most of what I know comes from having reviewed various depositions and the testimony related to this. I have not myself read any primary information provided by Kos or its analysts.

Q: Well, based on Mr. Bell's deposition, for example?

A: As I understand it, Kos was presenting itself as a platform company, that is, not a single-product company. Kos was presenting itself as having a delivery mechanism that could be applied to a variety of pharmaceutical products, the first of which but not necessarily the only of which or the most valuable of which was Niaspan.

Q: Are you aware that Kos expects that Niaspan sales this year will be about $100 million?

A: Would you ask that again, please?

Q: Are you aware that Kos anticipates that its sales of Niaspan in the year 2001 will be about $100 million?

A: I've reviewed no information on the current

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sales projections of Niaspan, so I —
Q: Well, given that it has an overall incidence of flushing of 88 percent, would it surprise you if I were to tell you that it's going to sell $100 million worth of Niaspan this year?
A: If you're telling me that that is a fact —
Q: Assume it.
A: — or a — would it surprise me that a drug that is a sustained-release form of nicotinic acid that can be given once a day at bedtime that has a negligible incidence of hepatotoxicity and is an entry into a marketplace with, you know, over $10 billion annual sales, that I would not be surprised that Kos could gather that level of sales in the United States.
Q: Even if it had an incidence — an overall incidence of flushing at 88 percent?
A: Even if it had an overall incidence of flushing at 88 percent, I don't find that to be surprising.
Q: Okay. Turning back to page 8 of your report, in the note that appears under the table, you say that it's reasonable to use the 2000-milligram dosage of Niacor-SR as a comparator to immediate-release niacin. Why is that?
A: There are multiple reasons why. The 2000-milligram dose of Niacor was the one that I would

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focused upon. First of all, there were only two pivotal trials performed on this product. The other pivotal trial compared the 2000-milligram dose of Niacor-SR to placebo. It didn't do any of the other doses. It didn't do the 1000-milligram dose, it didn't do the 1500-milligram dose, it only did the 2000-milligram dose.
Secondly, in its other pivotal trial, the active control — let me back up. The first pivotal trial, the one to which I alluded first, was a placebo control trial.
Q: Right.
A: And there, the only dose of Niacor that was used was 2000 milligrams.
Q: Right, I think you said that.
A: In the second pivotal trial and the only other pivotal trial that was performed, the active control — there was no placebo control — the active control was 2000 milligrams of immediate-release niacin. Therefore, the only valid statistical comparison that can be made is in the first trial, the only dose that was offered was the 2000-mg dose, and in the second trial, the only valid comparison is between the two 2000-milligram doses, the immediate-release 2000-milligram dose and the sustained-release

Page

2000-milligram dose. So, to me, it was logical to focus on that comparison.
Q: Is that true from the standpoint of both efficacy and safety?
A: It's very much true from that perspective, because one of the things that I certainly would look at, and I know my colleagues at the FDA are more than interested in looking at, is to assure that the safety advantages and the efficacy advantages of a candidate drug are compared against the relevant comparators. So, it would be very nice for a drug company — and indeed, they often try, that's why the FDA is so alerted to it — to look at the safety information on one dose and the efficacy information on another dose, a higher dose, and that's a fairly obvious and unacceptable way to look at these data.
Q: Do you have an opinion whether or not the FDA would have approved Niacor-SR if it were shown to be effective at the — and safe at the 1500-milligram dosage?
A: You're asking me a hypothetical, I believe, to say that would the FDA have approved Niacor-SR at 1500 milligrams if it were shown to be safe and effective at the 1500-milligram dose.
Q: Yeah.

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A: And I think that the answer to that is possibly, and again, going back to the risk-benefit analysis that we spoke of before, one has to look at the clinical need for this compound, and since Niaspan was already before the FDA and, indeed, was approved about a month and a half after these data were examined by Schering, I believe that the FDA would have looked not just at whether this drug was better than — in one way or another than immediate-release niacin, it would have had to have passed the muster of what the new standard would be, and I think that would be Niaspan.
Q: So, you think the FDA would have compared Niacor to Niaspan?
A: It would have considered it in its — in its evaluation. Again, it's a risk-benefit analysis — evaluation, and if there were an alternative that did not pose as much risk to the patient population, then I think they would stay with that alternative and not allow another riskier compound on the market.
Q: Is it fair to compare Niacor and Niaspan in the absence of head-to-head trials?
A: Is it fair?
Q: Yep.
A: I think it's fair to compare the compounds. One would be limited in what one could do with the

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results of that comparison. For instance, without a head-to-head comparative trial, one could not use these data in promotion, so that, for instance, if Niaspan were to — were to be superior to Niacor and both were approved products, Niaspan could not make the claim that it was superior unless it had been compared in the same trial.

Q: Okay.

A: That's a different question from whether the FDA would look at both these compounds in the whole panoply of those matters that it considers in reviewing a drug like this.

Q: Okay. Do you know what the primary end point or primary objective of the 115 study was?

A: I don't recall what the primary indications — the primary end points were of that study.

Q: Okay. Is it your opinion that there's something abnormal about the way that Schering did what you refer to as the due diligence on Niacor-SR?

A: To say that Schering's due diligence was aberrant is a monumental understatement.

Q: Okay. How long has it been since you've served as an executive in a major pharmaceutical company?

A: Seven years.

Q: And where — what pharmaceutical company was

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that?

A: Fujisawa Pharmaceutical.

Q: And what was your position there?

A: I was the president.

Q: Of the entire company?

A: Yes.

Q: And what geographic territory did that company —

A: All of North America.

Q: How long were you there? How long were you president of —

A: About a year and a half.

Q: A year and a half? When were you hired?

A: In early '92, and I left in mid-'93.

(Levy Deposition Exhibit Number 4, PR Newswire Release, 6/25/92, was marked for identification.)

BY MS. SHORES:

Q: I'd like to show you what's been marked as Exhibit 4 to your deposition.

A: Okay.

Q: This is an article dated June 25th, 1992 of PR Newswire, it appears to be, and it says in the third paragraph, which consists of one sentence that, "Nelson Levy, Ph.D., M.D., became president of Fujisawa Pharmaceutical Company unit in May."

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Is that consistent with your recollection?

A: No. For some reason — I've never seen this article before, but I brought Ted Odlaug into the company, so I was there well before him, and this is — you know, it's talking about both of us in the same — you know, at the same time.

Q: Do you recall what month you started?

A: I believe I started in March. I don't recall, but I believe I started in March of that year.

Q: And when did you leave Fujisawa?

A: I believe it was — I believe it was May or June of the subsequent year.

Q: Not January?

A: I don't — I don't — I just don't recall, but I thought it was May or June.

Q: Well, let's go with what your recollection is.

A: Okay.

Q: That would put you there about 14 months. Is that right?

A: Fourteen-15 months, yes.

Q: Why did you leave Fujisawa?

A: I was asked by Japanese management — Fujisawa was the North American subsidiary of Japan's third largest pharmaceutical company, which is Fujisawa Pharmaceutical Company Limited, and almost immediately

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upon my being hired in the company, our parent company recognized that they were going to be losing a fair amount of money, and I was asked to do a major reorganization of the — of all of the staff, and that entailed my having to fire over 40 percent of the sales force.

One of the things of which we were very proud was the fact that we were able to conduct this rather draconian exercise, reorganize the sales force, and then in that very brief period get the remaining salespeople so highly motivated and organized, et cetera, that their sales actually were almost twice what the entire sales force had been prior to my having to let 40 percent of them go.

In the course of that, I made a personal commitment to the sales force at a meeting that gathered them all together that the lay-offs were over, that we had been through hell and that it wasn't going to happen again. I had also prior to making that commitment gotten a commitment from my boss, who was the vice-chairman of the company, and I said I'll do this, but I don't want to do it again. We'll do it once, and we're done.

In the very next budget cycle, which was about six months later, the top management of Fujisawa

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Limited decided that we could cut the sales force again. I said I would not do that until they had made draconian cuts in their own organization. And that was not acceptable, and so we agreed to part under those terms.

Q: Were you asked to leave?

A: Yes, I was.

Q: You say in your report —

A: Well — well, let me qualify that. I was not asked to leave. I was told to do what they told me to do, that is, to lay off another — I guess it was another 30-some odd percent of the remaining sales force, and I said I would not do that, and I was given the choice of either doing it or leaving, and so I'm not sure how — it was — it was a very mutually agreeable endeavor. Unpleasant, however.

Q: Okay. You say in your report that you while you were at Fujisawa in-licensed four major drugs. Was it four or two? Your CV says two, that's why I'm asking you.

A: Oh, well, it's a question of what's major in responding to that. I would —

Q: Well, your report says four major, right, so —

A: Yes, it does, and I don't recall what my CV says. I actually in-licensed a few more than four, and

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when I — you know, when I said that, I — I'm not sure what I was thinking of in terms of what "major" is. I can tell you what they — you know, what they were and we can decide together what is major and what is not.

Q: Sure. No, your CV says two major, your report says four major, and I — you know —

A: Sure. The drugs were — one was a drug called N-monomethyl-arginine, which I perceive as a very major compound, at least it looked that way at the time —

MR. SILBER: You may want to spell these as you go along.

THE WITNESS: Oh, do I have to?

BY MS. SHORES:

Q: We can probably take care of that after.

A: Okay. One was Imuran, which was a drug that we got from Burroughs-Wellcome. Another was epidural clonidine, and — let's see, the — I'm trying to think which one I would have considered the fourth major, because there were a number of other ones. I would say the adenosine cardioplegia was probably what I was referring to.

Q: Let's start with the N-monomethyl-arginine.

A: We might make it easier on ourselves if we refer to it as NMA.

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Q: NMA, that's fine. I'll probably screw that up, too.

What drug — what did that treat?

A: This was a very exciting compound. It — it had the potential to ameliorate the — in its simplest sense the side effects of a group of drugs that are used principally in cancer therapy called the interleukins, IL-2 being the principal member of that group, and as a class, these interleukins tend to cause very significant febrile reactions and adverse reactions that make the drugs difficult to use, and the co-administration of NMA seemed to abrogate those side effects and looked to have a very exciting short-term use.

The more exciting medium-term and longer-term potentials of NMA lay in their ability to obviate the tissue damage that is associated with heart attacks and with strokes, and this is what the real upside for this drug was and what had me particularly excited.

Q: Did it treat cholesterol?

A: I don't think that was one of the — one of the potential uses for it.

Q: Okay. Did any of these drugs that you in-licensed when you were at Fujisawa treat cholesterol?

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A: No, none of those four. There was a drug, actually a statin, that was discovered at Fujisawa Limited in Japan, and I was involved with the out-licensing of that drug, but that's not one of the ones that I included in the four.

Q: Okay. Did any of the ones you included in the four involve sustained-release technology?

A: The reason I'm hesitating is that we later examined some sustained-release formulations of these — of these compounds after they had been in-licensed, and I don't believe that they were in the sustained-release form when we first in-licensed them.

The other area of hesitation was that one of these drugs, which I don't think I listed a moment ago, was a drug called amBisome, which was a liposomal formulation of a — of an anti-fungal agent called amphotericin B, and liposomal formulations can be viewed as a sustained-release mechanism.

Q: All right. With respect to all of these drugs that you in-licensed when you were at Fujisawa, were they being licensed for sale in North America?

A: Yes.

Q: Okay.

A: Well, some were for a broader territory than North America. They all were for North America.

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Q: Well, did the licenses that — the in-licenses that you were involved with, did you evaluate them for sale outside of North America?

A: No, my responsibility was not to — not to consider territories outside of North America, but licensing in my experience is always done as a team. It's not, you know, a one-man show. And when we would consider licensing a compound, we would always consult with our Japanese colleagues and with our European colleagues. Fujisawa had three principal subsidiaries. One was mine, North America; the second was in Europe headquartered in Munich; and the third, of course, was Japan.

We would always, you know, talk with each other and share our information with each other, and our market was such, that is, the North American market was such that we were able to license a compound simply for the North American market, regardless of whether it was going to be sold in Japan or Europe.

The converse was generally not true, that it would have been unusual for a product to have been licensed for the EU, for Europe, without some interests having been expressed either by Japan or us. In our company, because we were a Japanese — had a Japanese parent, certainly Fujisawa Limited would consider

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in-licensing a compound only for Japan, but that was somewhat unusual because it's a Japanese company.

Q: Did you personally have any responsibility for sales of pharmaceutical products outside North America when you were at Fujisawa?

A: No.

Q: How about at Abbott, any responsibility for sales of pharmaceutical products outside of —

A: When I was at Abbott, I — you know, I had — I did not have the sales or marketing organization under my aegis. I — you know, the R&D organization for which I did have responsibility —

Q: Sure.

A: — was worldwide.

Q: Sure.

A: We were the only one.

Q: Okay, but you didn't have any experience in selling pharmaceutical products outside of North America.

A: I — I —

Q: Personally.

A: — when I was at Abbott, I had —

Q: No sales responsibility at all.

A: — no personal responsibility in sales and marketing, period.

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Q: But let me just add Abbott and Fujisawa, in either of those jobs, did you have any sales responsibility for products outside of North America?

A: I had no sales responsibility at either Abbott or Fujisawa outside of North America.

Q: You say in your report that you — within this I guess now we're saying it's a 14-month period of time that you were at Fujisawa, that you filed an NDA for Prograf. Is that correct?

A: Yes, the flagship of Fujisawa was a drug that at that time we referred to as FK-506, which was an immunosuppressant drug, and the first indication that we saw it was the use of FK-506, Prograf, in liver transplantation, and that NDA was filed.

Q: What stage was that product in in terms of clinical testing when you first started at Fujisawa?

A: The reason, again, that I'm hesitating in answering that is that before I became president of the company, I had had a long association with Fujisawa and with LyphoMed, its predecessor before that, and so I really had been involved with FK-506 from the time it was in the laboratory, before it entered clinical trials.

Q: I see.

A: I don't recall exactly where it was in the

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continuum of clinical trials when I joined the company. I think that when I arrived at the company we were finishing up our three pivotal trials. We had done a pivotal trial in Europe and we had done two in this country, and I believe we were finishing up those data because the data were all crunched under my aegis.

Q: But you filed the NDA before you left or were asked to leave?

A: I believe so, yes. It was either filed before I left or it was completed, it was written before I left, and may not have been sent to the — you know, sent to the FDA, you know, before I left. I just don't recall that.

Q: And your recollection is you left in May?

A: I believe so, yes.

(Levy Deposition Exhibit Number 5, Lexis-Nexis Trade & Government Memos, 9/13/93, was marked for identification.)

BY MS. SHORES:

Q: I'd like to show you what's being marked as Exhibit 5 to your deposition.

A: This says September 1st, if I'm reading it — or the week of September 1st, and that doesn't surprise me. As I said, I wasn't sure whether it was filed while I was still there or the writing and so on was

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completed. I know I reviewed the completed NDA and, you know, it — it probably went through other levels of review and so on before it was finally shipped off to the FDA. I mean, according to this, it wasn't filed when I was there, and I don't dispute it.

Q: Okay. Can you explain why it took four months if it were finished when you left before it was filed?

A: There was a lot of review. There may have been some additional data that were — that were accrued. There may have been some questions that were raised by — by the Japanese. There may have been some questions that were raised by the FDA. There are so many reasons for not wanting to file the NDA.

We also had, if I remember correctly, considerable discussion about whether we should do what's called a rolling NDA filing or not. With a rolling NDA filing, one submits part of the — a part of the data and gets the review going and then submits the rest later. That has certain perils, and I just don't remember what strategy was followed.

Q: Okay. Prograf wasn't a sustained-release formulation, was it?

A: No.

Q: Okay. And it didn't involve applying any sort of a new drug delivery technology to it, to a known

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compound, did it?

A: It did in a sense, because the solubility of the product was somewhat of a problem, and it required some difficult formulation. It was not a sustained-release formulation, but the oral form of the product did require more than just routine formulation work.

Q: How much did Fujisawa invest in the development of Prograf?

A: I would only be guessing at that number at this point. I don't know what the total investment of Fujisawa was.

Q: Can you give me a range?

A: As long as I'm not held in any way — in any way to the accuracy of this, because it would be a little more than a guess.

Q: Well, is it —

MR. SILBER: Objection, calls for speculation.

BY MS. SHORES:

Q: — is it more than $50 million?

A: I believe that Fujisawa spent more than $50 million.

Q: More than $100 million?

A: I just don't recall now. I mean, I'd rather not, you know, engage in idle guessing. It was

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certainly the major component of our R&D budget. Wha

I — the part of the picture that — to which I was not privy is how much was spent in Japan, and I knew what was in my budget, but I wasn't the only budget, nor did I have any review or access to what the Europeans were spending.

Q: And do you know what the sales for Prograf were after you left?

A: Only indirectly, from, you know, from conversations I've had with my former colleagues and friends who are still there.

Q: And how much is it getting in sales?

A: Prograf is doing quite well in recent years, and its sales are approaching a billion dollars.

Q: And that's annual?

A: Yes.

Q: Your CV I think indicates that you filed three NDAs when you were at Fujisawa. What were the other two?

A: One was for adenosine use in — what did we call it — Adenoscan, and the second was for epidural clonidine.

Q: And did either of those involve sustained-release technology?

A: No, they did not.

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Q: Did either of those involve treatment of hypercholesterolemia?

A: No, they did not.

Q: Aside from your 14-month tenure at Fujisawa, how long has it been since you were an executive at a pharmaceutical company?

A: I have not been an executive at a pharmaceutical company, per se, since 1993.

Q: All right. So, the only — well, I'm asking you, how long — if you put Fujisawa to one side, how long has it been since you've worked at a pharmaceutical company as an employee?

A: As an employee?

Q: Yep.

A: I've not been an employee of a pharmaceutical company since 1993.

Q: Putting that aside, how long before that? I'm going backwards in time.

MR. SILBER: What was the last pharmaceutical job before Fujisawa?

THE WITNESS: I've only had two jobs in the pharmaceutical industry. One was at Abbott, and the other was at Fujisawa.

BY MS. SHORES:

Q: And how long were you at Abbott?

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A: Three and — three and a half, three and a third years.
Q: Okay. You say in your report that when you were at Abbott, you led the transformation of a moribund research program. What do you mean by "moribund"?
A: Abbott's — Abbott was a great company, and its R&D had been very unproductive, and Abbott had managed through superb marketing and sales and in-licensing to thrive as a company, but the pharmaceutical research component of the company had not discovered a single compound that made it to the marketplace in 22 years. Likewise, the research organization had become — well, unproductive certainly but demoralized and ill thought of within the company community because of its nonproductivity. That's what I mean by "moribund."
Q: Okay. What drugs did you discover when you were at Abbott?
A: One is called terazosin, that's the generic name, it's known as Hytrin, HYT R I N, was one. The second was a renin inhibitor. It was an antihypertensive, and I don't recall what they named it, because I left before they named it. It had a number when I was there. Biaxin, which is one of their very big sellers now, it's an antibiotic.

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Let's see, there was a — what we called a five lipoxygenase inhibitor, which was a new class of anti-inflammatory drug. There was a quinoline antibiotic, a first cousin of the very famous drug now Cipro or ciprofloxacin, and this drug was actually — after I left was approved and was subsequently withdrawn from the market due to a series of deaths that had surprised the company. They hadn't had the clues to that during the clinical trials, and the drug was approved and subsequently withdrawn.
Let's see, did I say Ritonavir?
Q: No.
A: Well, Ritonavir was the HIV protease inhibitor that was discovered when I was there. Then we had a joint venture which persists with Takeda, which was called TAP, Takeda-Abbott Pharmaceuticals, and there were — we conducted the clinical research on several of those compounds, although those compounds were not discovered at Abbott, they were discovered at Takeda, but were developed by Abbott North America.
Q: And all of these drugs you just mentioned were discovered when you were at Abbott?
A: Yes. Well, the — the three or four Takeda drugs were not discovered at Abbott. They were discovered by Takeda's research, and they were

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discovered, and I don't know when Takeda discovered them.
Q: Okay, but the others were discovered when you were at Abbott?
A: Yes, and there were some others. There was another form of — we had a — an anti-epilepsy drug, an anticonvulsant that was called Depakene when I arrived, and we discovered a more effective dosage form of that called Depakote. I mean, it had a — it actually had a sustained-release element to it.
Q: I'm not going to belabor all of these given the shortness of time, but let's take Biaxin. When was that approved?
A: Biaxin was approved I believe in about 198 — probably about 1986.
Q: So, 1991 would be wrong?
A: I thought it was approved before that.
Q: What about Ritonavir?
A: Ritonavir was approved in the late eighties, I believe.
Q: Not in 1996?
A: I don't think so.
Q: What about — what about Hytrin?
A: Well, Hytrin had two levels of approval.
Q: And what —

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A: It was approved as an antihypertensive in about 1984, I think —
Q: 1987 doesn't sound right?
A: Oh, it was well before 1987. And it was — it was — I believe it was — it was not long after I had left the company when it was actually approved. And then the exciting approval came several years later, I don't recall whether it was the late eighties or early nineties, but that was the indication for its use in benign prostatic hypertrophy, BPH.
Q: Were any of these drugs approved for sale outside of the United States when you were at Abbott?
A: I don't think any of those drugs were approved when I was at Abbott anywhere. I was only at Abbott for a little over three years, and we discovered them during that period, but the — the clinical trials were completed and the NDAs filed after I left.
Q: Okay. And you don't recall any European regulatory filings for any of those drugs while you were at Abbott?
A: Not for any of those. We had a variety of European filings that were done during my period there, but they were on in-license candidates and different dosage forms and this kind of stuff.
Q: Were you involved in the in-licensings of any

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of those?
A: Yes. I was — I was very fortunate at Abbott. I have a lot of gratitude for my period there. The — I think the company was gratified to see some vitality in its research organization, and I was given credit for it, and as a consequence of that, I was given exposure to other elements of the company that really were not under my aegis, because I think that they perceived me as a person who might be able to go beyond running R&D.
One of the most enjoyable interactions was with a guy named Frank Barnes, who was the VP of licensing and business development, and prior to him, although the man unfortunately passed away shortly after I arrived at the company, was a guy named Frank Irving, who was Frank Barnes' predecessor. So, Frank liked me, and, in fact, he and I have been good friends until he passed away a couple years ago, and he just decided he was going to show me — show me the ropes, if you will.
He sort of took me under his wing in the licensing arena, and then there was also a practical element to it, because all of the licensing opportunities, once they got past Frank, had as their first stop my shop, and so Frank wanted input from me and from various people with more specialized expertise

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in R&D to assist him in the evaluation of in-licensing candidates.
Q: Are you familiar with the acronym HRD?
A: No, I'm not.
Q: As it — let me just give you a hand, as it relates to European regulatory filings?
A: I'm just drawing a blank on that acronym.
Q: Okay. When you were at Abbott, were you involved in the applications for approvals of these licensed products in European territories?
A: Would you ask me that again, please?
Q: Sure. While you were at Abbott, were you involved in the applications for regulatory approval of any of these in-licensed products in any territory in Europe?
A: "Involved" is a very broad word. I didn't have responsibility for it, but because David Ordieb, who was the president of Abbott International, also thought well of me, he had me sit on the international R&D committee that was chaired by a guy named Hubert Loncin, and so I was involved. I had no responsibility for it, but Dave just wanted my input.
Q: Okay, but did you ever take an NDA that had been filed in the United States and transform that into something that was filed in any territory in Europe?

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A: Did I ever do it personally?
Q: Yes.
A: No.
Q: In your report, you say you became the CEO of CoreTechs Corporation in 1984.
A: Yes, that's correct.
Q: Who was the CEO before that?
A: I founded the company.
Q: Oh. And who were the officers of that company?
A: In 1984? I was the only officer.
Q: Who are the officers now?
A: Now there are two other officers.
Q: And who are they?
A: Excuse me, one is a fellow named Eric Coles, and the other is a woman named Gail Green.
Q: And what is the business address of CoreTechs?
A: 1391 Concord Drive is the address that I use.
Q: That's the same as your home address?
A: Yes, it is.
Q: How many employees does CoreTechs have?
A: Right now, CoreTechs has nine employees.
Q: Does your wife hold a position in that company?
A: No, she does not.
Q: Did she ever?
A: No.

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Q: Was she never the secretary of CoreTechs Corporation?
A: Oh, it's — it's possible that in the initial, you know, corporate filings when I — when I founded the corporation, I listed her as secretary. She's never had any active function in the company.
Q: I think it says in your report that you became the CEO and chairman of CoreTechs in 1993. I take it that's when you left Fujisawa?
A: Yes.
Q: And was there a chairman before that?
A: No. CoreTechs grew a bit, you know, from the time I founded it, and it actually was — I think it probably hit its largest number of people before I went to Fujisawa, and it was another one of the reasons for my leaving. CoreTechs was needing some — needing me back, if you will, and I just assumed the additional title of chairman now that there were more people running around.
Q: Do these nine employees work out of your home as well?
A: Out of my home?
Q: Yeah.
A: No. We had and still have offices that — the way we generally work is that each of the people work

out of the home, and then we have some shared office space that — where we gather for joint meetings. None of our homes — none of our wives would want us having joint meetings in our homes.

Q: Well, do you rent that office space or lease it or just borrow it from somebody or —

A: No, we rent it.

Q: So, where is the office space that you rent?

A: That's in Conway Farms in Lake Forest, which is an office complex. Some of the clerical people are there.

Q: Okay. You say in your report that CoreTechs implements a unique paradigm of technology transfer. What is that a reference to?

A: What we do, what the bulk of the business is, is to provide to early stage companies or to inventors what I perceive as the element that is not applied or is not provided by the venture capital community; that is, operating business experience and support. Typically when an inventor or an early stage company emerges, he needs some funding, but he also needs just some guidance in getting his technology over the developmental hurdles, and we've been able to come in and provide that.

The way CoreTechs is set up, it has individuals



with analogous experience to mine but in different areas of science. So, each of us has an advanced degree, and each of us — you know, Ph.D. or — in our respective fields, and each of us has been CEO, president type, you know, in our respective industries. So, we refer to ourselves as senior switch-hitters in that we understand the R&D side and we understand the business side and have worked in both those arenas and are able to help develop early stage technologies for companies.

Q: Is part of the —

A: That's somewhat unique, because almost all of the — virtually all of the other licensing organizations, all the other venture capital organizations, are comprised in the latter case of people whose entire business experience is in banking and finance, and in terms of the licensing people, they're almost all people who have experience with licensing, but they've never really had any operating experience and little, if any, R&D experience.

Q: Is part of the licensing advice that you give these startups, I think you said early stage companies or inventors, do you advise them as to the optimal time to seek a licensing partner?

A: Yes, that is certainly — in fact, I even



published a paper on that, the only business paper I've ever published, and the answer to that is yes, that's a part of the — that's part of the management of early stage technologies.

Q: When is it — I know it's hard to generalize, but is it fair to say that it is more optimal from the standpoint of the inventor or the startup company to license technology or a product later in the development stage than earlier?

A: My working hypothesis in this arena and the paradigm that we follow and that I certainly believe in is that for each technology, there are what I've referred to as key value-adding information or data, and the ideal time to license is after the generation of those key data. My perception of valuation or the growth evaluation of an early stage technology is a sigmoidal curve, where during the early stage of a product's development, when one is learning a lot more in the laboratory, say, or learning a lot more information, where the actual knowledge about the product may be going up linearly, the valuation stays pretty flat, because when it's a research project, it's just not valued very highly.

Then when one generates some fairly simple — often very simple value-adding information, the



increase in valuation goes up logarithmically or geometrically. Then it flattens again. And so with a pharmaceutical, from a licensing perspective, the greatest increment in value occurs in my opinion either just before the launch of clinical trials or just after one has approved some early clinical trial data.

For instance, the value of a pharmaceutical product that has had formal toxicology done in dogs and rats, say, the sort of toxicology that needs to be done to file an IND, has a value considerably higher than it did prior to that, assuming it passes that toxicology.

Q: Sure.

A: Or when one has done just a — just put it in man, done some phase I studies or maybe even some anecdotal phase II-A type studies, it's been in man and it's performed in man, even in just a few patients, the value — the perceived value of this technology rises considerably.

It flattens out thereafter until you get to — almost until you get to the point of its being an approved product, and — at least that's the paradigm under which we operate.

MR. SILBER: Laura, when you get to a sensible breaking point, we have been going for a while.

MS. SHORES: Sure, sure, let me just finish up

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on this.
BY MS. SHORES:
Q: So, if I understand your curve correctly, a product is worth almost the same right before it gets approved as it is after it gets approved, or it doesn't increase in value dramatically from —
A: Well, after it's approved, it's a different game altogether.
Q: Okay, I misheard you then.
A: When a product has been — you know, has secured regulatory approval in a major market, it's real, and one can then start doing some realistic financial analyses on the product, and it is — it now is looked at as a product asset of the company. It's no longer a research project.
Q: Is it fair to say that a product is more valuable at the phase III stage than at phase II, assuming that the —
A: Well, "more" is the operative word there. There are — a product that is in phase III has a little bit more value than a product that is in phase II, but I don't think that the differential is as great, for instance, as that that I cited before, where a product has never been in man and now has been in man. That's where the big jump occurs.

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Q: Okay.
This is probably a good time for a break.
MR. SILBER: Okay.
(A brief recess was taken.)
BY MS. SHORES:
Q: Dr. Levy, of CoreTechs's nine employees currently, how many are clerical employees?
A: Three of them are, you know, purely clerical, and two do a lot of — they're more than clerical people. They do some of our I — you know, our information technology type stuff as well as doing some — some level of clerical stuff.
Q: Well, let me ask it this way: How many are principals?
A: I'm the only principal, and the way we — well, let me leave it at that and then you can ask other things if you like. I'm the only principal.
Q: Okay, that's fine. I'll just leave it at that.
A: Right now. Previously, we had more than that, and I think we probably very shortly will have a couple more. The reason it's somewhat anomalous now is that I had a pretty severe back problem earlier this year and, you know, at that time — you know, I'm the — I'm the principal rainmaker, and I wasn't making much rain.
Q: Got you.

Page

A: Okay.
Q: I understand that.
Did you serve in the military?
A: I hate for this to go on the record, but I'm affectionately referred to by my old friends at the Bethesda Naval Medical Center as a member of the Yello Berets, because I was unfortunate enough to go to the National Institutes of Health as part of the Public Health Service back there in the Vietnam Era, and so that counted as military service, and I am an official veteran of the Vietnam Conflict, but I am embarrassed to say that my contributions were confined to Bethesda, Maryland.
Q: Okay. Switching topics again, when did you form an opinion that the FDA would not have approved Niacor-SR?
A: I can't say exactly what time, you know, in my course of reviewing this product that I came to that conclusion. I would say the conclusion crystallized and presented itself more clearly to me when I wrote the report.
Q: But as of the time that you wrote the report, you had formed that opinion?
A: I'm sorry, please say that again.
Q: As of the time you submitted your expert report

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in August 2001, you had formed the opinion that the FDA would not approve Niacor-SR?
A: When I wrote the report, I — at the time I wrote the report, I thought it was highly unlikely that the FDA would have approved this product with all the deficiencies that I perceived.
Q: Okay. Is there — on the issue of, again, my favorite issue, hepatotoxicity, is there a percentage — I mean, I don't care whether you want to use 1.5 times the upper limit of normal or 3.0 times it, whatever it is, but is there a percentage of patients who have liver enzyme elevations to whatever degree you think is clinically significant, is there a level at which the FDA would approve it or would not approve it? I mean, you can answer it any way you wish.
A: I don't think anybody, certainly including myself, has enough personal experience with different products going through the FDA, and there are people who have spent their entire lives in R&D and have never seen an approved NDA, even people that have been in the industry for a long time and have stayed at one company for long periods have themselves seen relatively few approved NDAs. So, I don't think that I can speak for what the FDA would do.
Q: Okay.

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A: I mean, the FDA can speak for itself. My opinion and my impression and my experience is that the FDA reviews each drug or at least each group of drugs differently, with different standards, all the time looking very carefully at one parameter, and that's the risk-benefit, and there is little question in my mind that a new class of therapy for a grave disease that had a very high incidence of liver enzyme elevations would get approved, and contrarily, a drug that had little import to the medical community and had even minimal hepatotoxicity associated with it would likely not be approved.

Q: Sure. Well, let's just confine the question then to — that's fair — to lipid-lowering drugs. Is there a level at which you think they would —

A: Well, once again, there are — you know, as you asked and I responded earlier, there are at least four classes of drugs that are involved with lowering lipids, and one of them, the statins, dominates this marketplace, and the others are minor players.

If a new class of drug were to emerge that was neither a nicotinic acid, a bile acid sequestrant, a fibrate or a statin and seemed to offer some significant improvement in the management of hyperlipidemic conditions, I think that the threshold

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of toxicity that would be acceptable would be higher than simply another addition — another statin or another fibrate or another niacin.

Q: How about a sustained-release niacin product, is there a level of hepatotoxicity that you think the FDA would find acceptable?

A: Well, you're asking me to speculate on what the FDA would or wouldn't do.

Q: That's right.

A: I think that a sustained-release niacin product would have to meet extremely high standards of safety, because the risk-benefit analysis is such, the chronicity of therapy that would be requisite to this drug is such that there would be little reason for the FDA to approve a drug that had an even measurable probability of doing harm.

Q: So, do you think the FDA would approve a sustained-release niacin that showed that — that the data showed caused patients in the clinical trials to have successive indications of elevated liver enzymes at three time the upper limit of normal, that it would approve a product that had 3 percent of such patients showing that, or is that not —

A: The only thing we know is that, to my knowledge, the only sustained-release nicotinic acid

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product that has been approved is Niaspan.

Q: Right.

A: And Niaspan had a considerably less than 1 percent incidence of enzyme elevations, and beyond that, we're speculating.

Q: So, you can't say beyond that what the FDA would or wouldn't do?

A: I can say in my opinion that, to use the number that you cited, 3 percent, would be too high for me if I were reviewing the product at the FDA.

Q: Would 2 percent be too high?

A: I would not be comfortable with 2 percent either.

Q: When were you retained by the FTC in this matter?

A: I believe it was about May of this year.

Q: So, May of 2001?

A: Yes.

Q: Have you done any other work for the FTC on any other project?

A: No, I have not.

Q: I think I read in some New York Times article that you were a consultant to the Government, and the article was published in 2000. What other consulting have you done for the Government?

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A: The only other consulting I've done for the Government is for the Internal Revenue Service.

Q: Nothing involving pharmaceuticals?

A: I would appreciate being very — very careful with what I tell you about what I do for them, because I know that they are very sensitive. So, I — the answer to your question is yes, it involves pharmaceuticals. I would not even mention the companies that are involved.

Q: Well, there's a protective order —

A: I understand that.

Q: — issued in this case.

A: I still will not respond to that.

Q: So, you won't tell me what companies are involved in that investigation?

A: I absolutely will not tell you anything about the IRS's business, because I'm well aware of the fact that it is their perception that — in fact, they are very strict about this. Even within their own organization, one group does not know the companies that the other group is working on, and I have been very clearly told that it is a violation of one taxpayer's rights for a competitive taxpayer to even know that they're under investigation by the IRS. So, I don't — regardless of any protective order, I don't

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think it would be appropriate for me to disclose that.
Q: Okay. Are the subjects of the investigation, if you will, are they branded pharmaceutical companies or —
A: Some have been branded pharmaceutical companies; some have been generic pharmaceutical companies. I can tell you — I don't mind telling you this, that the only arena in which I have been asked to voice opinions deals specifically with the application of their research and development tax credit.
Q: Can you tell me if Schering is —
A: I'm not going to —
Q: — involved in this investigation?
A: — even — I won't respond to any of those kinds of questions for the reasons I just said.
Q: What group within the IRS are you consulting for?
A: I don't know what — I don't — I don't know how they're organized.
Q: Okay.
A: So, I really can't respond to that either.
Q: You say in your report that the $60 million noncontingent payment can't reasonably be considered to have been a licensing fee for Niacor-SR and the other products in the agreement, and you also say that the

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fee was grossly excessive for the value received. Do you remember statements like that?
A: Let me look at my own report, if I may.
Q: Okay, you should look at — I'm not trying to trick you, I promise, but look at page 3.
A: Oh, here we go. You're referring to the first couple of pages of it?
Q: Yeah, page 3 is where my notes say this was.
A: I'm sorry, would you ask me the question again?
Q: Yeah, my question was — I was just trying to orient you. I think you say here that the $60 million noncontingent payment could not reasonably have been considered to have been a license fee for Niacor-SR and the five other products that were involved.
A: I absolutely feel that —
Q: Okay.
A: — the $60 million payment was grossly and inconceivably a license fee for this product.
Q: Okay. Are you saying that Niacor and the other products — and I know everybody understands that Niacor is the main product here — that they were not worth $60 million as an objective matter, or are you going further and saying you don't believe that Schering thought that they were worth that much?
A: There are three elements to my opinion in that

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matter. The first of these deals with the construct of the agreement itself, that a payment of $60 million, noncontingent payment of $60 million for this product, is so far beyond anything that I have experienced or know about, and at that time I believe was the — by far the largest noncontingent cash payment made for an in-licensed pharmaceutical, at least I know of none that were as large.
The second is that the due diligence conduct that was carried out in preparation for this — this — the execution of this agreement was so abysmally inadequate that it defies description.
And thirdly, after the deal was done, for a product for which Schering-Plough made the largest noncontingent payment of which I am aware and had in the course of this planned a very aggressive development program that was I believe to call for the approval of this drug in the European Union a mere 18 months after this license was executed, that fact notwithstanding, the licensee and licensor did almost nothing to execute the development of this compound.
This behavior was so out of the norm for anything I had ever experienced, I had ever heard of, and I could ever conceive of occurring that the picture to me seemed utterly and totally inexplicably

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ridiculous.
Q: So —
A: I don't know how much more strongly I can state that.
Q: No, I think I understand the strength of your conviction here, but my question is, I mean, it sounds like that you're saying that you believe that Schering, in paying the $60 million, was doing something other than just acquiring the rights to these products based on the lack of follow-up and the lack of due diligence. It sounds like that that's what you believe.
A: I'm aware but have not been asked to voice any opinion on the fact that the agreement or the letter agreement had two parts to it, and one part dealt with an issue that I have not been asked to opine on and will not. The other part deals with the punitive license for these products.
What I will testify to as strongly as I just did, that there is no way in hell that that $60 million was a license fee.
Q: Okay.
A: Schering is far too intelligent a company, with far too much experience, to have given a $60 million noncontingent fee for this product without some other consideration well beyond the products that allegedly

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were licensed.
Q: Okay. And you don't see that consideration being offered by the licensed products, so you think there was some other consideration at work?
A: I do not see that consideration being anywhere near provided by the licensed products, and so either Schering was in a very charitable mood or it got something else for it.
Q: Okay. What qualifications, if any, do you have as an expert to opine on what Schering's motivations were?
A: I'm not sure I understand that question.
Q: I'm asking you what qualifications — as an expert what qualifications you have to testify about what Schering's motivation was in paying the $60 million.
A: Well, I have 20 years experience in the pharmaceutical industry and have seen — either been part of, have seen, read about, experienced in one way or another many, many deals. I have a pretty good idea of what deals look like in our industry.
I also, as I said a moment ago, have considerable respect for Schering-Plough as a company. I have had one incidence directly where I was seeking Schering-Plough as an in-licensing participant and

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experienced firsthand the type of due diligence and behavior that they carried out in that instance and have never heard anyone describe Schering-Plough as a slipshod, mindless player in the pharmaceutical industry.
So, if I can take my 20 years experience and say that I've never seen a deal that even comes close to looking like this, number one, and number two, if my experience and understanding in the industry is correct in that Schering-Plough is a normal, you know, experienced and capable company, then I think it's reasonable to conclude that Schering either was in a very charitable mood towards Upsher-Smith or got something else for it.
Q: Okay. In forming that opinion, did you talk to any of the Schering people involved?
A: I have not spoken with anybody from Schering about this matter.
Q: Okay. So, you're concluding that Schering was either in a charitable mood, as you put it, or was getting something other than the licensed products out of the deal, you're concluding that without ever speaking to anybody at Schering?
A: I am making the conclusion that — I should add a third possibility to that, which I don't personally

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believe. One is that they were in a charitable mood; the second is they got something else for it; or the third is they're just flaming idiots, and as I said before, I don't believe that, but that certainly has to be looked at as one of the possibilities for this kind of behavior.
I don't think — I think I was provided enough information to draw that conclusion simply because I was provided, as far as I know, all the information that the person who made that decision had before him when he made it.
Q: Okay. Do you believe that you're qualified to give an expert opinion on how much the Niacor-SR license was worth?
A: "Worth" is an interesting word, and I think you would have to qualify that. I think I am quite qualified to make the statements that I made about my perception of this payment and this deal in general.
Q: I think you said there was no way in hell that the $60 million was a license fee. I take it it's your expert opinion that it wasn't worth $60 million. Is that correct?
A: As I said, the operative word is "worth."
Q: Well, do you think it was worth $60 million based on the information that Schering had at the time?

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A: The operative word is "worth." I don't think that I or anybody else would have made a noncontingent payment of $60 million for this license.
Q: Okay. Do you think you or anybody else would have made a $50 million noncontingent payment for this license?
A: Let me cut to the quick on that. I don't think anybody else would have made even a $5 million noncontingent payment on this product.
Q: How about $4 million?
A: I wouldn't have made any noncontingent payment for this product.
Q: And what is that based — why not?
A: Because I wouldn't have done the deal that way. I would have done the deal with all the payments contingent upon approval, successful approval of the product.
Q: Okay. Well, how much would you have paid — let's assume you could put it all in contingent milestone payments. How much would you or anybody else have paid?
A: I think the —
MR. CURRAN: Objection, vague. Are we talking about just Niacor-SR?
MS. SHORES: Yeah, Niacor-SR.

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THE WITNESS: I think the irony of that question is that the contingent payments that were part of this deal, without my having to invent something and speculate, I think one can look at the contingent payments that were built in this deal, which totaled $10 million upon the approval of Niacor-SR in various jurisdictions, $2 million for approval in Japan and $1 million for approval in each of the major countries of the EU, is about what the — the typical payments, and that would be about what I and probably any other person interested in licensing this compound would have paid.

So, I'm making the assumption in answering that that, number one, the due diligence that I found inadequate was repaired. In other words, that adequate due diligence was done and that I came to the conclusion that I wanted to license the product. After I came to that conclusion, which I'm creating my own hypothetical for now, if I may, after I had come to that conclusion, having done the additional due diligence that I would have required, then the deal that I would have constructed would have had nothing up front or very little up front, and the $10 million payments upon approval in the various jurisdictions that are actually in this agreement, with the

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associated royalty rates of 10 to 15 percent based on annual sales that again are in this agreement.

So, to me, this agreement looks — assuming one wants the product at all, which is to me a great assumption, but I'll give you that assumption, assuming one wants this product at all, this agreement looks reasonable, ordinary, typical, normal, except for the fact that it's got this ridiculous $60 million balloon stuck on the front of it, which is totally aberrant in every way, shape and form.

BY MS. SHORES:

Q: Okay. Is there an — and I think you've said that you would have had no money up front. Is it — had there been $10 million up front, with the rest of the terms being what they were, would that have been a reasonable license fee?

A: No.

Q: No.

A: The up-front payments, in my experience, are driven by the — if you will, the competition for the product. I mean, the licensee always wants to pay nothing up front. He wants to give nothing noncontingently. The licensor always wants to get as much as he can get up front. And when the up-front payments appear at all or certainly appear at any

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substantive level, it's because there's fairly intense competition for the product; that is, there may be five, six, seven, eight, nine — who knows, two dozen other major pharmaceutical companies equally able to license and market — develop and market the product who want it, and then it becomes an auction.

Q: Okay.

A: You know, and so then, you know, if Merck offers $2 million and I want the product and I'm from Lilly, I better offer $3 million up front, and that's how it gets up there.

In this instance, there was no such competition. There was no such auction going on. The company had tried for six months to find anybody to take it, and nobody did. And so now you have one company coming in and — and, you know, the up-front payment may be just to be a nice guy, I mean sort of in this — usually licensing people are nice people and collegial, they might have just made the deal look good by putting a million dollars up front. That's it.

Q: Okay. So, in your experience — or your opinion is that no one could have — that absent competition from other bidders, no one would have paid more than, what, a million dollars up front?

A: I wouldn't have paid more than a million

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dollars up front.

Q: Well, I'm asking you what you think is reasonable. I mean, I think that's what your testimony has been.

A: I hope I'm a reasonable person, and if I wouldn't pay more than a million dollars up front, I think anybody who would be willing to pay more than a million dollars up front was being — I can't say unreasonable, but was being irrational.

Q: Okay. In forming your opinion that there's no way in hell the $60 million was a licensing fee for the products, did you — you didn't do any liver biopsies of patients in the clinical trials, did you?

A: I did no liver biopsies in any of the patients in clinical trials.

Q: And did you consult with any research department? I mean, do you have a research department at CoreTechs?

A: Yes, we have a research department at CoreTechs, but it was not called upon to investigate this issue.

Q: So, did you consult with anybody in any R&D division of any company anywhere?

A: No, I didn't think it was appropriate for me to share any of this kind of information with someone

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else.
Q: Did you consult any animal toxicology data?
A: There were no animal toxicology data to which I was privy.
Q: All right. Did you seek the input of anybody with any experience in marketing pharmaceuticals in Europe?
A: I can abbreviate this line of questioning and say that I consulted with no one else about anything related to my expert opinion in this entire matter.
Q: So, you felt qualified to render an opinion that there was no way in hell the $60 million was a licensing fee by yourself?
A: I took the position that I would review the information that was available to the ultimate licensee, that is, to Schering-Plough, at the time it made that decision and essentially tried to afford myself all the opportunities, no more, no less, than they apparently had themselves. That is, I didn't go beyond the data or attempt to go beyond the data that were presented by the licensor —
Q: Well, actually, I think you relied on a number of internal Upsher-Smith documents that Schering wasn't privy to at the time, didn't you?
A: I think that —

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Q: Project meeting minutes and stuff like that?
A: Yes, the information such as that that you just — that you just mentioned, the product — I mean the project team meeting minutes impacted my decision on what the parties did after the agreement was signed.
Q: Have you seen the expert report of Jim Furniss?
A: I don't recall which expert he was. Could you refresh my memory?
Q: Yeah, he was a Schering expert who opined on the issue of what price Niacor could have gotten in Europe?
A: Yeah, I do recall that report.
Q: Who do you think is more qualified to give an expert opinion on that subject, you or Mr. Furniss?
A: I don't think that I'm qualified to make a qualitative judgment. I can say that I can only speak to my own expertise, I can't speak to his. I don't know him. I've only read his report. I think I am qualified as an expert, and that's all I really can testify to.
Q: On the issue of pricing in Europe, you think you're qualified as an expert in that?
A: I think that I have enough experience in the pharmaceutical industry to make the comments that I made in my report, and that's — I would stand with

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that.
Q: And if somebody were asking you who — to recommend an expert on the issue of pricing of pharmaceuticals in Europe and the choices were you and Mr. Furniss, who would you recommend to them?
A: I don't know Mr. Furniss at all —
Q: Well, you've read his report, right?
A: I've read what was a very brief report, I believe.
Q: Did you read his qualifications and his background?
A: I read his qualifications.
Q: And my question is whether you would recommend to some person you or Mr. Furniss.
A: I think that I can only speak to the fact that I would not be at all uncomfortable recommending myself, and that's really all I can speak to.
Q: You said in your report that inexpensive, over-the-counter niacin was available in several European countries. Can you identify any such products?
A: Could I identify any such what?
Q: You say that over-the-counter niacin was available in many countries in Europe. Can you identify what products you're talking about?

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A: What the names of the products are?
Q: Yeah.
A: I can't name the names of the products that are available.
Q: Okay. Do you know whether that niacin is combined with other chemicals, whatever is available in these European countries that you're talking about?
A: I believe that niacin is available both in combination and not, but I don't know the names of the products with which niacin is associated in the EU.
Q: What is the basis for your opinion that over-the-counter niacin is available not combined with any other product in the EU?
A: In the course of reading various of the depositions of parties in this matter, that issue was mentioned and discussed, and that's the basis upon which I made that statement.
Q: So, it's just based solely on the deposition testimony that you've read in this case?
A: That's correct.
Q: Okay. Did you review the prosecution files on any of the parents that are involved in the sustained-release niacin products?
A: That's an interesting question, because I — that's the one area where I did try to gather more

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information, because the patent history as presented in the documentation provided to Audibert was rather scant, and so I did conduct a number of patent searches trying to look — not so much at the — I mean, I obviously wasn't trying to look at the file wrapper in those kind of situations, but I was trying to see if I could get any information on enlarging my understanding of the patent position and found nothing else that was substantive other than what had been provided.

Q: As I add up your experience working for major pharmaceutical companies, at least as an employee, I get about, I don't know, four and a half years. Is that about right? If you add Abbott and Fujisawa.

A: If you're asking for the period in which I was an employee of a pharmaceutical company?

Q: Yes.

A: That is about right.

Q: Do you know how long Mr. Audibert has been an employee of a pharmaceutical company?

A: I don't recall precisely how long he was employed, I believe it was about 20 years or more.

Q: You take issue with Mr. Audibert's assumption that Niacor-SR would have been the only approved sustained-release niacin product in the EU until 2002. Do you recall that?

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A: Yes, I recall that.

Q: And my recollection is you took issue with that assumption on the ground that Kos' Niaspan product could have been approved before then.

MR. SILBER: Objection, misstates his testimony.

MS. SHORES: He hasn't testified to that at all.

THE WITNESS: I'm not sure I understand your question. What I would respond to that general area of questioning is that as I understand it, Mr. Audibert made the assumption that Niacor-SR would be the only sustained-release niacin product in the EU up to the year 2002. What I knew was that the Kos product was approved in the summer of 1997 —

BY MS. SHORES:

Q: Where?

A: — in the U.S. and would make either of two assumptions: Either the product would not sell in this country and would fail in this country, in which case it would not — no one would seek to market it anywhere else most likely; or were it to succeed even modestly in this country and were there to be a perceived market for a sustained-release niacin in the EU, then Kos or a Kos licensee would have seen fit to take it into the EU

Page

and could do so well before the year 2002.

So, the bottom line of this is that if Niacor-SR was going to be approved in the EU, then Niaspan could be approved in the EU at least as quickly and certainly before the year 2002. If, on the other hand, Niacor-SR were to fail and were not to be approved in the EU, then the whole issue becomes moot because of Audibert's assumption of its being the only one prior to the year 2002 is not operative, because there isn't any.

Q: Is Kos' Niaspan on the market in any European country today?

A: Not to my knowledge.

Q: So, Mr. Audibert was right about that, at least.

A: No, Mr. Audibert made the assumption that Niacor-SR would be the only product approved prior to the year 2002, and he's totally incorrect about that since Niacor-SR is not approved in the EU.

Q: Yeah, maybe you didn't hear what my question was. My question was whether he was right in assuming that Niaspan would not be on the market in Europe in 2002.

A: I can't say. It's not 2002 yet.

Q: How about — do you think it's going to be on

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the market in 2002?

A: I have no idea what Kos' plans are. In fact, one of the bits of information that I had asked for and hoped to have prior to trial is exactly that, you know, what the status of Kos' efforts are in bringing the product into the European Union.

Q: Okay. Are you familiar with a statin in development called Questor?

A: No, I'm not.

Q: Okay.

Let me just take five minutes and finish up my allotted time for the moment.

(A brief recess was taken.)

BY MS. SHORES:

Q: Mr. Audibert made some assumptions about what market share he could obtain in Europe. Do you recall those?

A: Yes, I do.

Q: Do you think those were reasonable or unreasonable, assuming the product had been approved or would have been approved?

A: Assuming that the product would have been approved, if I remember correctly — and please correct me if I'm wrong — he assumed that he would get 1.5 percent of the total market for hypercholesterolemic

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drugs, and I thought while that was a small number, was an exceedingly aggressive number and well beyond what I thought was a reasonable projection for a couple of reasons.

First of all, his assumptions were based on the worldwide market with the exception of North America, but his assumptions in reality only dealt with the European Union, which represents, you know, roughly half of the international market, of the non-U.S. — non-North American market. So, he was excluding a big chunk of the world in — particularly in Japan and the Far East, because Schering doesn't have a strong presence there. So, that roughly meant that he was going to have to get about a 2 percent market share in the EU, ballpark calculation.

Recognizing that the niacin products have a minuscule fraction of the market, I believe it is well — way less than 1 percent, I think it was even less than 0. — than 0.5 percent, he would have to greatly expand the market for the niacin class of compounds and then get all of it, and so I thought that this was far too aggressive an assumption, even though when one throws out a small number like 1 and a half percent, on the surface it can look modest.

Q: So, you don't think Schering could have

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achieved that?

A: Well, if we go with a hypothetical, you know, the assumptions that —

Q: Yeah.

A: — I think you're meaning.

Q: Right.

A: That the drug was approved, the drug was approved in the time frame and with the indications that Mr. Audibert projected, which, as I've said before, I don't believe would have occurred, but even if one assumes that, I still don't think that the product would have achieved 1 and a half percent of the non-North American worldwide market for hyperlipidemic agents.

Q: Are you currently involved in any lawsuits?

A: Yes, I am.

Q: And what sort of lawsuits are you involved in?

A: Well, some are the Internal Revenue Service matters that I don't want to speak you on.

Q: Okay.

A: And the other is a lawsuit that I hope is dismissed on December 4th, which involves a libel suit that was brought against me as a defendant by a local football coach.

Q: Under our agreement or Schering's agreement

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with our co-respondent, Upsher-Smith, we have divided up our allotted, seven hours, into three-and-a-half-hour segments. I think mine is approaching the end. I reserve the right to resume in the event that Mr. Curran on behalf of Upsher doesn't use all of his allotted time.

Thank you very much.

A: Thank you.

MR. CURRAN: Should we take a lunch break now?

MR. SILBER: Yeah, that probably makes sense.

(Whereupon, at 12:15 p.m., a lunch recess was taken.)

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AFTERNOON SESSION

(12:55 p.m.)

EXAMINATION

BY MR. CURRAN:

Q: Good afternoon, Dr. Levy. I'm Christopher Curran of the firm White & Case representing Upsher-Smith.

Sir, you graduated from Yale University in 1963?

A: Yes, sir.

Q: Did your course of study relate to the valuation of pharmaceutical drugs?

A: At Yale?

Q: Yes.

A: No, sir.

Q: And then in 1967, you received your M.D. degree from Columbia University College of Physicians and Surgeons, correct?

A: Yes, sir.

Q: In studying and attaining your M.D. degree, did your studies focus on the valuation of pharmaceuticals?

A: I think obtaining an M.D. degree and the various basic science and clinical courses that I had to take certainly related to the use and valuation of pharmaceuticals.

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Q: The financial valuation of pharmaceuticals?
A: To a very limited extent, because we had some courses in medical economics that related to the economic role of various elements of the health care system as it relates to the total health care cost.
Q: It's not your position that anyone with an M.D. degree has expertise in valuing pharmaceuticals, is it?
A: I would — I would say that everyone with an M.D. degree has more knowledge relevant to the evaluation of a pharmaceutical than does the typical layperson without such training. If you're — if you're asking whether the M.D. degree is sufficient to render a person able to make a full valuation of a pharmaceutical, then I would say most likely not.
Q: Let's talk about you personally. You referred to a specific course you took at Columbia. What was that course again?
A: I don't recall the title of the course.
Q: But it had — you called it medical economics, is that what you said?
A: We had courses in the — in the area of medical economics.
Q: As part of that course, did you analyze the financial valuation of pharmaceutical price — pharmaceutical products to be licensed in and out?

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A: Now you're asking me, you know, an array of different questions. These were general courses meant to give physicians an understanding of the costs and economic participation of each of the elements of health care in the overall care of a patient. They were not meant to teach us how to in-license or out-license drugs.
Q: Or how to value drugs for purposes of in-licensing or out-licensing, correct?
A: Well, I would not agree to that, because the term "value" is a very broad-based term, and certainly a physician in the course of his training and experience as a physician probably develops the most important information requisite to valuing a drug; that is, the clinical utility of a drug, which is by far the most important element contributing to the value of the drug.
Q: The financial value?
A: Any value.
Q: Okay. Did you study comps in med school?
A: Would you define "comps"?
Q: Yes, comparables.
A: I don't know what you mean by "comparables."
Q: Okay. Sir, then you went to the National Institutes of Health, correct?

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A: No, that's not correct. I did an internship.
Q: Where did you do your internship?
A: I did part of it at the University of Colorado Medical Center and part of it at the Massachusetts General Hospital.
Q: Why didn't you list that in your report?
A: There were a lot of things that I didn't list in my report, sir. I just didn't think that was something that I wanted — that I needed to list in terms of, you know, where I did my internship.
Q: Now, at the National Institutes of Health, you did research in virology and immunology, correct?
A: Yes, that's correct.
Q: And you published the world's first paper on the mammalian gene therapy, correct?
A: That is correct, yes.
Q: Has anyone published one since?
A: I think there's been a fair number published since then.
Q: Did your work at NIH deal with the financial valuation of pharmaceuticals for purposes of in-licensing or out-licensing?
A: The reason I'm hesitating in answering your question is that I think that any of the experience that one gets as a health care professional, as a

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person doing research on one of the medically oriented sciences, basic sciences or clinical sciences, all contributes to one's understanding and appreciation for the value of different therapies.
Q: Okay, that's why you were hesitating?
A: The reason I was hesitating was I was trying to formulate my answer, sir.
Q: Now, you went to NIH — did you say before to avoid serving in Vietnam?
MR. SILBER: Misstates his testimony.
MR. CURRAN: It's a question.
THE WITNESS: I wouldn't dignify that question with an answer. The answer to that is no. The answer — I went to the NIH because I was fortunate enough to have the opportunity to serve my country doing medical research at our — at the National Institutes of Health in Bethesda, Maryland and was one of the people selected out of 19,000 applications — applicants.
BY MR. CURRAN:
Q: So, you applied for that position at NIH?
A: I applied for that position and got it.
Q: So, you weren't forced to go to NIH, were you?
A: I was not forced to go to NIH, that's correct.
Q: You elected to apply.
A: That's correct.

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Q: Okay. And you got in, and you elected to go.
A: That's correct.
Q: Sir, in your time at Duke, did you specialize in valuing pharmaceutical products for purposes of in-licensing and/or out-licensing?
A: I did not specialize in any of the aspects of commercialization of pharmaceuticals, but once again, my experience at Duke both as a researcher in the basic sciences as well as the clinical sciences and my caring for patients and learning about the needs of various patient populations for different kinds of treatments certainly developed, again, a considerable and enormously valuable perspective on the valuation of any mode of therapy, most particularly pharmaceuticals.
Q: So, now, at the time you left Duke in 1981, were you an expert in the valuation of pharmaceutical products for in-licensing and out-licensing?
A: I would not characterize myself in 1981 as an expert on the in-licensing or out-licensing of pharmaceuticals.
Q: Do you think anybody would characterize you at that time as having been an expert in that field?
A: I can't speak to what other people would perceive me as.
Q: I'm sorry, what was the last —

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A: I can't speculate about what perceptions others might have had about me as anything other than — on any subject, and I think I could only speculate as to what I would perceive myself to be. It would not have been unreasonable because of the nature of the research that I did and the exposure that I had for someone to have perceived me as having expertise in this arena.
Q: Well, I'm not saying having expertise in this arena. I said, were you an expert in the financial valuation of pharmaceuticals for in-licensing and out-licensing?
MR. SILBER: Asked and answered.
THE WITNESS: I don't believe that's what you said, number one, and number two, as I tried to testify before, each of the bodies of experience that I got along the way, up, to and including my period at Duke ending in 1981, contributed greatly to my expertise in the valuation of pharmaceutical products.
You asked me whether when I left Duke in 1981 I would consider myself to be an expert on the in-licensing and out-licensing of pharmaceuticals. You did not say anything about financial in your questioning. I said I myself would not have considered myself an expert.
You then asked me whether others might have

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considered me so, and I said it's possible that they might have, but I can't speak to how others might or might not have perceived me.
BY MR. CURRAN:
Q: Okay, are you done with that answer?
A: When I'm quiet, I think I'm done.
Q: Okay. At the time you left Duke, were you an expert in the financial valuation of pharmaceuticals for purposes of in-licensing and out-licensing?
A: When I left Duke, I knew very little about the general area of finance.
Q: Does that mean you did not — you were not an expert at that time?
A: My answer speaks for itself.
Q: Are you declining to answer that question?
A: I'm not declining. I think I've already answered it.
Q: Sir, after Duke, you went to Abbott Laboratories, correct?
A: That's correct.
Q: And you were the vice president of pharmaceutical research, correct?
A: That's correct.
Q: What were your responsibilities in that position?

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A: I had the responsibility for all the pharmaceutical research and development of pharmaceutical products at Abbott Laboratories.
Q: In the entire company?
A: The entire company.
Q: You were responsible for the whole R&D department?
A: I didn't say for the whole R&D department. I said for pharmaceuticals only.
Q: For pharmaceuticals.
A: Yes.
Q: Okay. Were you responsible for the R&D department as far as pharmaceuticals were concerned?
A: Yes, I was.
Q: So, everybody else in that area, R&D for pharmaceuticals, was reporting to you. Is that correct?
A: Yes. Yes, all the people in research dealing with pharmaceuticals reported to me. As I indicated earlier, there were in some of the foreign jurisdictions country managers who had reporting to them various people involved with clinical research, and those people were not under my aegis. They reported directly to the country manager in charge of the country involved, and they usually had — not

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always, but they usually had a dotted line to me.
Q: And when you got to Abbott Laboratories, their research program was moribund, correct?
A: In my opinion, Abbott's pharmaceutical research was moribund.
Q: And you turned that around?
A: It's my perception that I did turn that around, yes.
Q: And you take credit for Hytrin, Biaxin, Ritonavir and other drugs that came out of Abbott during that time frame, correct?
MR. SILBER: Objection, misstates his report.
THE WITNESS: I don't take credit for those, for any of those drugs. You know, as the leader, I set the tone of the organization, I recruited key people into the organization, I fought for respectability of the organization within a company that was referred to then as purely market driven, with R&Ds having little input into the decision making, and spent a lot of my time trying to change that perception.
I spent a lot of my time building relationships between the R&D world within the company and the various commercial components of the company in order to both gain some respectability for us and to gain the credibility requisite to the funding needed to effect a

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turnaround in the company. I think it would be insulting to the people who worked in the R&D areas for me to take credit for their discoveries.
I think that where my credit is most due is in creating a milieu in which fine research could occur and convincing management to help fund the creation of that milieu where fine research could occur.
BY MR. CURRAN:
Q: Did you start the programs that led to several marketed drugs, including Hytrin, Biaxin and Ritonavir?
A: Again, "start the programs"? The way we worked was — I can tell you my modus operandi was to solicit from the entire R&D staff ideas in a variety of areas. We then set up within the company what was a model that I had learned in academia in terms of peer review. We actually even called them study sections, where we had an array of scientists both within and without the company to examine the vitality of the various ideas that were put forth, and out of that peer-reviewed process emerged some projects, some of which led to those various compounds. I had the final approval within R&D as to whether those projects would be recommended to top management for funding.
Q: Were you uncomfortable with my terminology when I asked if you started the programs that led to those

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marketed drugs?
A: Yes, because I don't feel comfortable taking credit for other people's work. I didn't start those programs. Those programs in a fair sense were initiated by various people who were under my aegis. You know, for instance, the renin program was — if I were to name a person who started it, it was Jake Plattner. The Ritonavir program, if I named a person who started it, it was Jonathan Greer. The Hytrin program, if I named a person who started it, it was Jaroslav Kinel, and so on. If I wanted to name the person who started the Biaxin program, it was Prabha Fernandes.
So, it would be unfair of me and totally inaccurate of me to say that I started those programs. I supported those programs, and I created the milieu that enabled those programs to be done, and at best, I created a milieu and brought in people into that milieu that could generate those kinds of concepts and ideas and projects and implement them.
Q: In your judgment, did you succeed in helping Abbott's reputation and credibility?
A: I'm very proud of that. I think that — well, what some of the people who were at Abbott and are still at Abbott would say is that the period during

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which I headed R&D were the golden years of Abbott's research. That is not my term; that's theirs. We had something very special during that period, and virtually everything — everything — that Abbott is selling today was initiated during that period.
Q: You referred earlier to a product coming out of Abbott that was a first cousin of Cipro.
A: Yes.
Q: Which product was that?
A: You know, I've forgotten the brand name that it carried. It was a floxacin, because it was a member of the quinoline antibiotic series. I just have forgotten the name of the drug, because that name was actually applied after I left the company. The product was approved under the aegis of a man named Andre Pernet, and that would have been — oh, I would say in the late eighties or — more — perhaps even the early nineties when that drug was finally approved.
Q: But was that drug developed while you were at Abbott?
A: It was discovered when I was at Abbott, and the preclinical development was begun; that is, some of the formulation and toxicology studies. But as I'm sure you're aware, the path that a new compound travels in the pharmaceutical industry is a rather long one and

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lengthy one, and the discovery projects that led to the emergence of those compounds or that compound in particular was begun under my aegis. The actual development in terms of the bulk of the clinical trials and so on were done after I left.

Q: Now, that's the drug that you also testified earlier was subsequently withdrawn from the market?

A: Yes, it was.

Q: And you also referred to people dying on account of that drug?

A: I don't think I said on account of that drug. What happened, as far as I understand it — and I am — my knowledge of this is what's in the public domain. I have no, you know, no privileged knowledge of what happened. As I understand it, there were a number of deaths associated with administration of that drug post-approval and that the drug was voluntarily withdrawn by Abbott.

Q: So, there were deaths associated with that drug.

A: Yes, sir.

Q: And this was a drug that had been approved by the FDA?

A: Yes, sir.

Q: How does that happen, that a drug gets approved

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by the FDA and it turns out that it is associated with deaths?

A: Well, again, as I'm sure you're well aware in the position that you have as counsel to a pharmaceutical company, you are well aware of the fact that drug discovery, drug development and drug marketing is a business fraught with considerable risk. Drugs fail at various stages, including post-approval. Clinical trials represent a relatively select population of patients, even large clinical trials, a very small population compared to the population at large, and the clinical trials are done on patients that may or may not represent the full spectrum of genetic diversity in the patient community at large.

For instance, this morning we heard — I was asked questions about some of the exclusion criteria that were applied to the Niacor-SR trials, and so patients were excluded from the studies that happened to have slightly elevated hepatic enzymes. Once the drug is approved, there's no proscription against physicians using drugs in various and sundry ways, including off-labeling, and it's conceivable that a hepatotoxic drug could have been used in a patient population that already had mild hepatotoxicity and that the drug would exacerbate that and even cause

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death. So, an analogous thing could have happened with this quinoline antibiotic or with other drugs that had been withdrawn post-approval.

Q: Now, this antibiotic developed at Abbott, was its problem — was its safety problem hepatotoxicity?

A: Sir, I don't recall what the nature of the toxicities of that drug were. I just have no recollection of that at all.

Q: But it turned out that that drug was toxic to humans?

A: It killed humans, yes, sir, or it was associated with the death of humans and was purported to have caused those deaths.

Q: Purported by whom?

A: I don't recall that, sir. I mean, I think that, as you know, whenever a serious adverse event occurs when a patient is taking a drug, that becomes a reportable event, and those events are reported to the regulatory agencies involved as well as to the company that sponsors the drug, and I don't know all the circumstances with that.

What I believe I remember — and I'm really digging deep into my memory on a matter that was not of particular importance or focus to me — I believe that there were deaths that were reported to Abbott and also

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to the FDA and that Abbott, in anticipation of the FDA's withdrawing the drug, voluntarily withdrew the drug. I believe that's what happened, but I don't know that for certain.

Q: Now, Abbott you said discovered the drug, correct? Is that what you said?

A: That's correct.

Q: Yeah, and then conducted years of clinical trials on the drug, correct?

A: I — the trials were conducted after I left the company. I can only presume that there were years of trials.

Q: Well, on what basis do you presume that?

A: Because it usually takes years to conduct clinical trials on a drug to gain approval by the FDA.

Q: Have you ever done any digging into the allegations that this antibiotic product was associated with killing people?

A: I have done no investigations into it. I did talk with two very prominent people in the discovery and development of that drug, Andre Pernet himself and Prabha Fernandes, both of who remain, you know, good friends of mine, and Andre was pretty distraught over it, because it had been he who championed that particular analog, as opposed to one or two that

virtually everybody else in the organization thought had a better profile but was about a year behind, and Andre was quite anxious to get this drug approved for a variety of reasons, some of them personal and some of them corporate, and felt very guilty about that, because it wound up essentially killing the whole program, because the later compounds had a better preclinical safety profile and probably would not have had the problems that that drug had. We'll never know that, because they were not taken further into development.

So, your question was whether I did any investigation on it. Investigation would imply — would to me imply more than I did, but I certainly — Andre actually called me, because he was upset, and I was his boss, and he wanted to talk. And Prabha has been a very good friend of mine, you know, since we were both at Abbott. I hired her at Abbott, and she has remained a friend since then, and she's talked a bit about it, but I wouldn't constitute — that in my mind would not constitute an investigation.

Q: Weren't you kind of curious to get to the bottom of the issue?

A: I would have to say that as a scientist, I'm always curious about unforeseen events like that, I



recognized that it was not my place to attempt to get confidential information out of Abbott to which I was not privy, nor was I so bored with the other elements going on in my life that I wanted to make a project out of finding out what went wrong with that drug.

So, your question was, was I curious? Yes, I'm curious. I'm still curious as to exactly what happened. Would I likely have found out anything more than what's in the — what's made public were I to have given in to that curiosity? Probably not, because I think that all the information that was available to anyone, even under, you know, confidential conditions, was certainly made available to the FDA and to any other body that wanted to investigate it, and I don't think they have any clear answers. One rarely gets clear answers as to why idiosyncratic effects occur.

Q: So, you never asked Abbott to provide you with information relating to this matter?

A: I thought there was no — I had no right to ask Abbott for information on that matter.

Q: So, you didn't.

A: I did not.

Q: What was Andre Pernet's position at Abbott?

A: He was vice president of pharmaceutical research, and he followed — well, there were two other



vice presidents of pharmaceutical research between me and him, and he was — so, he was — Norm Weiner followed me, Fred Murad followed him, and Andre followed Fred Murad.

Q: But now while you were at Abbott and while you were vice president of pharmaceutical research, Andre Pernet reported to you, correct?

A: Yes, sir.

Q: What was his position then when he was reporting to you?

A: He was referred to as the area head of antibiotic research.

Q: And you say he was distraught about the fact that this antibiotic purportedly killed people, correct?

MR. SILBER: Objection, misstates his testimony.

THE WITNESS: I don't recall what I said before. What I will say now in response to that is Andre sought me out, called me up when this happened, told me about it, and cried, and he came over to my house, we had dinner together, and I think just as a student-mentor almost kind of relationship, he and I talked through the — through the issue, and so I think he — you know, when a man calls up his mentor and



cries, I suspect that means he's a bit distraught.

BY MR. CURRAN:

Q: Were you distraught?

A: I wouldn't characterize my reaction as distraught. I mean, I didn't cry. I didn't feel any guilt over the issue whatsoever. I had no role in it. I think that any human being is distraught over the loss of another human being, and so to that extent I'm sure I was sad. "Distraught" is probably too strong a word for what I felt.

Q: So, now, this was a drug discovered at Abbott while you were in charge of all pharmaceutical R&D, correct?

A: That's not correct. I initiated the program in quinoline antibiotics. At that time, there was a class of drugs, the lead compound of which was a drug called norfloxacin, that's made by Merck, and this had a very exciting spectrum, and we initiated a project to try to find other members of this class that would have certain advantages relative to norfloxacin.

We formulated a chemical team, we had some chemical — chemistry objectives and some pharmacology and microbiological objectives, but by the time I left the company, that specific lead compound had been synthesized but was in the process of being evaluated

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in all the clinical — not clinical, preclinical testing, and so it hadn't emerged yet as a product candidate.

Q: But the compound had been discovered, correct?

A: The compound had been discovered.

Q: And while you were at Abbott, correct?

A: Yes.

Q: And Andre Pernet was a subordinate of yours there, correct?

A: Yes, sir.

Q: And he was the principal champion of this drug, correct?

A: That is correct.

Q: And when it ended up killing people or purportedly killing people, he was distraught about it, correct?

A: Yes, sir.

Q: Sir, were there any other drugs developed or discovered during your stint at Abbott that purportedly killed people?

A: I can't think of any drugs that were discovered when I was at Abbott — in fact, I can't think of any drugs that have even been made by Abbott in any way other than this one drug that has been associated with an unusual frequency of death. I'm sure that almost

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every drug is associated with death in some way or other, but not to any noticeable or measurable extent.

Q: Well, this drug was pulled from the market because —

A: Yes.

Q: — it was associated with the death of people, correct?

A: Yes. Every drug — it's a cliche, but every drug has side effects, and if used in enough people, virtually every drug, including the most benign drugs, aspirin and Tylenol and these types of drugs, you know, have been and will be associated with serious adverse events. If a drug is used in millions and millions of people, even if a minuscule fraction of those people have an idiosyncratic reaction, an unusual reaction to the drug, it will be seen, but this doesn't imply that there's anything inherently wrong with the drug.

The quinoline antibiotic that we were speaking of earlier went beyond this and caused serious adverse effects in a far more than acceptable number of patients, and it had to be withdrawn. I can't think of any other drug that I was involved with at Abbott — in fact, I can't think of any other drug at Abbott, period, that has had to be withdrawn for safety reasons.

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Q: Sir, you were the director of antibiotics at Abbott, correct?

A: When I first arrived, this lasted for maybe three weeks, I was the — my actual title was director of biological research, but most of Abbott's biological research was antibiotics, so I never really knew what my title was. It didn't last very long, because they told me I was going to be a vice president, they just had to get it approved. So, I was director of antibiotics or director of biological research or some director of something for a brief period, then I was made a vice president.

Q: Sir, what business is CoreTechs Corporation in?

A: CoreTechs does two things. What it spends most of its time on and derives most of its revenue from is the development of early stage companies, and the other part of the revenue of the company involves consulting assignments such as the one I'm involved with now, but usually not in support of litigation, but rather, consulting assignments for typically the investment community looking to evaluate various opportunities.

Q: Well, you said early stage businesses, is half of — is half of CoreTechs' business —

A: Oh, far more than half.

Q: More than half.

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A: Most of our revenue comes from the value of the equity that we get when we build — when we build a business.

Q: Now, in what industries?

A: The — because I'm the principal rainmaker, most of the business now is in the health care arena. What we were a couple of years ago and really until I started having problems with my back dealt with principally three areas. One was health care, one was material science, that is, all different forms of new materials, and then the third was in the communications — you know, IT, as it's commonly thought of. That's the smallest part of our business, but Gail Green is a computer scientist and has that part of our business, and we hope to grow that a little bit, but that's been a relatively minor part now.

I would say that approximately, oh, 75 percent or even more is in the health care arena, and about, oh, 15 percent in the material science arena, and 10 or so in the IT.

Q: Now, what do you do for these early stage companies?

A: About anything that needs to be done. We — the typical modus operandi — it isn't always done this way — we always do it for equity. We are never paid.

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We don't — we are not consultants to them. We don't charge them by the hour or the day or — it's always done for a piece of the business, and almost always one of us will go on the board of directors, and we'll just help the principals in the company do whatever has to be done.

I mean, sometimes it involves helping them raise money. Sometimes it involves helping them design and implement various research and/or development programs. Sometimes it helps — it involves helping them find, recruit personnel. Just anything — we are really functioning as officers of the company, sort of part-time officers of the company during this nascent period for the company, although we are not officially officers of the company.

But our role is as a director, not as a company officer. We're really — we refer to ourselves as working directors. I mean, that's sort of the cliche, again.

Q: Yeah. And is that because you're consulting the company as you serve on the board of directors? Is that why you call it working directors?

A: I'm sorry. I don't understand your question.

Q: Typically a representative of CoreTechs serves on the board of directors of the client company. Is

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that correct?

A: That's correct.

Q: And in addition to serving as a director, the CoreTechs representative advises and consults with the officers of the company, correct?

A: Well, where I'm not comfortable with the way you're expressing it is you're saying in addition to being a director. I think that a director of an early stage company often is involved in a more active participation in the company's activities than is the — say the director of General Motors, and so I think that a directorship in most early stage companies involves either some form of operating assistance and/or financial assistance.

Many times directors in these early stage companies did provide significant financing, so they've been asked — asked for and received a board seat. Most of the time these individuals provide as their principal contribution financing, and as a lesser contribution, operating guidance.

In our instance, we have almost our entire contribution as operating assistance, and sometimes, but not always and certainly not an obligate aspect of our participation, some financing. So, we're sort of the flip side of a venture capitalist, if you will. A

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venture capitalist might be 90 percent money and 10 percent operating help. We might be more 10 percent financing and 90 percent operating help.

Q: And now where does CoreTechs get the money to finance these startup companies?

A: In two ways. We have internally generated funds that we keep, retain, and put in in short-term instruments, so it's fairly liquid, so that we can, if we so elect, provide some financing to the company. And secondly and much more prominently, we have a nic level of credibility with professional investors and can help the company build a relationship and get funding from these professional investors.

When we do that, and we're very strict about this, because I don't feel comfortable with some of the other operations of other types of entities, we never take a commission on the money. So, if I help a company raise money, for instance, all the money goes to the company. We don't make any money, you know, as a broker for money. We pretty strictly want to stay away from being perceived as or operating in any way as a broker.

Q: Do you ever help your clients value their companies?

A: Oh, yes, all the time.

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Q: How do you do that?

A: In various ways. It depends on the company, depends on the technology, depends on the nature of the business, and there is no — and I think, again, one of the things that we take some pride in, it's sort of an obsession with me, is I don't like fixed formula being applied to all situations. I think that every company is different, and the thought process that should be brought to every opportunity is different.

So, we'll — the valuation of any research project or any early stage company is a — is something that I think has to be customized to the individual activity at hand.

Q: Do you ever do quantitative analysis in valuing these entities?

A: I would appreciate your defining what you mean by "quantitative analysis."

Q: Number crunching.

A: I guess I'd ask you to define — I mean, number crunching, do we use an adding machine? Yes, I mean, I'd ask you to define what you mean by "number crunching."

Q: Do you ever do a net present value calculation on anticipated revenue streams of these startup companies?

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A: That's a — that's a calculation that is often used and I personally find of limited value for most situations.

Q: When you say it's often used, what do you mean by that?

A: It's just a very standard parameter that, you know, people doing financial analyses like to see. It's something that — it's just — sort of like the SGOT/SGPT that we were talking about earlier. It's just one of many parameters that can be applied, but I think it has little precision and little utility until there is an actual marketable product in hand and real market research can be conducted and real valid and viable financial projections can be developed and meaningful NPV analyses or projections can be made.

I think when one doesn't have a product in hand, the market research supporting the sales projections on the product are very tenuous, and the NPV calculation really is dependent upon two groups of numbers, you know, one are the sales projections, you know, for the product, and the second is the discount rate, and then you just plug it into the formula.

Well, you know, I think you're well aware of the term GI/GO, garbage in/garbage out. Well, if you plug garbage into an NPV formula, you'll get garbage

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out.

Q: Do you ever conduct NPV analyses for these companies that you're advising?

A: I think I testified a moment ago that, yes, we often do, particularly when the product — when the company has a product in hand. You know, for instance, one of our companies has a food product. This product exists, it's got no regulatory hurdles. We were able to conduct some formal market research with this product, focus groups, and we were able to — since there were analogous products out there that sold for certain prices and in certain markets, we were able to build some financial projections that would have an accuracy of, you know, plus or minus 90 percent, which is pretty good for market research.

And then the NPV calculations have some possible meaning, not much, at least to me not much, because one is still fraught with the fact that all NPV calculations are based on two very uncertain variables. When you're projecting sales in the future, and as much as you may try, not too many people can see too far past a year, and usually these projections go out five years or even ten years. And then secondly, one has to somewhat arbitrarily choose a discount rate, and if I want to make the numbers look good, I'll choose a low

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discount rate. If I want to make the numbers look bad, I'll choose a high discount rate. The fact is that no one knows what that discount rate should be.

All of these situations are far riskier than T-bills, and if T-bills are — you know, now they're a little bit lower, but T-bills typically have been 7-8 percent, but what multiple of a T-bill is the risk of this new product or this new venture or this new whatever? That's your discount rate. It's almost infinite.

You know, when you have a new product that's never been on the market before, even if you have the product in hand — never mind all the vagaries of the preapproval process, where it's even more ridiculous — but even when you have a product in your hand, you don't really know what that product's going to do. So, you're going to have to pull a discount rate out and plug it into your formula.

I don't think that's a very precise exercise and wouldn't put a lot of weight on whatever the numbers came out in that.

Q: I'm sorry, so, did you or did you not do an NPV valuation on this food product you referred to?

A: We did do an NPV calculation on the food product.

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Q: And what's the food product?

A: It's called the Lox Box, and it's a device that takes a piece of raw salmon and converts it into lox in two days in the refrigerator.

Q: What was the analogous product that you looked at for market projections?

A: There was no analogous product, but lox is bought and sold, and so we knew what people — we knew that nobody was going to pay — you know, lox cost, you know, $20, $25 a pound if you buy it in the delicatessen. So, certainly we knew that the upper limit that somebody was going to pay to produce his own lox was a fraction of that. Then you just sort of work down from there.

Q: And you ended up with market projections that you were confident in. Is that right?

A: I didn't say that, sir. I said —

Q: That's a question. It's a question.

A: I'll say it again — well, as I said —

Q: Can you answer the question?

A: I'll be happy to answer the question once I understand it, sir.

Q: Okay, go ahead. Go ahead.

A: As I understand your question, you're asking me, you know, how much I relied on those numbers, and

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as I've said repeatedly, I think that making financial projections about the sales of any product, particularly when that product is a new product, as ours was, for instance, are fraught with great peril and should be looked at with little confidence. You do the best you can.

In market research, in general, it's a very imprecise world. I mean, those of us who were in laboratory research often have been known to make snide remarks about the use of the term "research" when applied to the phrase "market research," because it just doesn't — there's so much more subjectivity involved with it.

Q: Have you ever worked in a market research position?

A: I have not worked in a market research position.

Q: So, on this food product, this Lox Box, you did an NPV calculation, but you had little confidence in the outcome. Is that right?

A: One does many things in developing the financial analysis of a business. Something that's very, very easy to do is an NPV calculation. When we were — when we were trying to estimate for ourselves what sort of needs this program, this project, this

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company would have, we tried to figure out what might the sales be, and we did that as best we could, but we realized that this was going to be a very imprecise exercise, and just because an exercise is imprecise, it's sometimes, often, better than doing nothing. So, we do what we can do.

Q: What other analytical tools did you use to value this Lox Box product?

A: Well, to value it, we were building this company with the idea that it ultimately could be acquired by another larger food company or by some private individual interested in taking over a company like this, and so the main thing that we looked at was what sort of selling price we needed for the Lox Box to have it be profitable on a per unit basis.

We knew what the components of the device could cost, and we had an idea from several focus groups that we ran what the public would potentially pay for this product. So, we knew what we could sell it for.

We then built from that number of what we thought we could pay for the production of the product, in other words, what our cost of goods could be. We then had plenty of information on what margins were required by the various retail companies that sell these types of products. For instance, Bloomingdale's

Page

and Nordstrom's and, you know, Marshall Fields and Crate & Barrel and William Sonoma. We knew what margi requirements they had, and that ranged from about 53-5 percent to 62 percent.

So, knowing what the public would pay for it, knowing what margins we had to give our own customers our retailers, we then could back up and figure out what we could spend to build the product, and then from that, we could figure out how much we could earn on a per-unit basis. What really we were interested in is what the potential earnings could be of this — you know, of this product, and hence, of the company.

Then from that, recognizing that people typically will pay between 8 and 20 times earnings for an enterprise, we had a ballpark figure of what we thought, if this product were to be successful, we could sell the company for. That's really the exercise we went through.

The net present value calculation we did because it's so easy to do. It's, you know, entering a couple of numbers in an Excel program, and you get a number out. We didn't really — I — if you were to ask me now what the NPV calculation was, I couldn't tell you. I could tell you to the penny, you know, the COG, the cost of goods, I could tell you the units, I

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could tell you, you know, where it sold, how many it sold, those are the numbers that are important to us.

Q: On the Lox Box you're talking about?

A: Yeah.

Q: What's the COG?

A: I said I could tell you. I don't have to tell you these kinds of numbers, because it's a closely held company, and I don't really want to share my proprietary information with you. I don't think that has any bearing on, you know, on this case.

MR. CURRAN: Mr. Silber, can you instruct the witness to answer the question?

MR. SILBER: He's given you his answer.

MR. CURRAN: And that's fine by you?

MR. SILBER: Um-hum.

BY MR. CURRAN:

Q: So, you won't tell me, huh?

A: I — sir, I'm happy to tell you things that are not proprietary information or even if they are proprietary information if in my best and honest judgment they have bearing on this case. I think for me to tell you something just because you're wanting to know is not of particular importance to me. I don't think your knowing what it costs us to make the Lox Box is any of your business or has any bearing on your

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business or your client's business.
Q: Okay. Now, in valuing this Lox Box thing, you still had to project sales volume, correct, to value the product or the company?
A: We had to — we had to speculate about how many units could be sold depending on various scenarios, and by far the most imprecise number was that one. I mean, we really didn't focus on it very much, because we realized that the — well, I can tell you this. I don't — I mean, this is germane to the sort of things you're asking me.
The range of annual units sold went from about 9000 up to 2 million. That's the enormity of the range, and this was a well-defined product that existed, and so you have this enormous range. It all depended — for instance, we knew that if QVC took it and, you know, Home Shopping Network took it and pushed it and liked it, it would quadruple our sales. We knew that if Oprah Winfrey said two words about it, it would quintuple our sales. We knew that if William Sonoma took it, it would make a three-fold difference in our sales, because these are such enormous players in this marketplace.
So, any speculation — we hoped that they all took it. We hoped that they all took it and we would

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get our 2 million units, but we also realized that even if they didn't and we sold a mere 10,000 units, we were prepared for the downside, that even at that low end of the sales, the company would still be profitable, and albeit small, it still could be of interest to somebody interested in running a company, you know, that's got, you know, a half million dollars a year in sales and it's got, you know, X percentage going to the bottom line.
Q: Well, what's the name of this company that — that has this Lox Box?
A: It's Colescraft Corporation, and the name has actually been changed to The Perfecur Corporation, P E R F E C U R. That's the DBA. I believe the — well, I know the company has been filed as Colescraft.
Q: How do you spell that?
A: C O L E S C R A F T.
Q: Where did that name come from?
A: One of my colleagues and long-time friends is Eric Coles, the man I mentioned before, and Eric's mother passed away shortly before we formed this company — oh, I'm sorry, no, she was dying when we formed this company, and Eric thought it would be nice to name a company sort of after her, she having formed another sort of invention-based, technology-based

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company in the sewing area that never got off the ground, and she had named that company Colescraft, and so we named this company Colescraft just for her.
Q: Are you a co-inventor of this Lox Box?
A: Yes, I am.
Q: Do you have it patented?
A: Yes, I do. Well, patents have been applied for. We haven't had any issue yet.
Q: Where did you apply for patents?
A: U.S.
Q: Anywhere else?
A: No, sir.
Q: You don't have any patent protection in Europe?
A: No, we don't. Don't get any ideas now.
Q: What I don't understand is how can you have such a big range, from 9000 to 2 million units, in your sales projections.
A: We went through a number of scenarios. In this particular instance, the entire company was funded internally. So, we wanted to see how bad this could be, and we looked at a variety of scenarios, and in the retail marketplace — we did a lot of market research, because the product was in hand. We could show it to people.
We realized that the sales of this product were

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dependent upon a number of unknown variables, some of which I mentioned to you before, and we didn't know whether we would be successful with, you know, with those various venues that I spoke of.
Q: Have you tried to sell any equity in this Lox Box company?
A: No, we — that's not our business. The only time equity is given in our business is if we elect to take outside investors, and we rarely are faced with that opportunity, because most of the time when we are involved with early stage companies it's that we are a minority shareholder, you know, we're coming into somebody else's company and helping him or her build that company, and we get a minority equity position in it. So, we're not in a position to sell our equity or sell the company's equity.
In a few instances, of which this is one, we were the founders and inventors that drove the company, in which case we could sell equity, but we just elect not to do that.
Q: All right, let's put aside Lox Box for a minute. Just more generally, how do you — what analytical tools do you use to value a startup entity that doesn't have any products currently on the market?
A: Most of the time, when we get involved with a

— in fact, almost all the time when we get involved with an early stage company, we don't present to ourselves or to potential investors any valuation numbers. That may sound strange to you, and I realize it's somewhat unusual in this industry, but as I have indicated a few times today, I'm one of the principal rainmakers or maybe the principal rainmaker in the company, and I try to be careful about the representations that I would make to, you know, to a potential investor.

Whatever number I were to conjure up using NPV or any other mechanism would be GI/GO, and I just choose not to do it. So, for instance, we had one — a company we've done relatively recently that's an antiviral, and, you know, I've raised about $5 million for this company without uttering one element of, you know, of rationale, numerical rationale for the valuation.

We arbitrarily decided what the pre-money valuation of the company would be, and this was based not on any NPV calculation but more on what similar types of companies have been valued at in recent years and really what we — what we thought was a fair valuation to investors.

The financial projections, sales projections, I



mean, as I say, I've raised $5 million for the company without a single sales projection. I mean, one could — this particular company, I can tell you this part of it, has a very novel therapy — a potentially very novel therapy for hepatitis C. That's a very bad disease. There is no therapy for hepatitis C. I'm sure Rich could tell you that.

It also has another element to the company where one of the technologies dealt with the propagation of hepatitis C, something else, again, which is very difficult to do, and we asked for certain pre-money valuation, and all the investors that we would deal with are fairly sophisticated people, and they could see that if company were to succeed, it's a — you know, it's going to have a market capitalization in excess of $500 million, maybe a billion. If it doesn't succeed, it's got a value of zero.

So, the number is somewhere between zero and a billion dollars or more. What am I going to do, tell them it's a hundred thousand or $100 million or $150 million or $200 million? It's all nonsense.

I mean, you look at it — I mean, these kinds of decisions, at least in this sense, are experience and rationality based. You know, if one has a treatment for hepatitis C, a disease that is — that



affects millions of people and for which there is now only an inadequate therapy, some of it put out by Schering-Plough I might add, we're in pretty good stead, and that's all we had to do.

MR. SILBER: Chris, if you get to a breaking point, we've been going for about —

MR. CURRAN: I'm sorry, if we —

MR. SILBER: If we get to a sensible breaking point, we have been going for a little while.

MR. CURRAN: Okay, sure.

BY MR. CURRAN:

Q: So, is it a fact, then, that often in situations where you're dealing with a startup company with uncertain revenue streams, you don't use financial analytical tools, but you instead use judgment?

A: I don't think that's what I said, but let me try to clarify. I find classical financial analyses — let's just be more specific, net present value calculations — to be very unhelpful in almost every situation, and particularly in a situation where the product itself is not on the market or is not yet marketable.

Even in the most generous of situations, that is the example I used, the Lox Box, which had no regulatory hurdles to deal with, it had merely a



marketing and sales effort and some luck to drive or not drive the business, even there, as I said to you, the numerical — the financial projections were — had an enormous range, and whatever NPV calculation we would do would vary enormously based on whether we choose a, you know, 10,000 units sold or 2 million sold. So, what good is that? I mean, I'm not going to plan based on that.

So, one does it simply because every once in a while somebody may ask for it, so there it is, and — or we may look at it. Who knows? I mean, it's so easy to do. It's a mindless calculation to do with, you know, with a good old Excel program. So, all we had to do was plug in, you know, numbers ranging from, you know, sales of 10,000 of them to sales of 2 million of them, and, you know, we might put in different discount rates and get out a bunch of numbers, which to me meant nothing, because I knew what went into those numbers. I think the more you know what goes into them, the less confidence you have in them, at least for me.

Q: Has anybody ever asked you to do a net present value calculation?

MR. SILBER: Anybody ever?

MR. CURRAN: Yeah, ever.

THE WITNESS: Actually, I don't think I have

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ever been asked by anybody to do one. I have always been on the asking side rather than the askee side, and I have performed them many times just because I'm curious. I mean, just do it. Why not? As I said, it's so easy to do it.

I have asked some of those people that, you know, you asked me about earlier, you know, to — you know, to prepare a table with NPVs with various scenarios. That's the only way I've ever dealt with them. I've never myself found it useful to choose a single NPV and look at it and say, that's gospel. I always present it as a matrix, regardless, whether I — and most of them I don't even do it, but if I do do it, I present it as a matrix with different discount rates and different sales numbers.

BY MR. CURRAN:

Q: In what situations have you asked others to prepare an NPV analysis?

A: When there was a product in hand, an approved product in hand, and we were able to — either able or willing to conduct the requisite market research so that we could generate some numbers with which we had some comfort, then I have often asked for those numbers.

For instance, in this antiviral project that I

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mentioned to you a moment ago, it didn't even dawn on me to carry out an NPV analysis, because it — you just have a look at it and say, you know, here's — we either have or we don't have a treatment for hepatitis C. Does it really matter whether it is a $100 million drug or a $3 billion drug at this stage of the game? I'll take either of them. They'll both be successful. One is just a lot more successful than the other.

But I'm not so wealthy that I would scoff at a $100 million drug. It certainly wasn't going to be less than that. I didn't need some, you know, some NPV to tell me that, and most people wouldn't.

MR. CURRAN: Do you want to take a short break?

MR. SILBER: Yeah, sure.

MR. CURRAN: Well, no, not yeah, sure. I mean, if you don't want —

MR. SILBER: Yes, I would like to take a break, that's fine.

MR. CURRAN: Okay.

(A brief recess was taken.)

BY MR. CURRAN:

Q: Sir, niacin or nicotinic acid has been shown to reduce levels of total cholesterol, correct?

A: Niacin has been shown to reduce levels of total cholesterol, yes.

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Q: And sir, niacin has been shown to reduce levels of low-density lipoproteins, correct?

A: Yes.

Q: Those are LDLs, right?

A: Yes.

Q: And sir, niacin has been shown to reduce levels of triglycerides, correct?

A: Yes.

Q: And sir, niacin has been shown to reduce levels of Lp(a) lipoprotein, correct?

A: I'm less familiar with those data, but I think that's correct.

Q: And sir, niacin has been shown to increase levels of high-density lipoprotein cholesterol, correct?

A: Yes.

Q: Those are HDLs, correct?

A: Yes.

Q: So, sir, niacin affects all cholesterol lipids in the proper direction, correct?

A: I don't want to be pedantic in responding to that, but to be scientifically accurate, the answer is I don't know, because as we seem to learn more and more about these lipid profiles, we learn that there are some good and bad HDLs, and so your question I think

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said that it affects all the elements of the lipid profile in the proper direction, and I can't say that that is absolutely correct, because I don't know. I'm not sure anybody knows, but I know I don't know.

Q: Sir, under current thinking within the field, niacin moves all the lipids in the right direction, correct?

A: I would repeat what I just said. I think that there has been an accumulation of literature in recent years that have looked for subpopulations even within the LDL and the HDL. I don't know — but I don't know of any in the triglyceride compartment, and I really don't know if anybody has looked at what niacin does to each of these sub-subpopulations. I just don't know the answer to that. I suspect there are people that do know the answer to that, but I'm not one of them.

Q: Sir, the effects that niacin has on blood lipids have been shown to reduce the incidence of coronary artery disease, correct?

A: I think I would have to answer that in the same way I answered your previous couple of questions in that I don't think that one is completely accurate in saying that the effects of niacin, the known effects of niacin, on the various sub and subpopulations of lipids is fully consistent with that distribution of lipids

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that has been associated with a decrease in coronary artery disease. As I said before, I think that one has to speculate about information that I don't believe is — exists, or if it does exist, it certainly is not known by me.

Q: Sir, a reduction in levels of total cholesterol has been shown to reduce the incidence of coronary artery disease, correct?

A: A reduction in the level of total cholesterol has been associated with a reduced incidence in one aspect of cardiovascular disease.

Q: Sir, I'd like to have you refer to your report. Do you have that there in front of you?

A: Yes, sir.

Q: I'd like to refer your attention to the bottom of page 4. I'm going to read two sentences to you, and then I'm going to ask you if what I read is accurate or not. The two sentences begin at the bottom of page 4.

"Niacin (also known as nicotinic acid) is a chemical substance, best known as a vitamin, which, in high oral doses, has been shown to reduce levels of total cholesterol, low-density lipoprotein (LDL) cholesterol, triglycerides and Lp(a) lipoprotein and to increase levels of high-density lipoprotein (HDL) cholesterol in the blood. Such effects on blood lipids

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have been shown to reduce the incidence of coronary artery disease."

A: I see that.

Q: Are those sentences accurate or inaccurate?

A: I think that in trying to answer your question accurately, I have to say that that statement is accurate within the common knowledge of people in the medical and probably in the pharmaceutical world, but must be qualified by the fact that there may be differences from that opinion based on these sub and sub-subpopulations that I alluded to earlier, and this information is constantly accruing.

It wasn't too long ago that we assumed that there was cholesterol, period, total cholesterol, and if it was high, it was bad, and if it was low, it was good. Then we learned about low density and high density, and we had to modify that opinion. We've learned about lev-forms and dextro-forms of different — of these types of compounds that may or may not have different effects in the cardiovascular physiology.

So, I mean, I'm testifying under oath, and I don't want to say that I know that the lipid profile changes that are found here are absolutely and forever more going to hold true as being associated with a reduction in cardiovascular disease, because there may

Page

be modifications of that.

Q: So, these two sentences as written are not accurate. Is that correct?

A: That's not what I'm saying.

Q: Well, what are you saying? This is your report, right?

A: Well, sir, maybe if you gave some —

MR. SILBER: He has already answered your question, Chris.

BY MR. CURRAN:

Q: No, let me withdraw that question. This is your report, right?

A: Yes, sir.

Q: You wrote it, right?

A: Yes, sir.

Q: Were you trying to be accurate when you wrote it?

A: Yes, I was, sir.

Q: Have you gotten smarter since you wrote it?

A: I hope so, sir.

Q: Do you now disagree with those two sentences as I just read them from your report?

A: I don't disagree with them.

Q: Do you agree with them?

A: Sir, you're asking me — this was a relatively

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brief report. It was not a treatise on hypercholesterolemia and the treatment thereof. So, in a brief section devoted to what niacin has been shown to do and not, I took the — an accurate but broad-brush approach.

You are now focusing on that very narrow segment of this report, two mere sentences, and as in many generalization statements, when one looks at it more specifically, there are exceptions, and now we're talking about the exceptions, and I'm trying to be accurate and say that there may be exceptions to this statement.

Now, were I to have focused on all of those potential exceptions in this report, I would have written pages on one narrow segment of it. I chose not to do that. I believe what I wrote is accurate with the qualification that I've tried to give you that there may be exceptions to that and the information may change.

Q: All right, let's talk about your report generally. Is it generally accurate, subject to the details and certain exceptions?

A: I feel that my report is quite accurate and represents my opinions as accurately as I could express them.

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Q: So, you couldn't have done a better job on those two sentences?
A: That's not what I said. What I said was that if I had chosen to take, rather than two lines, 20 pages, I could have cited the various publications, the various theories, the various lipid electrophoretic profiles, the various different disease states within the cardiovascular realm, the different genetic abnormalities, et cetera, et cetera, et cetera, and written a treatise on this. That wasn't what my charge was. It did not call for that.
What I wrote there is generally quite accurate and I think would be consistent with the general opinions of any expert in this field, but I think if such an expert, including myself, were quizzed as specifically on those two sentences as you have done, he would feel it germane to say that there may be exceptions to those two sentences. It doesn't make those sentences inaccurate; it simply qualifies them.
Q: Just to be clear, I'm not quizzing you or asking you specifics or whatever. I'm asking if the two sentences you wrote that I read are accurate or not.
MR. SILBER: That question has been asked and answered.

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BY MR. CURRAN:
Q: Do you agree with that?
A: Yes.
Q: You wrote those sentences, correct?
A: Yes, I did.
MR. SILBER: That question has been asked and answered.
BY MR. CURRAN:
Q: Did you copy them from some other book or resource you had?
A: I won't dignify that with an answer.
Q: Please, go ahead, dignify it.
A: I won't dignify that with an answer.
Q: Are you refusing to answer that question?
A: I'll respond when you have another question to ask me.
Q: Why did you choose to write the following sentence: "Such effects on blood lipids have been shown to reduce the incidence of coronary artery disease"?
A: Because it is a generally accurate statement, and it introduces — the purpose of this segment of my report was to introduce — recognizing that this report was not being written for the scientific community, this report was being written for the lay community,

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for the legal community, perhaps for a judge who may or may not be, you know, particularly informed in this area, and I was trying to fairly represent the general and generally accepted perspective of niacin and its effects on blood lipids and their consequent effects on cardiovascular disease, and I think I've done that here.
This entire interchange has been because you have somewhere along the way tried to get me to say that this represents all the effects and all the things done by niacin to blood lipids have all good effects on coronary vascular disease, and I said there may be exceptions to that, and we have been going around in circles ever since.
Q: Sir, is it generally accepted in the scientific community that the effects of niacin on blood lipids reduce the incidence of coronary artery disease?
A: I can't say what's generally accepted. As I said, the state of knowledge about blood lipids and coronary vascular disease is in a state of flux. It's been in a state of flux for 20 years or more — more than 20 years. It was — we were — it was in a state of flux when I was in medical school and did some early laboratory studies in this area. So, it changes as we learn more, and I really can't speak to what the

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current state of knowledge is in this area.
I think maybe you ought to consult a guy like Joe Goldstein who might be able to give you more up-to-date information about that.
Q: Who is Joe Goldstein?
A: He's a Nobel Laureate in this area.
Q: Why can't you say what's generally accepted in the scientific community in this area?
A: I'm trying to answer your questions honestly and effectively and accurately, and regardless of whether you like my answer, my answer is an honest answer, and if you want me to say something other than that, I'm not comfortable doing it. I don't know — I only know what I think. I can't speak for what the rest of the universe thinks, and I don't know what they're reading, I don't know what they're thinking today, and you're asking me this question today.
Q: Yeah, and I'm not talking about the rest of the universe. I'm talking about the scientific community that focuses on cholesterol fighting.
A: That's what I'm trying to say to you. I don't represent the scientific community that focuses on cholesterol metabolism. I have never proposed or purported myself to be an expert on cholesterol metabolism. And so I don't want to speak for a

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population of people that may or may not share this opinion.
When I wrote this, I believed it to be and I still believe it to be generally accurate, and what I'm trying to say to you is it may be subject to some exceptions of which I am not aware.
Q: Sir, in your opinion, is niacin efficacious in improving the blood lipid profile?
A: There are a couple of operative phrases in your question, "effective" and "blood lipid profile," and all I can say is niacin has some effects in some patients sometimes that have generally been assumed to be advantageous vis-a-vis cardiovascular disease.
Q: What's your opinion?
A: I just gave you my opinion.
MR. CURRAN: Can you read back his last answer?
(The record was read as follows:)
"ANSWER: There are a couple of operative phrases in your question, 'effective' and 'blood lipid profile,' and all I can say is niacin has some effects in some patients sometimes that have generally been assumed to be advantageous vis-a-vis cardiovascular disease."
BY MR. CURRAN:
Q: I guess I was thrown off by your use of the

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passive voice, but the statement in the answer she just read, do you adopt that as your opinion?
MR. SILBER: He just stated it.
THE WITNESS: I'm comfortable with what I just said.
BY MR. CURRAN:
Q: As your own opinion?
A: As my own opinion.
Q: So, are you qualifying your statement in your report that niacin is efficacious in improving the blood lipid profile?
A: If I were to have been asked to write a detailed analysis of the effects of niacin on blood lipid profiles, I would have added to this report some of the exceptions and some of the details and some of the modern information that have come from things like isotachophoretic studies and ion exchange studies on serum lipid profiles that provide a second and third level of detail. I wasn't asked to do that, nor am I qualified to do that off the top of my head, and so I would say that what I wrote is generally accurate, and I'm comfortable with it and would change nothing about it.
If I were to be asked to provide more detail or to focus on these particular two sentences in the

Page

report, I would add more detail to it. I wouldn't negate any of those statements. I would simply qualify them further.
Q: Sir, side effects and specifically flushing have historically kept immediate-release niacin from becoming a highly successful drug, correct?
A: Flushing has been one of the side effects that the patient population has found unacceptable and has limited their consequent use of that drug.
MR. SILBER: Are you testing him on his report again?
MR. CURRAN: I'm seeing if he agrees with what he wrote, yeah, and to my disbelief, he disagrees and qualifies everything.
THE WITNESS: I don't disagree and qualify everything. I added some potential qualification to two specific sentences that deal with one scientific element or scientific paradigm in the report.
BY MR. CURRAN:
Q: Sir, the thesis behind a sustained-release niacin product is that slow release of the drug into the bloodstream would reduce or obviate the flushing reaction, correct?
MR. SILBER: You may refer to your report if you're trying to find out if he's testing you to see if

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you can recall verbatim what you said.
MS. SHORES: Well, I'll object to the obvious coaching of the witness.
MR. CURRAN: You can try to rehabilitate when I'm done.
THE WITNESS: Would you mind telling me where in my report you're reading?
BY MR. CURRAN:
Q: Absolutely. Feel free to look at your report, your cheat sheet, any other documents you brought with you in answering any of my questions today, okay?
I refer you to the bottom of page 5, the bottom paragraph. Do you see where it — there's the statement, "the thesis being that slow, continuous release of the drug into the bloodstream would obviate the flushing reaction"?
A: I see that.
Q: Okay. Do you want me to ask the question again?
A: Please.
Q: Okay. Sir, the thesis behind a sustained-release niacin product is that slow, continuous release of the drug into the bloodstream would reduce or obviate the flushing reaction, correct?
A: I'm not sure what you're saying when you say

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"correct." What are you asking me?
Q: I'm asking you if the statement's correct.
A: I believe it's correct, and that's why I wrote it.
Q: Okay. So, then, the answer to my question is yes, right?
A: I just gave you the answer to your question. I believe the statement — I believe that what I wrote there is correct.
Q: My question wasn't what you wrote there. My question was as follows: The thesis behind a sustained-release niacin product is that slow, continuous release of the drug into the bloodstream would reduce or obviate the flushing reaction, correct?
A: I'm more comfortable, sir, responding to the words that I wrote since these words were considered and were in my opinion accurate expressions of my opinion, and I would say that I would read the entire sentence. "Prior to the development of Niacor-SR, attempts had been made to diminish the side effects of niacin by administering the drug in a sustained-release formulation, the thesis being that slow, continuous release of the drug into the bloodstream would obviate the flushing reaction seen with the standard tablets and capsules that release a large bolus of the drug

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with each dose."
Q: Yeah, but you see, there's a funny thing about the way this whole procedure works here. I get to ask the questions of my choosing, okay? You don't get to ask yourself the questions. I'm going to ask this question again, and I'd like an answer to it.
MR. SILBER: That question has been answered.
BY MR. CURRAN:
Q: The question is, the thesis behind a sustained-release niacin product is that slow, continuous release of the drug into the bloodstream would reduce or obviate the flushing reaction, correct?
A: I can't answer that question without using the terminology that I used before.
Q: Sir, the FDA requires the conduct of two pivotal clinical trials in connection with the registration of a new branded pharmaceutical product, correct?
A: That's not necessarily correct. They sometimes require less and they sometimes require more.
Q: Okay. Sir, I'd like to refer your attention to page 6 of your report. Do you see the section with the heading that's C, Clinical Trial Data on Niacor-SR (All These Data Were Provided by Upsher-Smith to Schering Prior to the Schering-Upsher Agreement).

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Do you see that section?
A: Yes, I see that section.
Q: Okay. Do you see the first sentence there which reads, "The FDA requires, as one of the major elements for the registration in the U.S. of a new, branded (as opposed to generic) pharmaceutical product, the conduct of two so-called 'pivotal' clinical trials"?
Do you see that sentence?
A: Yes, I do.
Q: Is it accurate or not?
A: As I read that sentence now, sir, I would revise it slightly to say the FDA almost always requires, et cetera.
Q: Okay. Why do you feel it necessary to qualify that sentence in that fashion?
A: Once again, as you have kindly pointed out to me, that sentence, while generally accurate, does have some potential exceptions, and in an effort to be fully and accurately responsive to you, I've answered your question as best I can, and I said that were I to write that sentence again today, I would — having been prompted by your fine questioning — add those two qualifying adverbs.
Q: What are the exceptions that you've just

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thought of today?
A: What are the — ah, the FDA, when faced with a drug that it considers vital to the national medical interests, particularly drugs that are in one major category, that is, anti-AIDS drugs, is often willing to consider the use of a single pivotal trial or even less in approving the drug. It likewise will do that with some other categories, cancer, for instance, hepatitis C, for instance, where there is a — where it deems that the public's interest would be well served.
I have personal experience with exactly such a situation with a drug called pentamidine, which several years ago was the only treatment for what we call AIDS pneumonia, pneumocystis carinii pneumonia, and pentamidine was the only drug available for that, and the FDA approved an NDA that was a rather abbreviated NDA and actually didn't have any trials that would be considered classical, well-done pivotal trials, but nevertheless, the FDA reviewed those information, those data, and thought that it was in the public's interest to put this drug on the market for use in this grave disease.
The FDA has shown a willingness and an ability to do that in other instances, and it would — and it still does. So, I think that were I to write that

sentence again, thinking about that specific point, I would have qualified it in the manner that I just did.
Q: So, sometimes the FDA doesn't require any pivotal clinical trials, correct?
A: Sometimes the FDA in its judgment can abbreviate any of the burdens it chooses to impose upon the petitioner.
Q: So, the answer to my question is yes?
A: I just gave you the answer to your question.
Q: Sir, at the time of the Schering-Upsher agreement, Upsher-Smith had finished two clinical trials that it hoped the FDA would consider as pivotal, correct?
A: The only information that I have clearly are summaries of two so-called pivotal trials that Upsher represented as having been completed. In one instance, the data had been processed and the final report supposedly had been written, and I was shown, as was Mr. Audibert, a summary of the results of those trials or that trial. The other trial was supposedly finished in that the last patient had been enrolled and the last data collected, but the final report had not been written.
Since I was not privy to any of the — either the raw data or the — even the final reports of any of



those trials, I can't testify here as to whether Upsher did or did not complete two trials. All I can say is they said they did.
Q: Then why did you write in your report that Upsher-Smith had finished two clinical trials?
A: Why did I write in my report?
Q: Yeah. Why did you write it if you can't say it?
A: I in writing this report gave Upsher the benefit of the doubt in that I made the bold assumption that they weren't totally fabricating their reports that they sent to Mr. Audibert. I don't — I see no reason to have assumed that Upsher-Smith would have provided to Schering fabricated information, and so I rightly or wrongly chose to accept the conclusions and the statements that Upsher made.
Q: So, it's an assumption of your opinion in this matter that Upsher had finished two clinical trials that it hoped the FDA would consider as pivotal, correct?
A: Would you rephrase that, please, or restate that?
Q: I'll restate it.
So, it's an assumption of your opinion —
A: What is an assumption of my opinion?



Q: It's an assumption underlying your opinion — does that help you? Do you know what an assumption
A: I think so, sir.
Q: When you assume a fact, right?
A: Um-hum.
Q: So, if you have an opinion, you — and if — you may assume certain facts to be true for purposes of your opinion?
A: Um-hum.
Q: Does that help?
A: You're helping me wonderfully, sir.
Q: Okay. Do you want me to restate the question now?
A: You're doing fine. Keep going.
Q: Okay. Are you being like flippant again now?
A: I don't think I'm being flippant. I'm trying to be honest and responsive to you.
Q: All right. Well, let's try this question again, then.
Is it an assumption underlying your opinion in this matter that Upsher-Smith had finished two clinical trials that it hoped the FDA would consider as pivotal?
A: No. If Upsher had indeed completed those pivotal trials, then my assumptions regarding those trials would stand; that is, if the information that



Upsher provided to Mr. Audibert and to Schering-Plough was accurate, then the assumptions I made about that information in my opinion would support the opinions that I proposed. If it had not completed the trials and if the data that it provided to Schering-Plough indeed were not accurate or in some way fabricated or false, my opinion on this matter would be even more harsh than it is.
Q: Is it your view that your opinion in this matter is harsh?
A: I would say that that is a function of from whose perspective one is looking at the matter. The fundamental issue, as was brought out by your colleague in some of her questioning, dealt with whether I think that the $60 million payment made by Schering-Plough to your client was a legitimate licensing fee, and I in the strongest and perhaps harshest possible terms said it is not. It could not be. It never could have been. I think that you and your client may perceive that as harsh.
Q: I asked what your view of your opinion was.
A: I think it's accurate.
Q: Is it harsh?
A: Sometimes accurate things are harsh.
Q: Is this one harsh?

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A: I think if I were in your shoes, I would perceive it as harsh. I don't perceive it as harsh.
Q: So, you don't perceive it as harsh?
A: As I said, whether it's perceived as harsh or not is a question of from which perspective you're looking at it. From my perspective, it's accurate and honest. From your perspective, I presume it's perceived as harsh, but only you can answer that.
Q: Now, in this libel suit brought against you, what are you alleged to have said?
A: It involves an effort of about 40 parents to have removed the high school football coach, and he alleges that we undermined his credibility with the superintendent of schools.
Q: What are you alleged to have said?
A: Nothing in specific that I'm alleged to have said.
Q: It's a libel suit, right?
A: It's a libel suit.
Q: And he's not alleging you said anything specific?
A: There is a whole litany of elements where I and these various and sundry people have said that he is not respected by his students or by his players and doesn't support the players, doesn't express concern

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for players when they're injured, doesn't prepare himself or his assistant coaches for games, has not in any way updated his own coaching skills, does not encourage or even permit physical conditioning in the on or off season, you know, a variety of — I mean, that's the general line of the things that we are alleged to have said.
Q: Do you admit saying those things?
A: Sir, I'm not sure that I want to get into any further discussion of a matter that's now being litigated, and I don't know what use or lack thereof can be made of this kind of deposition.
What I will say is as I understand — I've learned more about libel law than I ever wanted to know. He was judged to be a public figure, and the issue now is whether any of these statements had any malicious intent or were knowingly inaccurate, and the answer to that is clearly no, and there is abundant testimony to that effect, that there was neither malicious intent nor was there any, you know, knowingly false statements.
Again, as I understand libel law — and again, I'm really uncomfortable on this ground, and you're not asking me as an expert in this situation — that in order for matters to be considered libelous, there has

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to be an element of objectivity, so that saying that somebody is a lousy coach is a subjective opinion. Saying that this lousy coach beats his wife is something that's establishable in fact. Everything that I said and others said were subjective opinions to which we apparently — we apparently have a right to voice, and that's as I understand the case.
Q: Did you, in fact, criticize this football coach?
A: Yes, I did criticize this football coach.
Q: Was it harsh criticism?
A: I think you'd have to ask him that.
Q: I'm asking you.
A: I think — again, I feel — unless you want to question me on this, I feel — proud may be too strong a word, but I feel very good about everything I did in this case. If you want to know, I went to him first with the various complaints. I went to him and the athletic director and had a seven-hour meeting with both of them going over all of these matters. I wrote a letter, which I showed to him prior to its being sent, to the superintendent of schools that enunciated each of the concerns that I had, and that's what I did.
I think that other than doing nothing, I think I behaved in a manner that is consistent with what a

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parent or an interested party should do in this matter and everything related to this matter.
Q: Do you consider your criticism of the football coach harsh?
A: I would say that "harsh" is not the adjective I would use. I think in all fairness it was painful to him. I did not think that he was a bad person. I think that he was a person who had let a lot of time pass without his updating his skills or knowledge and that this had now caught up with him, and I think it was hurtful to him to have this put before him. I think it was very embarrassing to him in a community where he's lived his whole life to be removed from what is the most prestigious athletic position in our community, even though we're the home of the Chicago Bears. And I think that he was hurt by it, he was emotionally hurt by it. So, I think he would think it was harsh. I don't — I never meant it to be harsh, and I don't myself think that the way it was handled was harsh.
The only other thing I could have done was to do nothing, and the reason I did it was that I have had several sons go through the program, I had a son — my second youngest son who was elected captain of the team, and he and his two co-captains came to me in

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tears and said we really can have a good team next year, we win when we do win in spite of Tommy, not because of him. Please, dad, can you do something to help us? And that's when I asked to speak with Tommy.

I spoke with the young — with the boys and found out what their criticisms or concerns were. I then related this to Tommy himself and to the athletic director, as I said. So, I don't know what I could have done other than do nothing. So, I don't have any remorse or, you know, concerns about my own behavior.

Q: That litigation is still proceeding, correct?

A: Yes.

Q: Sir, now, you reviewed the clinical trial data that's in the record in this case, correct?

A: I reviewed the clinical trial data? No, that's not correct. I never have seen the data. I've only seen the summaries provided by Upsher-Smith.

Q: So, if your report says that you reached certain conclusions based on data from these clinical trials, that would be inaccurate?

A: No, because once again, I am relying on the fact that the information, including the summary information, that Upsher provided was accurate, and included within that information were some tables and figures containing the summarized results particularly

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of one of the pivotal trials and to some degree the second pivotal trial, and I made the assumption that those data as summarized were accurate. You asked me whether I had examined the data themselves, and I have to say I did not.

Q: Sir, based on the information that you reviewed, you conclude that Niacor-SR had approximately the same efficacy as a cholesterol-lowering drug as do standard immediate-release niacin products, correct?

A: I — would you mind pointing out to me where I say that in my report?

Q: Well, yeah, I mean, I'll point it out where you say it, but why do you have to look at your report to know what your conclusion is?

A: Well, as I said before, sir, I weighed each of the words in this report fairly carefully, and I'm not accustomed to testifying openly and orally like this, and I would rather look at what I wrote and had a chance to consider before responding to your question so I can be more accurate in doing so.

Q: So, you need to look at your report while testifying to give an accurate answer. Is that what you're saying?

A: I don't think that's what I'm saying at all, and I'm simply saying that it is my desire to testify as accurately as I can on this and any other question you ask me, and I think that the accuracy of my response would be — would benefit from my reviewing what I've already written, and if I choose to make a minor or major modification in it, as I honestly did before for that one sentence about which you quizzed me earlier, I'll do it again.

Q: Take a look at page 6 of your report. The second full paragraph, there's a first sentence there which I'll read, and then I'll ask you whether it's accurate or not.

"Based on the data from these clinical trials, all of which were provided to Schering prior to the execution of the Schering-Upsher Agreement, I would conclude that Niacor-SR had approximately the same efficacy as a cholesterol-lowering drug as do standard (immediate-release) niacin products."

A: Um-hum. Ah, I think there's — in focusing on that particular sentence, there is two things that I might add to that. I realize in reading the sentence that it says, "Based on data from these clinical trials, all of which were provided." I didn't interpret it this way, but I realize the grammarian in me is calling attention to the fact that the "all" is an unclear modifier.

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What I meant in that sentence was that all the data that were provided underlay part of my opinion. What I realize might be interpreted here from this sentence is that all the data on the clinical trials had been provided, and as I said before, that was not the case. So, that's a grammatical qualification.

Then secondly, I think that to be more comfortably accurate, I would have to have added a dose qualifier to this, because the approximate equivalent efficacy of Niacor as a cholesterol-lowering drug was at a dose-for-dose level, so that at the 2000-milligram dose of Niacor-SR, I believe the efficacy was similar to a 2000-milligram dose of the immediate-release niacin product. Perhaps I might have been more accurate in stating that fact, I didn't think it was necessary and still don't.

But as long as you want to focus on that sentence, I think that I might have found a better grammatical way to use the term "all," and I might have added to it, "at equivalent doses, they have an equivalent efficacy."

Q: So, you didn't think this all through when you wrote this report, huh?

A: Oh, I thought it through.

Q: You did?

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A: Yes.
Q: How come you didn't write it the way you're comfortable with it?
A: Well, I think to any reasonable person it is accurate and consistent with my opinion. When one is looking for inaccuracies or flaws in a somewhat adversarial manner, sometimes one needs to be even more qualifying than I think is necessary for a report such as this.
Q: Are you surprised that this report is being used in an adversarial proceeding?
A: I'm not terribly familiar with the world of litigation, depositions and the use of reports. I said to counsel when I prepared this report that I wanted to be particularly careful, because I realized it was a legal document, and I'm not accustomed to preparing legal documents. So, I tried to be quite careful in preparing it.
I was not experienced in terms of the use of each of the specific words in a proceeding such as this. I just had not been through that.
Q: So, you didn't think —
A: I would qualify that. I would say, again, that as I'm sure you know, having written documents, briefs and the like, one is never finished. One can make

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revision after revision after revision after revision to make each sentence clearer and clearer. An example of that, as Mr. Silber will testify, I'm somewhat of a — at least perceive myself as being somewhat of a grammatical perfectionist, and I'm embarrassed by the hanging "all" there, and I probably would have deleted that in the next version if I had recognized it.
So, one is never done. I'm perfectly comfortable with everything in this report. I think one can always make a sentence bigger, clearer, more qualified, but there's nothing inaccurate in that sentence.
Q: How would Mr. Silber know whether you're a grammatical stickler?
A: Because I told him.
Q: Oh. It just came up in conversation, huh?
A: Yes, it did.
Q: Yeah. Sir, are you aware that Upsher-Smith attempted to find a European licensing partner for Niacor-SR prior to the Schering-Upsher agreement?
A: I am aware of efforts of a consultant whose name escapes me at this moment who was hired to — by Upsher-Smith in either late '96 or early '97 to find a European licensee for Niacor-SR, and I am — and I have seen some of the summary reports of his progress in

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finding such a licensee.
Q: Is David Pettit the name of the consultant?
A: I believe that is the name.
Q: Is his company the Morton Company?
A: I thought it had a different name from that, but it did start with M. I may be mistaken.
Q: What's your understanding of what Mr. Pettit did?
A: I can only surmise what he did, sir, because there are no — I don't believe that he was deposed, and if he was, I didn't see that deposition, and my only knowledge of what he did comes from the secondhand commentary of other people's depositions or those sort of progress report summaries that were exhibits to somebody's deposition, I don't remember whose. So, I don't know what procedure he went through.
People who do this kind of work are —
Q: I'm not interested in other people.
A: Well, I would only presume that he attempted to contact the in-licensing executives or the licensing executives at various of the companies that he listed and perhaps sent them some preliminary information, perhaps tried to get them to execute a confidential disclosure agreement, and then were they interested in executing it — a confidential disclosure agreement,

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had meetings with them and provided them the same sort of information or analogous information as was provided to Mr. Audibert, but I am purely assuming that just knowing how these types of people generally work.
Q: So, you don't know yourself what Mr. Pettit did?
A: I don't know what he did other than what various executives of Upsher said he did and the documents that I've seen said he did.
Q: What documents are you talking about?
A: Pardon me, sir?
Q: What documents are you talking about?
A: I believe there were a few summary documents that were prepared that if I remember correctly — and I believe this is correct, but I'm not certain — I believe these were attachments or exhibits to one of Upsher-Smith's — one of the executives of Upsher-Smith's depositions, and I believe that there were two summaries of the status of his contacts, and it simply listed — each of these simply listed several companies, 40-50 companies, in the European Union with which he had made contact and a brief comment on the status of their interest or lack thereof in the product.
Q: What's your understanding as to the status of

Mr. Pettit's efforts as of the date of the Schering-Upsher agreement?

A: I don't recall what the dates of those summary documents were. I believe that they quite closely approximated the brief period that Upsher and Schering were interacting regarding this product. I believe that the summary document was dated even May of '97, which would have antedated the agreement with Schering by a month or a little more than a month. I'm not sure that they were dated in May, but I know that it was sometime in the spring of '97.

Q: Now, Upsher retained Mr. Pettit in late '96, early '97. Is that your testimony?

A: I don't recall exactly. I testified a moment ago that I believe he was retained in late '96 or early '97. My recollection is that he worked on this project for about six months.

Q: Have you reached any conclusions as to whether or not Mr. Pettit was successful in his efforts?

A: Based on the summary documents that I saw, he — it was listed that very — that most of the companies on his list had expressed no interest in the product, almost all of them; that there were a few, but I don't recall the number, but, you know, two or three or so where the verdict had still not been rendered,



where the companies were still considering whether they would consider the product. As far as I could see, with none of these companies on his list was there any serious level of evaluation or negotiation underway.

Q: What does that mean, "serious level of negotiation"?

A: Where the potential licensee had completed its due diligence on Niacor-SR and had begun — had expressed an interest in licensing the product and had begun negotiations for the terms of that license.

Q: But there were companies that were still evaluating Niacor-SR. Is that correct?

A: I don't know whether those companies — as I said, most of the companies had expressed no interest, had said they had no interest in the product. There were a few where the company's response was still outstanding, and whether they were still evaluating the product or whether their response had simply not yet made it to the summary list I can't say.

Q: Was Mr. Pettit successful in getting any companies to express initial interest in Niacor-SR?

A: Well, the operative elements in your question are "successful" and "any interest." The summary sheets that I saw didn't present much detail on what the companies did or didn't do, and so I don't know



whether they hung up the phone on him or whether the reviewed a data package. I don't know whether they signed a confidential disclosure agreement. I just don't know to what extent they had presented — they had expressed any interest at all. That just wasn't provided.

Q: Wasn't provided? What do you mean?

A: The summary sheet that listed these 40 or 50 some odd companies and their response had just a few word summation of the result, and so in terms of whether Mr. Pettit was successful, I would say he was quite successful in having made contact with quite an extensive list of eligible licensees in the European theater, and he didn't miss too many that were potential candidates for a drug like this.

And so I think that he was successful in terms of his effort for the company in having served the company well in looking at a large number of companies ranging from medium-sized, even small to medium-sized companies, all the way up to the major players in the European Union, and I think provided a good service in that regard to Upsher-Smith, and I would consider that a successful effort.

I think that from Upsher's perspective, a successful effort would have been for one of these 40



or 50 companies to have expressed an interest in licensing the product, and that didn't occur.

Q: And you base your conclusion as to what occurred or not based on the summary sheet that was provided to you or the summary sheets that were provided to you?

A: I base my conclusion about what Mr. Pettit did — is that what you're asking me?

Q: Yes.

A: My conclusions on what Mr. Pettit did or didn't do come from having read the depositions of several executives from Upsher-Smith and having examined those summary sheets, and that's all the information that I was ever provided on what Mr. Pettit did or didn't do.

Q: How many companies contacted by Mr. Pettit signed confidentiality agreements?

A: I don't know the answer to that question offhand, and I don't think that that was presented in any tabular fashion as to whether a CDA was signed or not signed for each of them. If I remember correctly — and I'm doing this from a very imprecise memory — I believe that there were a couple of them where there was an annotation that a CDA had been signed, but I'm not even sure about that, and I don't have that document with me or in front of me.

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Q: Would that be something important for you to know?
A: No, not for responding to your question.
Q: No, I mean, your ultimate conclusion here that Niacor-SR was not worth anything close to what Schering paid for, that conclusion, I mean, would Mr. Pettit's success in identifying a European licensing partner as an alternative to Schering-Plough be something of interest to you?
Let me state that differently.
A: I don't understand that question.
Q: Please, look at page 13 of your report.
A: Okay.
Q: Do you see the section on the top half of the page?
A: Yes, I see that.
Q: Why did you put that section in your report?
A: The heading under which that Section G is listed is entitled The Licensed Products, and I think that one of the parameters to which I was made aware in reviewing these various documents was that effort on behalf of and interest in these licensed products by parties other than Schering, and so I thought it was germane to the discussion to consider that.
I think — excuse me, I think as I testified

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earlier, as I understand that element of this legal matter that I've been asked to consider can be crystallized into my perception of the validity of the $60 million noncontingent payment as a licensing fee for this product, and as I testified earlier, the licensing fee and particularly the magnitude of the licensing fee is very largely determined by the competition from other companies, other potential licensees, for that product.
So, some commentary on the existence or lack thereof of that competition is quite germane to this report, to my conclusions.
Q: I'm sorry, why is it germane to your conclusions —
A: Why is what germane to my conclusions?
Q: The interest or lack thereof expressed by other potential licensees of Niacor-SR in Europe.
A: I think, as I just testified, the central question that I believe lay before me was whether or not this $60 million noncontingent payment made by Schering-Plough to Upsher-Smith could be considered a legitimate license fee for Niacor-SR. A major element to such a consideration is whether any other party was bidding for this license, and if so, how much they were bidding.

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The fact that, as far as I could gather, Mr. Pettit was the only party seeking on Upsher's behalf a European licensee for Niacor-SR and since he had not identified, to my knowledge, any party who had made an offer of any sort for this product, I am able to conclude that there was no bidding competition for this product, and I think the fact that there was no bidding competition for this product makes even more absurd the magnitude of that so-called license fee.
Q: So, your conclusion, your ultimate conclusion and your opinion rests in part on your understanding as to the interest of other potential licensees?
A: Would you repeat that, please?
(The record was read as follows:)
"QUESTION: So, your conclusion, your ultimate conclusion and your opinion rests in part on your understanding as to the interest of other potential licensees?"
THE WITNESS: One of the components upon which my assessment of the veracity of the $60 million noncontingent payment as a license fee was based was on the competition or lack thereof from other companies for this product.
BY MR. CURRAN:
Q: Are you aware of whether Mr. Pettit or anyone

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from Upsher met with other potential licensees in, say, the month before the Schering-Upsher agreement?
A: The only thing of which I'm aware are those bits of information that discussed what Mr. Pettit had done on behalf of this product and on behalf of your client, and I've testified earlier that I don't recall exactly what depositions Mr. Pettit's activities were discussed in. I believe it was Ms. O'Neill's and perhaps Mr. Bell's, but I just don't recall that, and the only other information I have is the summary sheet. I have been provided no information other than that and so can't guess what he was doing during the month of June or whenever it was.
Q: Do you know what the status was of discussions between Upsher-Smith and Servier as of June 17th, 1997?
A: I have been provided no information on any details of what the status of interaction with Servier were or were not. The only information I have been provided is that to which I relate — that which I relayed to you earlier.
Q: Do you know whether or not Servier had initially expressed an interest in licensing Niacor-SR?
A: Without looking at the list and refreshing my memory, I don't recall which of the companies on this list, which I understand here listed 41, were still

outstanding in their interest or lack thereof in the product.

Q: Do you know whether or not Servier signed a confidential disclosure agreement with Upsher?

A: Without re-examining the references to Servier and those lists that — which I alluded to a moment ago, I don't recall off the top of my head what Servier did or did not do.

Q: Yeah, well, you know, I don't mean to be playing any memory game here. I mean, I don't care what company we're talking about, but are you aware of Upsher meeting with any pharmaceutical company in the world about the potential licensing of Niacor-SR in Europe in the month leading up to the Schering-Upsher agreement?

A: I don't recall — I don't recall the testimony or the information that would have suggested that they did or did not meet with other companies in the month, you know, prior to their executing this — this agreement with Schering. I do not think that either the deposition testimony or the summary sheets expressed any serious interest on the part of any of these companies in this product at that time.

Q: So, you don't know anything about any meetings that took place between Upsher and any other



pharmaceutical companies in the month leading up to the Schering-Upsher agreement?

A: I don't recall what the testimony was in — about that specific issue from the Upsher executives, who are the only people who could have commented upon that issue in deposition since to my knowledge Mr. Pettit himself was not deposed or at least I didn't see that deposition. If the meetings occurred, I don't recall whether they did or didn't, and I don't recall whether they were alluded to in those depositions. I don't know whether meetings occurred.

Q: Isn't that —

A: What I would say is that whether meetings occurred or didn't occur would not have any bearing on my opinion, because meetings — different companies have very different thresholds for holding a meeting. Some companies have a very high threshold, for instance, Johnson & Johnson has a very high threshold for executing a confidential disclosure agreement and for having meetings. Other companies have a lower threshold for these kind of initial contacts and are much more willing to have meetings.

For instance, one of the companies that I do a lot of work with has a very low threshold for meeting, but that doesn't mean that they have any serious



interest in the product. It just simply means that they want to go and look at it, because they want to be sure that they do or don't have an interest. It doesn't get serious until offers are put on the table. Meetings are nice, but you can't take meetings to the bank, and you certainly can't use them in negotiations for $60 million up-front payments.

Q: Sir, on page 13 of your report, you characterize Mr. Pettit's efforts as unsuccessful, correct?

A: Again, I'd rather put it in the full context of the sentence. What I said was that he tried unsuccessfully for over six months to find a licensee for the European rights to Niacor-SR. As I testified earlier, I frankly think that Mr. Pettit was quite successful in even having brought the number of parties to even a superficial examination of this product that he did. That's not as easy as it seems. One has to make contacts, one has to convince the people that it's even worth looking at nonexclusive information.

So, he chose a good list of companies, a good spectrum of companies. He, as far as I can see, made legitimate contacts with these companies and did his job well. He didn't invent Niacor-SR, and I'm sure that he perhaps more than any of us wished that



Niacor-SR had been a better product than it ultimately turned out to be. It would have made his job a lot easier.

Q: In the sentence, the first full sentence on page 13, you state that he tried unsuccessfully for over six months to find a licensee for the European rights to Niacor-SR, correct?

A: Um-hum, that's what I wrote.

Q: On what basis do you conclude that his efforts were unsuccessful?

A: That is a question that I can answer I think fairly clearly, and I'm almost surprised that I can answer it so clearly, because that has a definitive end point. As far as I know, he did not execute a license for Niacor-SR during that period with anybody, and so if you're asking me — if you're defining success as finding a licensee, he was unsuccessful.

Q: Okay. So, because Upsher signed with Schering, Mr. Pettit's efforts were unsuccessful. Is that what you're saying?

A: I am saying that during the six-month period when he looked — when Upsher entered the agreement with Schering, one can only presume that Upsher is an ethical company and ceased its efforts to find another licensee, and I will be happy to grant your client that

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bit of ethical well-being; that Mr. Pettit's efforts would have stopped when the agreement with Schering was executed. What we know is that up to that point, Mr. Pettit had been unsuccessful.

We also know that Schering-Plough, at least we know from the testimony of various executives in this matter, took but — I believe, what, five days from start to finish to make that assessment, and so we can say that up to approximately June 12th or thereabouts, Mr. Pettit had been unsuccessful.

Q: Where do you get the six months in that statement?

A: As I said, I think that he was hired in December, and he was finished for the reasons I just said in middle of June.

Q: When do you think he made his first mailing to potential licensing partners?

A: I have no way of knowing that. Usually when people are engaged in these matters, they're pretty prompt and assiduous, and so I would think that very shortly after Mr. Pettit was engaged, he began making phone calls and making contacts on behalf of his client.

Q: How would you have gone about attempting to find a licensing partner in Europe for Niacor-SR? If

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you had been Mr. Pettit and you were retained in late '96, early '97, what would you have done?

A: Again, you know, I am embarrassed that I perhaps have been flippant in a couple of my comments to you, and I want to restrain that element of my personality, if I may.

We have a fairly rigorous modus operandi in our little organization in that we try to put in-licensing candidates through a fairly decent level of internal and sometimes even external due diligence before we even take on the project, because we're a small organization, and the only thing that really helps us is that we have a fairly high level of credibility with executives in companies, particularly fairly senior executives in companies.

So, before we would take on a project, it has to pass our muster before I would present it to a senior executive in another company, and were I to have seen the data that Mr. Audibert shared with Upsher in — or that, I'm sorry, that Upsher shared with Mr. Audibert, there is little question that I would not have allowed our company to be engaged in marketing this product.

MR. SILBER: Chris, if I may — Nelson, I just want to see if you're okay, if you want a break.

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THE WITNESS: I'm fine.

BY MR. CURRAN:

Q: Are you saying that if you were Mr. Pettit, you wouldn't have taken on the assignment from Upsher to find a licensing partner? Is that what you're saying?

A: That's correct.

Q: So, in your opinion, was it inadvisable for Mr. Pettit to take on this assignment?

A: That's not what I said, sir.

Q: It's a question. It doesn't matter what you said before.

A: It is.

Q: I don't care what you said at all today or any other time in your life. It's just a question.

Was it inadvisable for Mr. Pettit, in your opinion, to take on this assignment?

A: I can't speak for Mr. Pettit. Your questions to me were whether we would have taken it on, and —

Q: They wouldn't have come to you.

A: I'm sorry? I didn't understand what you said.

MR. SILBER: He said they wouldn't come to you.

BY MR. CURRAN:

Q: Let's assume, okay, that you were working for Mr. Pettit and he had taken on the project, hey, we're going to find a licensing partner for Niacor-SR in

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Europe, go do it. What would you have done?

A: I would have said to him that I think that presenting this package to senior executives in potential licensees would compromise our credibility and that until we had further information about this product, we should not represent it, because Mr. Pettit — and if you're supposing that I would be his surrogate in some way — represented this product, it's no different from your selling a used car or your selling my old Lox Box.

I think that if you're going to be credible in this effort and if you're going to be able to go back to that person to whom you try to sell this to sell another thing, I think you'd want to have some credibility, and I don't think that I could have represented this product with enthusiasm knowing what I know about it.

Q: I want you to assume that, again, you work for Mr. Pettit. He says, okay, I hear your comments, you don't want to work, you don't want to do this project, he says, nonetheless, let's go out and do our best. What do you do?

A: I would recommend to Mr. Pettit that we go back to our client, Upsher, and discuss with Upsher the potential deficiencies that we see in the data set or

the package that I have and I presume Mr. Pettit had, that information that was provided to Mr. Audibert, and I would ask for some of those data and some of the information that I alluded to in my report as being missing. I would examine that information if Upsher were willing to let me see it and may or may not modify my opinion, but I don't think that I would have been comfortable — in fact, I know I would not have been comfortable calling the sort of people that I know and saying to them, I've got a good in-licensing candidate for you, which is what I'd have to say, with the information that was given to Mr. Audibert.

Q: Okay, let me make this a pure hypothetical.

A: Um-hum.

Q: I want to put you in Mr. Pettit's shoes. Upsher-Smith comes to Mr. Pettit and presents Mr. Pettit with what is a very promising product, and you and/or Mr. Pettit recognize that and believe it to be a promising product for Europe.

A: Okay.

Q: And you're charged with finding a European licensing partner.

A: Okay.

Q: What do you do?

MR. SILBER: Just to clarify the hypothetical,



you're talking about a hypothetical drug, not Niacor-SR?

MR. CURRAN: Yeah, that's right. He refuses to answer the question about Niacor-SR, so we'll use a hypothetical drug.

THE WITNESS: I think I answered the question about Niacor-SR.

BY MR. CURRAN:

Q: Okay, okay, let's just make it some drug that you think has promise.

A: As I understand you, some client, be it Upsher or somebody else, came to our organization or Pettit's organization with my being a part of that organization with a drug or a product of any sort and presented us the data that it had on that product. We internally were able to look at that data package and feel that this product did represent a good opportunity for a potential licensee.

Is that the hypothetical you're presenting?

Q: Yes.

A: Then what would I do?

Q: Yes.

A: I think that the first thing that I would do would be, as I think I indicated before, would be to try to have answered from data that the client had any



remaining questions that I might have, because recognize that I'm going to have to go before executives in the potential licensees and discuss this product, and I'd like to make sure that all the questions that I might anticipate and that are answerable were answered in the information that was provided.

With that information, I would revise the information that the client had provided to us, so that I now have a dossier with which I'm comfortable. I would then try to ascertain what companies would be likely viable licensing candidates based on my knowledge of the sorts of drugs that they market, the sorts of sales organizations that they have, the sorts of territories that they serve, the potential of the product, et cetera, so that I would try to hone the list to high probability licensing candidates rather than shotgun it to every company out there, because again, you know, Pettit and I are a small organization, we don't have time to go to 1600 companies. We'd rather narrow it down to a few companies where we think we can be most effective.

Then, most likely, I would know somebody fairly senior in that company, and I would contact him or her and tell them about the opportunity I had and ask them



if they were interested. Most likely, most if not all of these companies that were contacted telephonically would say, yeah, send along your package nonconfidentially. They would — I would do so. They would look at this package. I would follow up with them, and the next step would be for them to ask for confidential information.

I would then provide them the full dossier that we had, probably, if their interest continued, meet with them to discuss next steps, and most likely those next steps would entail answering questions that had arisen during their due diligence. We would enter into an iterative process where they're asking questions and I'm trying to answer those questions or have those questions answered until we got to the point where they either said, thanks, but no thanks, or said, we're interested, let's start talking deal. What do you want?

Then we would enter the next phase, which would be the discussions of the general terms of our potential agreement, and that would cover such things as remuneration for the licensee or licensor, what performance criteria the licensor wants to impose upon the licensee, and territories may or may not emerge. I mean, if you — I think you've narrowed it to the

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European Union, and so we might have a company who has only got marketing strength in Italy, and we might be loath to offer them the rest of Europe, or we might have a company that is universally strong, in which case the territory would not be much of an issue, but we would get into discussion of those kinds of issues.

We would over the next few weeks negotiate a deal that we were comfortable with or we would not be able to negotiate a deal with which we were comfortable. I mean, I hope I'm responding to your question. That's basically the way I think I would proceed.

Q: Have you personally ever done such an assignment?

A: Oh, yes.

Q: When?

A: When in time?

Q: Yeah. Yeah, in time.

A: Last year or this year and — yeah, I've done it periodically over the course of the last — since 1984.

Q: Always with CoreTechs?

A: Yes, because when I was with either Abbott or Fujisawa — when I was with Abbott, I was a member of the licensing team and didn't have responsibility for

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negotiating deals. When I was with Fujisawa, I had business development people who had responsibility for negotiating the deals, and I had sign-off authority on it, but I was not the person going to the table and negotiating the deals.

Q: Okay. When's the most recent time that you undertook this type of an assignment, finding a licensing partner in Europe?

A: Oh, in Europe?

Q: Well, let me back up. Have you personally ever undertaken such an assignment in Europe?

A: I've never specifically focused on a licensing assignment in Europe only, because it's been my experience that a product generally has to be acceptable for the U.S. market not before but in addition to being acceptable for the EU, and I realize that's my experience. That is not a universal experience, and there are plenty of people who focus on the European market and have a different experience, but in my case, because I'm U.S.-based and have most of my experience in the U.S., that I would do deals for the U.S. and other territories, not just for the EU.

The exception to that has been Japan, but because of my pretty good relationships with a number of people in Japan, I've done deals just for Japan.

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Europe, I've done a couple of deals just in the EU, but not for pharmaceutical products.

Q: Okay. So, you've never done a licensing — you've never personally done a project in which you were attempting to identify a European licensing partner for a pharmaceutical, correct?

A: I'm going back to your question. You asked me — I went through a whole process of what I would do were I to be working for Mr. Penit and the procedures that I would go through, which entailed basically the whole process of getting hired by the client and negotiating the deal. You then asked me whether I had done that process for a pharmaceutical just in the EU, and my answer to that is no.

Q: Sir, in your analysis and conclusion in this matter, do you consider the amount of correspondence and communications between Upsher and Schering after they entered into their licensing agreement?

A: Do I consider it?

Q: Yes.

A: I'm not — I don't understand your question.

Q: You've reached conclusions in this matter, correct?

A: Yes, I have.

Q: Are those conclusions based in any way on the

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amount of communications or correspondence between Upsher and Schering after their licensing agreement was entered into?

A: There are three principal elements upon which my conclusion is based. The first was the deal itself, the agreement, the elements of the agreement, most particularly the $60 million noncontingent payment and some of the other elements that were missing from this agreement; secondly was the due diligence that antedated the agreement; and the third was the behavior of the parties after the agreement had been executed.

Q: Do you want my question read back?

A: You're welcome to read back whatever you want. I think I just responded to it.

Q: Okay. So, when you say the behavior of the parties after the agreement, are you referring to correspondence and communications between the parties?

A: That's one element of the behavior of the parties.

Q: Well, do you specifically consider the communications and correspondence between the parties as one element that is relevant to your conclusions and analysis?

A: I examined the deposition testimony and those exhibits to which I was privy that related to the

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interactions between the parties, written and otherwise, as well as the individual activities of the parties as expressed either in oral testimony or in minutes of various and sundry meetings and from that information drew a conclusion as to what the parties did after the agreement.

Q: Sir, is it your belief that there was almost no communication regarding Niacor-SR between Schering and Upsher after their licensing agreement?

A: It is my opinion that very little communication occurred between them considering that they had entered into a major deal, a deal that indeed Schering had valued so highly as to make the highest noncontingent payment in the history of the pharmaceutical industry.

Q: When you say the $60 million payment, you're talking about the $60 million paid over three years, correct?

A: $60 million license fee, which was — to which they were obligated to pay from day one. They happened to make the payments over two years.

Q: I'm sorry, they happened to make the payment over two years, is that what you said?

A: They made a payment, they made a payment upon signing and I guess a payment at one year and two years.

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Q: They didn't have to; that was called for under the licensing agreement, right?

A: Well, yes.

Q: That was as a result of the negotiation, correct?

A: I would say that this resulted from activities other than negotiation for a license.

Q: What do you mean by that?

A: I think, as I've testified many times today, that there could only be three reasons for Schering's having made this payment. One, they're blithering idiots; two, they got some other consideration — now I can't even remember what the third one would be.

Q: Why don't you think about it.

MR. SILBER: Was that a question or a comment?

MR. CURRAN: That's a question. I'm not rushing him.

THE WITNESS: I think I testified earlier to it, but I'll try to recall what I — what I said. I can't recall exactly what it was, but whatever it was, it was pejorative, and maybe that's why in my desire not to be terribly pejorative I can't recall it.

BY MR. CURRAN:

Q: So, by "blithering idiots," that's not pejorative?

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A: That's perhaps pejorative — I said that that is the only possible reason other than their receiving some other consideration.

Q: Well, what do you mean by "blithering idiots"? Do you mean they were negligent, showed bad judgment

A: I would say — you know, as I testified earlier, it has always been my perception of Schering-Plough as being one of the fine companies in our industry. So, I don't consider it a viable explanation at all, and in this room where we are want to consider hypotheticals, I'm offering you the only hypotheticals that I could conceive of for this kind of payment having been made, and the hypothetical about which we're talking, that is, that the Schering-Plough were a bunch of blithering idiots, is not to me a viable alternative, because I don't believe that Schering-Plough is a collection of blithering idiots, but unless they received some other consideration — oh, I remember the third one.

They were feeling generous, so in other words, they wanted to make a gift to Upsher with no consideration. I suspect that Schering is a very philanthropic company, but I don't suspect it has that degree of philanthropic leaning towards another member of the pharmaceutical community. So, I don't think

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that's a viable alternative either, that they were doing it out of generosity or out of ignorance. So, that leaves only that they received other consideration as the viable explanation.

Q: Now, you've read depositions of Schering personnel in this case, correct?

A: Yes, I have, sir.

Q: And you're aware that it's the position of those people and Schering itself that the consideration they paid was, in fact, for Niacor-SR and the other products in the licensing agreement, correct?

A: I'm aware that some members of Schering's executive cadery have maintained in their testimony that that $60 million was a license fee.

Q: Now, do you believe that they're liars?

A: A few moments ago we indulged in the use of the term "harsh." I think that to the extent that they maintain that this was a license fee for Niacor-SR, they are being untruthful.

Q: Now, a moment ago you said that Schering was a fine company, didn't you?

A: Yes, I did.

Q: And they're a fine company, so you're unwilling to say that they're blithering idiots. Is that right?

A: I would not like to characterize Schering as a

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collection of blithering idiots, yes.
Q: So, you're more comfortable characterizing them as untruthful, correct?
A: I'm not characterizing the whole company as untruthful. I think that — I don't know what motivated this bit of nefarious behavior. It I believe violates the ethical standard by which I believe Schering is known in the industry. This endeavor involved remarkably few members of Schering's executive community, which is itself unusual, and so if there was dishonesty, then this dishonesty appeared to be confined to a relatively few people, and so it would be unfair to the many thousand employees of Schering to characterize them or their company as dishonest.
Q: Now, is it your belief that the projections that Schering personnel made with respect to Niacor-SR were bona fide or alternatively pretextural?
A: It was my opinion, as I expressed in my report, that the financial projections made by Audibert — I assume that's to which you're referring?
Q: Sure.
A: I thought the projections were more ambitious than I would have made and were inconsistent with — were considerably more aggressive than were the projections made by some members of Schering's own

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executive codery, as well as at least one expert that has been engaged by the Federal Trade Commission in this matter.
Q: So, do you think Mr. Audibert was intentionally over-aggressive in those projections?
A: Sir, I — in becoming familiar with this matter, as I testified earlier, I have come to the conclusion that this $60 million payment was so absurd as to defy belief, and I have tried to imagine how it ever could have been promulgated, and there are various interpretations that would put various parties within the Schering-Plough organization and within the Upsher-Smith organization in a less than honest light.
I don't know which scenario is correct, and I don't know whether Mr. Audibert was an unwitting pawn in this matter or was a knowing pawn in this matter or was a principal player in this matter. I don't know from whence the dishonesty arose, but there's dishonesty somewhere.
Q: You've reached that conclusion?
A: As I said before, there are only three viable explanations in my mind. Two of them are not viable; that is, that Schering is a collection of blithering idiots or that Schering felt some charitable leaning towards Upsher-Smith. That leaves only that they

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received other consideration. If they did, indeed, receive other consideration, they have been untruthful in their testimony throughout this matter.
Q: Do you believe the licensing agreement itself to be some sort of a sham or coverup?
A: A sham or coverup? Would you help me understand what you're meaning by that?
Q: Well, you said you've reached the conclusion that there was dishonesty, correct?
A: Yes.
Q: I just want to know if that licensing agreement dated June 17th, 1997 is a coverup of dishonesty in your opinion.
A: I'm not sure what you mean by a "coverup," and I'm asking you to tell me before I can answer that question.
Q: Now, do you know who negotiated that licensing agreement?
A: It was not entirely clear in the testimony, at least it was not entirely clear to me who actually negotiated the terms of the agreement. There were only a few players, and I'm not sure which of them actually worked out the final terms of that deal with Mr. Troup from Upsher-Smith.
Q: Do you know any of the people who participated

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in the negotiations?
A: I don't really have a clear record of the negotiations. This happened so quickly that to me, at least my recollection of the record, doesn't describe a meeting where the parties sat down and dickered about terms to any great extent. There's no, you know, clear minutes of an ongoing, iterative negotiating process of the type to which I'm familiar. This whole thing happened in four or five days, you know, from signing of CDA to execution of agreement, which was so quick that I'm not sure who negotiated what, and there doesn't seem to be any clear path or clear description of who in the process was the negotiator if there was one.
If you ask me to guess, I think that the guy who talked business terms with Upsher-Smith, that is, the person from Schering who discussed business terms was probably Mr. Kapur, but I don't really know that, but because there were so few players that were involved in this whole matter, it leaves either Mr. Kapur or Mr. Lauda, Mr. Audibert, perhaps Mr. Wasserstein, and I think of those four, Mr. Kapur is most likely to have been the person who spoke with Mr. Troup about the terms of the agreement, but I don't know that to be the case. I am purely surmising that.

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Q: In your opinion, have all four of the individuals you've just mentioned been untruthful in this matter?
A: As I said before, sir, I don't know how this plot emerged and how this process emerged. What I know is it doesn't begin to meet a basic smell test, and where that errancy has its root, I am not able to testify.
Q: You haven't attended any depositions in this case, correct?
A: I have attended no depositions in this case.
Q: You haven't had an opportunity to size up any of the witnesses and so forth, correct? In person.
A: I have not met any of the persons who have been deposed in this case. I don't believe I've ever met any of them, and so I have no a priori opinion about them personally. I can read their testimonies and perhaps draw some conclusions about what they did or didn't do, but that's all.
Q: What's your source of documents in this case?
A: All the documents that I have examined in this case have been provided to me by Mr. Silber of the Federal Trade Commission.
MR. CURRAN: Let's take a short break, then we will wrap up.

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(A brief recess was taken.)

BY MR. CURRAN:

Q: Sir, what are the standards in the European Union for new drug applications on sustained-release products?
A: I'm not sure I understand your question, sir. What do you mean by what are the standards?
Q: What are the regulatory standards for approval or disapproval of a sustained-release product?
A: Again, I'm not sure I — you know, that's such a broad-based question. I think that in general, they want a proof of safety and efficacy. I think that their standards in that regard for the most part are consistent with that that the FDA requires just in terms of looking for safety and efficacy of a product.
They have a little bit of an element of economic contribution that our FDA is not supposed to consider in terms of the economic importance of the drug to the medical community, because they have a — many of the companies — many of the countries do have pricing authorities that have to be considered as well as the safety and efficacy of the drug.
Q: Do you consider yourself an expert as to the requirements in the European Union for new drug applications on sustained-release pharmaceuticals?

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A: Oh, I think I am well qualified to comment on that subject, yes, sir.
Q: How many new drug applications on sustained-release products have you filed in the European Union?
A: As I said before, I believe, I have not had the responsibility specifically to file new drug applications in all reality anywhere. New drug applications are filed by a corporation. The major interfaces with the regulatory authorities are in regulatory affairs. In the two corporate jobs that I've had, regulatory affairs reported to me, but they were not, you know, a — so, I had responsibility for it, but I think your question said, if I understand you correctly, I did it, and it's sort of analogous to the comments that — it's analogous to the comments I offered to you when you were asking about who discovered or whether I had discovered drugs.
I don't think that that's — it's not appropriate for me to take credit for filing a — you know, an NDA like that in the European Union. That's not something that I have been asked to do.
Q: I'm not so interested in giving or awarding credit. I just want to know if you've had personal and substantial involvement in the filing of an NDA in the

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European Union on a sustained-release product.
A: I'd have to think through the list of all the compounds with which I've been associated over the years, and way back in 1990, we examined — and I actually don't recall whether we filed it in the EU or not, I think we did — a sustained delivery form for a drug called betaseron, I was doing some work with Triton and then subsequently a company called Burlax. I don't really think that is what you're asking in terms of a sustained-release formulation. It was another kind of delivery system.
Q: That was an injection, right?
A: Yes, betaseron is an injection.
Q: No, I'm talking about sustained-release tablets.
A: I understand. That's why I'm trying to think — you know, I have not prepared an answer for that. I'm just trying to run through my mind all the compounds with which I've been associated and had some substantial input, and — the application for amBisome, which is a liposomal formulation of amphotericin B that was licensed to Fujisawa was filed in the EU. I had involvement with that, but I think you asked me whether I had substantial involvement, and I'd have to say that my responsibilities, as I said before, were not for the

EU, so I don't want to mislead you or, you know, the Court in saying that — I would not characterize that as substantial involvement.

So, I'm not — I would reserve the right to answer that question when I have had a chance to think more thoroughly about all of the compounds with which I've had interaction, and I may come up with one or two where I have, but I'm not recalling anything at this moment.

Q: Sir, what type of pharmacokinetic study or data would have been required in connection with the filing of an NDA in Europe for Niacor-SR?

A: Off the top of my head, I don't know what specific types of pharmacokinetic studies would have been required in 1997 for the — you know, for a sustained-release formulation in the EU.

Q: What type of pharmacokinetic study would have been required for the filing of an NDA on Niacor-SR in the United States?

A: Multi-dose pharmacokinetic studies looking for the stability of the pharmacokinetic parameters upon multiple dosing, because one of the concerns that one has with a sustained-release formulation is that there will be not just tachyphylaxis but temporal differences in the pharmacokinetic parameters that are associated



with the administration of the drug, and so since this is a chronic dosing product, it is my opinion that the FDA would require a multiple dosing pharmacokinetic study.

Q: Is a multi-dose pharmacokinetic study more difficult than a single-dose pharmacokinetic study?

A: I don't think either of them are particularly difficult. It's just it's a little bit more work.

MR. SILBER: I'd like to check on your time. I think your time may be up.

THE REPORTER: Yes, it's up at 4:45.

THE WITNESS: I would have to go, should have gone 15 minutes ago really.

MR. CURRAN: Well, we certainly don't want to interrupt your travel plans. I'm instructed I have no further time.

(Reading and signature not waived.)

(Whereupon, at 4:45 p.m. the deposition was concluded.)



CERTIFICATION OF REPORTER

DOCKET/FILE NUMBER: D09297

CASE TITLE: FTC vs. SCHERING-PLOUGH/UPSHER-SMITH

DATE: NOVEMBER 20, 2001

I HEREBY CERTIFY that the transcript contained herein is a full and accurate transcript of the notes taken by me at the hearing on the above cause before the FEDERAL TRADE COMMISSION to the best of my knowledge and belief.

DATED: 11/21/01

SUSANNE BERGLING, RMR

CERTIFICATION OF PROOFREADER

I HEREBY CERTIFY that I proofread the transcript for accuracy in spelling, hyphenation, punctuation and format.

DIANE QUADE



CERTIFICATE OF DEPONENT

I hereby certify that I have read and examined the foregoing transcript, and the same is a true and accurate record of the testimony given by me.

Any additions or corrections that I feel are necessary, I will attach on a separate sheet of paper to the original transcript.

NELSON L. LEVY, Ph.D., M.D.

I hereby certify that the individual representing himself/herself to be the above-named individual, appeared before me this ____ day of _____, 2001, and executed the above certificate in my presence.

NOTARY PUBLIC IN AND FOR

MY COMMISSION EXPIRES:

WITNESS: NELSON L. LEVY, Ph.D., M.D.
DATE: NOVEMBER 20, 2001
CASE: FTC vs. SCHERING-PLOUGH/UPSHER-SMITH
Please note any errors and the corrections thereof on this errata sheet. The rules require a reason for any change or correction. It may be general, such as "To correct stenographic error," or "To clarify the record," or "To conform with the facts."

| PAGE | LINE | CORRECTION | REASON FOR CHANGE |
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## Lawyer's Notes

## $

$1 million
$10 billion
$10 million (2-3)
$100 million (5-7)
$150 million
$2 million (2-2)
$20
$200 million
$25
$3 billion
$3 million
$4 million
$5 million (3-3)
$50 million (2-3)
$500 million
$60 million (19-29)

## 0

0
0.2 (1-3)
0.5
0.6 (1-2)
00088 (1-2)

## 1

1 (5-7)
1.4 (2-4)
1.5 (17-27)
10 (3-4)
10,000 (2-3)
10-milligram
1000
1000-milligram
11/21/01
115 (2-2)
12:15
12:55
12th
13 (3-3)
1391 (2-2)
14
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15 (3-3)
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1500 (2-2)
1500-milligram (2-3)
1600
160091
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18
18-gauge (1-2)
19,000
1919
1963
1967
198
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1984 (3-4)
1986
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1990
1991
1992
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1996
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20 (10-11)
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2001 (5-5)
2002 (4-9)
22
23
25th

## 3

3 (6-10)
3.0
30-some
3000
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4 (2-4)
40 (5-7)
40-50
40-milligram
4000
41
44 (1-2)
48
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4th

## 5

5 (2-3)
50 (2-2)
53
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6 (2-2)
6/25/92
60045
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United States of America
Federal Trade Commission

In the matter of
Schering-Plough Corporation
Upsher-Smith Laboratories, Inc.
and American Home Products Corporation

Docket No. 9297

# Expert Report

by

## Nelson L. Levy, Ph.D., M.D.

August 13, 2001

Restricted Confidential,
Attorney's Eyes Only

United States of America
Federal Trade Commission

In the matter of
Schering-Plough Corporation
Upsher-Smith Laboratories, Inc.
and American Home Products Corporation

Docket No. 9297

# Expert Report[1,2] by Nelson L. Levy, Ph.D., M.D.

## I. Biography of Dr. Levy

I was graduated *summa cum laude* and Phi Beta Kappa in 1963 from Yale University, where I was a Scholar of the House. In 1967, I received my M.D. degree from Columbia University College of Physicians and Surgeons. I then went to the National Institutes of Health (N.I.H.), where I did research in virology and immunology and, in 1971, published the world's first paper on mammalian gene therapy, as well as the first review on the relationship between viral infections and endocrine disease. In 1970, I went to Duke University, where I earned a Ph.D. in immunology and also did residency training in neurology. Until 1981, I remained at Duke as a tenured professor of microbiology and immunology. My laboratory did research on cancer immunology, multiple sclerosis and the brain's control of the immune system.

In 1981, I left academia to become the Vice President for Pharmaceutical Research at Abbott Laboratories. I led the transformation of a moribund research program, which had not discovered a drug in over 20 years, into a vibrant, productive body, highly competitive within the industry. At Abbott, I started the programs that have led to several marketed drugs, including Hytrin (for hypertension and benign prostatic hypertrophy), Biaxin (for bacterial infections, including that with the ulcer-causing *Helicobacter pylori*) and Ritonavir (HIV protease inhibitor for AIDS.)

In 1984, I became the Chief Executive Officer of the CoreTechs Corporation, which implements a unique paradigm of technology transfer, starts and helps build science-based companies and provides consulting services to the branded and generic pharmaceutical industries.

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[1] I understand that discovery is still on-going and that new information may affect my analyses and necessitate my revising my report to consider and incorporate the new information.
[2] The rate charged for the review of documents and the preparation of this report was $350 per hour.

In 1992, I became the President of Fujisawa Pharmaceutical Company, the $250 million, 1500 employee North American subsidiary of Japan's third-largest pharmaceutical company, where I re-focused and re-vitalized the sales and marketing organizations, in-licensed four major pharmaceuticals and filed an NDA for FK-506 (Prograf), Fujisawa's leading product. In 1993, I returned to CoreTechs, where I am now CEO and Chairman.

I have had broad experience with the conduct, oversight, review and use of clinical trials and their resultant data. This experience derives from multiple perspectives. In academia, I was a principal investigator on trials and thus had the responsibility for the design and implementation of protocols and the interpretation of the results. As a research director, I have had oversight responsibility for the design and conduct of trials and the interpretation and use of the resultant data. As a consultant, board member and chief executive, I have responsibility for oversight of the conduct of clinical trials and for the use of the data from such trials to support registration of pharmaceutical products and to pursue the business interests of the company. My experience also includes in-licensing[3] and out-licensing a variety of products and technologies (most of which were in the healthcare arena), where the licensors and licensees have included academia and companies ranging from start-ups to major international corporations.

I am on the Board of Directors of one public and four private companies and on the Scientific Advisory Boards of four other companies, three of which are publicly-traded.

I am married to Louisa Stiles Levy and the father of six sons. I am a coach for various age-group sports, a participant in triathlons and a lover of rhythm and blues music.

[3] Four terms related to licensing are introduced in this paragraph and defined as follows:
Licensor: The party that provides the property granted by a license agreement
Licensee: The party that receives the property granted by a license agreement
In-licensing: Activities of a licensee
Out-licensing: Activities of a licensor

## II. Introduction and Summary Opinion

The key question to be addressed by this report is whether a certain $60 million non-contingent payment made by Schering Corporation (hereinafter "Schering") to Upsher-Smith Laboratories, Inc. (hereinafter "Upsher-Smith"), in accordance with an agreement (hereinafter "the Schering-Upsher Agreement"), dated June 17, 1997, can reasonably be considered to have been a licensing fee for Niacor-SR® and a few lesser pharmaceutical products.

From the information I have examined, I have drawn the following four conclusions:

- The $60 million non-contingent payment made by Schering to Upsher-Smith can not reasonably be considered to have been a license fee for Niacor-SR and the five generic products licensed under the Schering-Upsher Agreement. This fee was grossly excessive for the value received and greatly exceeded the non-contingent fees paid in other unrelated transactions by Schering for any other products and technologies, including those with far greater value than that of products received under the Schering-Upsher Agreement.

- The due-diligence process followed by Schering in the evaluation of Niacor-SR was so cursory and inadequate as to fall immeasurably below that that I have ever encountered in the pharmaceutical industry. A single, upper-mid-level employee carried out all, or almost all, the due-diligence in less than five days. He did so without input from R&D, patent counsel, Regulatory Affairs, Manufacturing, Finance or any of the persons with responsibility for actually marketing and selling the product. It is inconceivable to me that any pharmaceutical company would spend anything approaching $60 million for a drug that had not yet received regulatory approval for marketing without performing due-diligence far in excess of that performed by Schering.

- And Schering missed, or ignored, major flaws in Niacor-SR® that should not have been missed by even the cursory due-diligence described above. Most noteworthy were data showing that Niacor-SR may be toxic to the liver, the very type of toxicity that had plagued previous drugs like Niacor-SR.

- After execution of the Schering-Upsher Agreement, neither Upsher-Smith nor Schering gave any indication that they were serious about Schering's development of Niacor-SR in its territories. The timelines that were presented to the Schering Board of Directors for the development and marketing of Niacor-SR

had been very aggressive and would have required the immediate establishment of a multidisciplinary project team to plan and implement the enormous effort necessary to gain regulatory approval, to manufacture and to market a new pharmaceutical. I saw no evidence of anything even approaching such an effort. Likewise, after the execution of the Schering-Upsher Agreement, there was almost no communication regarding Niacor-SR between Schering and Upsher-Smith, a very unusual situation for parties with a supposed mutual interest in the development of a pharmaceutical product.

## III. The Licensed Products

### A. List of Products Licensed to Schering Corporation under the Schering-Upsher Agreement

For the world, except the U.S., Canada and Mexico:

| | |
|---|---|
| KLOR CON® 8 | Extended-release potassium chloride tablets, 8 mEq per tablet |
| KLOR CON® 10 | Same, 10 mEq per tablet |
| KLOR CON® M20 | Same, 20 mEq per tablet |
| Pentoxifylline | A generic drug used to improve the blood flow in peripheral arteries, presumably by decreasing the viscosity of the blood |
| Niacor-SR® | See below |

For the world, except Canada and Mexico:

| | |
|---|---|
| PREVALITE® | Upsher-Smith's brand of cholestyramine, a generic bile acid sequestrant used to lower cholesterol |

All parties agree that almost all the value of the licensed products, as perceived at the time of the Schering-Upsher Agreement, lay in Niacor-SR. Accordingly, the remainder of this report will consider only Niacor-SR.

### B. Niacor-SR®

Niacor-SR® (hereinafter Niacor-SR) is a sustained-release formulation of niacin, meant for twice-daily administration, that was developed by Upsher-Smith Laboratories. Niacin (also known as nicotinic acid) is a chemical substance, best known as a vitamin, which, in high oral doses, has been shown to reduce levels of total cholesterol, low-density lipoprotein (LDL) cholesterol, triglycerides and Lp(a) lipoprotein and to increase

levels of high-density lipoprotein (HDL) cholesterol in the blood. Such effects on blood lipids have been shown to reduce the incidence of coronary artery disease. Despite niacin's efficacy in improving the blood lipid profile, the total sales of all niacin products in the world's major pharmaceutical markets represent less than 2% of the sales for cholesterol-lowering pharmaceutical agents. There are two principal reasons for niacin's relatively small market share: 1) niacin's unpleasant side effects and 2) the existence of several alternative, and more acceptable, drugs.

Niacin, when administered in its usual, immediate-release form, causes, in almost all patients, a flushing reaction (a warm to hot feeling in the skin, associated with redness and, often, itching.) This reaction is so unpleasant that most patients who try niacin refuse to continue taking the medication. Niacin also has several other less frequent side effects. One is acanthosis nigricans, a skin rash often seen on the back of the neck or in the armpits; it is not dangerous but can be bothersome. Others include exacerbation of peptic ulcers and gout and worsening of the control of diabetes mellitus.[4]

There are three classes of drugs that generally are preferred over niacin by patients and physicians for the treatment of patients with abnormal blood lipid profiles. Most popular are drugs collectively known as statins, which account for more than 92% of the market and which act by inhibiting an enzyme, HMG-CoA Reductase, that is involved in cholesterol biosynthesis. The two other classes of drugs are the fibrates, which lower triglyceride levels and increase the breakdown of LDL cholesterol, and bile acid sequestrants that act in the gut, where they bind bile acids, prevent their reabsorption from the digestive system and, thereby, cause the liver to use blood cholesterol to synthesize more bile acids, which thus reduces blood cholesterol levels. Both fibrates and bile acid sequestrants do have side effects and are used much less often than the statins.

Prior to the development of Niacor-SR, attempts had been made to diminish the side effects of niacin by administering the drug in a sustained-release formulation, the thesis being that slow, continuous release of the drug into the bloodstream would obviate the flushing reaction seen with the standard tablets and capsules that release a large bolus of the drug with each dose. Unfortunately, such sustained-release niacin preparations induced significant liver toxicities and thus were considered unsafe.

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[4] A.G. Goodman, L.S. Gilman *et al.* (editors). *The Pharmacological Basis of Therapeutics, Seventh Edition.* Macmillan Publishing Company, New York, pages 834-5.

Niacor-SR was developed by Upsher-Smith Laboratories as a sustained-release formulation of niacin that would be administered twice-daily and would lower LDL cholesterol and raise HDL cholesterol but lack the aforementioned liver toxicity.

### C. Clinical Trial Data on Niacor-SR (All These Data Were Provided by Upsher-Smith to Schering Prior to the Schering-Upsher Agreement)

The FDA requires, as one of the major elements for the registration in the U.S. of a new, branded (as opposed to generic) pharmaceutical product, the conduct of two so-called "pivotal" clinical trials. Pivotal trials are well-controlled studies, in a substantial population of patients, that demonstrate convincingly both the safety and efficacy of the pharmaceutical product. At the time of the Schering-Upsher Agreement, Upsher-Smith had finished two clinical trials that it hoped the FDA would consider as pivotal. The results of one of the trials (#920115) had been analyzed and the study report completed; these results were provided to Schering. The other trial (#900221) had been completed, but all the data had not yet been analyzed, and the study report had not yet been completed; nevertheless, data were presented to Schering on some aspects of the efficacy of Niacor-SR and on the withdrawal of patients from this study because of adverse effects and safety concerns.

Based on data from these clinical trials, all of which were provided to Schering prior to the execution of the Schering-Upsher Agreement, I would conclude that Niacor-SR had approximately the same efficacy as a cholesterol-lowering drug as do standard (immediate-release) niacin products. Niacor-SR, however, did not sufficiently obviate the flushing reaction seen with standard niacin products and, most importantly, had a much inferior safety profile (liver and gastrointestinal toxicities).

Upsher-Smith planned to complete the report on study #900221 in June of 1997[5]; i.e., within two weeks after execution of the Schering-Upsher Agreement. The company then planned to complete various other requirements and file the New Drug Application (hereinafter "NDA"), including the study reports on the two pivotal trials, in December, 1997. Schering's stated plan was to use the data in Upsher-Smith's NDA to support applications for registration of Niacor-SR in the European Union (hereinafter "EU") in 1998. While the data from pivotal trials for a U.S. NDA, because of the known high standards of the FDA, are almost always acceptable to the EU regulatory authorities, such authorities likely would have required that additional clinical data be accrued in EU countries. No such studies had been initiated by Upsher-Smith by the time of the Schering-Upsher Agreement (or thereafter), and, I believe, it would have been difficult

[5] SP16 00079

for Schering to plan, conduct and analyze such studies and make the requisite filings in support of registration in the EU by the end of 1998.[6]

I have reviewed the data, provided by Upsher-Smith to Schering prior to execution of the Schering-Upsher Agreement, from the two aforementioned clinical trials and would offer the following opinion on the results of the two trials:

**Clinical Trial #920115[7]**

1. This was a double-blind, active control study comparing the effects of Niacor-SR to those of immediate-release niacin. ("Double-blind" refers to a study where neither the patient nor the administering/evaluating personnel know whether test drug or control had been given.) (An "active control" study is one where the effects of the test drug are compared to those of a drug known to be effective; this contrasts to a "placebo-controlled" study, where the effects of the test drug are compared to those of an inactive substance, typically the vehicle in which the test drug is dissolved or suspended.)

   Group A (active control) received 2,000 mg/day immediate-release niacin
   Group B received 1,000 mg/day Niacor-SR
   Group C received 1,500 mg/day Niacor-SR
   Group D received 2,000 mg/day Niacor-SR

2. Niacor-SR, at 2,000 mg/day (Group D), was shown to be as efficacious in reducing LDL cholesterol and triglycerides and in elevating HDL cholesterol as 2,000 mg/day of immediate-release niacin (Group A). The lower doses of Niacor-SR were efficacious but less so than immediate-release niacin.

[6] Projections developed by Schering specified the end of 1998 as the time when filings for regulatory approval of Niacor-SR would be made in the EU.
[7] SP16 00061-112

3. A number of concerns regarding the safety of Niacor-SR were raised by the study. The following table shows the data leading to such concerns.

| | Group A Niacin 2000 mg | Group B Niacor-SR 1000mg | Group C Niacor-SR 1500mg | Group Niacor-SR |
|---|---|---|---|---|
| | Percentage of Patients Affected | | | |
| Had at least one Adverse Event | 86 | 84 | 80 | 85 |
| Discontinued from study and/or had to reduce dose of test or control drug | 33 | 32 | 39 | 57 |
| Withdrawal from study for safety reasons | 17 | 9 | 20 | 32 |
| Flushing (overall incidence) | 98 | 87 | 81 | 87 |
| Flushing (severe) | 79 | 62 | 53 | 63 |
| Elevation of liver enzyme SGOT (AST) in blood | 5 | 9 | 12 | 31 |
| Elevation of liver enzyme SGPT (ALT) in blood | 3 | 6 | 18 | 34 |
| Nausea | 5 | 4 | 4 | 20 |

Group A, the control group (immediate-release niacin), and Group D had approximately the same efficacy; so it is most reasonable to compare their toxicities as well; hence, they are bolded. Since Groups B and C were less efficacious than 2,000 mg/day of immediate-release niacin (Group A), the toxicities of Groups B and C should rightfully be compared to lesser doses of immediate-release niacin that, presumably, would have had efficacy similar to that of Groups B and C and less toxicity than Group A.

a. **Most significant was the increased incidence of the elevation of liver enzymes in the blood of patients taking Niacor-SR.** SGOT and SGPT are enzyme proteins that are released into the bloodstream when liver cells are damaged. Elevation of these enzymes in the blood is generally considered a sign of liver disease or damage. In my opinion, such enzyme elevations in patients taking Niacor-SR would have alerted any person familiar with drug toxicity issues to the strong possibility that Niacor-SR was an hepatotoxic (i.e., toxic to the liver) drug. Such would be particularly true in view of the known hepatotoxicity of previous sustained-release niacin preparations. Such data would have mandated a detailed examination of the effects of Niacor-SR on the liver prior to any consideration of in-licensing the drug. Such detailed examination, in my opinion, would have included, at the least:

i. Examination of liver biopsies in patients treated with Niacor-SR;

ii. Examination of the reversibility and persistence of the enzyme elevations; i.e., do the enzyme elevations disappear after the drug is stopped, and do the elevations persist with prolonged administration of the drug;

iii. Detailed examination of the histopathology[8] results from animal toxicology studies done prior to the clinical trials.

b. Niacor-SR appears to have an adverse effect profile at least as bad as that of immediate-release niacin. Since it is the adverse effect of niacin that has largely prevented its acceptance by patients and physicians, such results would not bode well for the success of Niacor-SR in the marketplace and, certainly, would have discouraged any potential licensee.

c. The incidence and severity of flushing, while diminished in patients taking Niacor-SR (relative to patients taking immediate-release niacin), was still very high and, in my opinion, still would have prevented most patients from using Niacor-SR. Since reduced flushing was to be the major selling point for Niacor-SR, I think the still-high incidence and severity of flushing, particularly in view of the increase in hepatic and gastrointestinal toxicity of Niacor-SR, would have discouraged any potential licensee.

**Clinical Trial #900221[9]**

1. This was a double-blind, placebo-controlled trial. Patients who received Niacor-SR (as opposed to patients who received placebo) were given Niacor-SR at the following doses:

| | |
|---|---|
| Week 1: | 500 mg/day |
| Weeks 2-10: | 1,000 mg/day |
| Weeks 11-19: | 2,000 mg/day |

As noted above, because the study report had not yet been completed, little information on the results of this study was available to Schering at the time of the Schering-Upsher Agreement. Following is a compilation of that information that was available:

2. Niacor-SR did reduce LDL cholesterol and triglycerides and raise HDL cholesterol.

[8] Histopathology refers to abnormalities seen during microscopic examination of tissues and organs
[9] SP16 00074-84

3. No data were available on the incidence of specific adverse effects or toxicities, but two bits of information did not bode well for the safety of Niacor-SR:

a. Only 62% of patients receiving Niacor-SR completed the 19 week study, compared to 81% of those receiving placebo.

b. Over 32% of patients receiving Niacor-SR withdrew from the study specifically because of safety issues, compared to only 8% of patients in the placebo group.

These results, taken together with the results from Study #920115, certainly would have raised serious concerns, in any person familiar with the development and marketing of pharmaceuticals in the U.S. or EU, about the safety and marketability of Niacor-SR.

## D. Regulatory Concerns Regarding Niacor-SR

1. Safety Issues. These have been discussed in the previous section.

2. Pharmacokinetics. Pharmacokinetic studies show how effectively the drug enters and leaves the circulation. Parameters, such as the rate of absorption of the drug from the gut into the bloodstream, the maximum concentration of the drug reached in the bloodstream, the half-life of the drug in the circulation and the total fraction of the drug dose that enters the circulation, are measured. Such studies are always required for an NDA submission but are particularly important for a drug that purports to be a sustained-release formulation. Upsher-Smith had performed preliminary pharmacokinetic studies with a single dose of Niacor-SR but, the FDA demanded that the studies be performed with repeat doses of the drug. As a first step in the performance of such studies, the company had to develop a reliable assay to measure levels of the test drug in the circulation and excreta. It was apparent from minutes of Upsher-Smith's project team meetings[10] that, at the time of the Schering-Upsher Agreement, they had not even accomplished this first step in the performance of the requisite pharmacokinetic studies. Without the generation of consistent and reliable multiple-dose pharmacokinetic data, Upsher-Smith could not win approval of Niacor-SR in the U.S. or other major markets of the world.

[10] USL 12584, USL 12585

## E. Upsher-Smith's Patent Position on Niacor-SR Was Weak, Especially in Non-NAFTA Countries

At the time of the Schering-Upsher Agreement, Upsher-Smith had no issued patents, and only one patent application, in the EU. A cross-license agreement between Upsher-Smith and Kos Pharmaceuticals, Inc. (Kos), moreover, meant that even the meager patent rights Schering did receive under the Schering-Upsher Agreement were, in effect, non-exclusive.

1. The following was Upsher-Smith's entire patent position on Niacor-SR, as presented to Schering prior to the Schering-Upsher Agreement:[11]

Evanstad Patent (Evanstad, Malhotra & O'Neill, U.S. patent # 5,126,145)

a. Composition-of-matter patent for a controlled-release tablet containing a water-soluble medicament.

b. Issued in the U.S. on 6/30/92.

c. Issued in Australia and India.

c. Filed in Japan and Korea, status pending.

d. **BUT not filed in the EU**, Schering's major market for Niacor-SR.

O'Neill Patent (O'Neill & Evanstad, U.S. patent # 5,268,181)

a. Method-of-use patent for the suppression of nocturnal cholesterol synthesis with a prolonged-release dosage of niacin.

b. Issued in the U.S. on 12/7/93.

c. Filed throughout the EU on 6/29/93, status pending.

2. Upsher-Smith had entered into a patent cross-license agreement[12] with a competitor, Kos Pharmaceuticals, Inc. The licenses granted by the agreement gave to Kos the right to sub-license products made under Upsher-Smith's patents, while Upsher-Smith was not granted the corresponding right regarding

[11] SP16 00062-64
[12] USL 11399-11418

Kos's patents.[13,14] Thus Kos would be able to practice Upsher-Smith's patents (for instance, make a product identical to, or better than, Niacor-SR) and then license the product in any territory to any major pharmaceutical company and thereby create direct competition to Schering. This situation, in effect, rendered as non-exclusive the supposed exclusive license granted to Schering by Upsher-Smith in the Schering-Upsher Agreement.

**F. Niacor-SR Faced a Direct Competitor, Niaspan® (Kos Pharmaceuticals,Inc.) Which Was Well-ahead in Development and That Had Distinct Performance and Safety Advantages**

1. Niaspan is another sustained-release formulation of niacin that was developed by Kos Pharmaceuticals, Inc. Schering knew that Kos had filed the NDA on Niaspan in May, 1996.[15] Upsher-Smith, which, at the time of its Schering-Upsher Agreement with Schering, was projecting filing its NDA on Niacor-SR in December, 1997, thus was at least eighteen months behind Kos. (Niaspan was approved by the FDA in August, 1997.)

2. Niaspan had some clear advantages over Niacor-SR that were apparent at the time of the Schering-Upsher Agreement:

   a. Niaspan was a once/day product, while Niacor-SR had to be administered twice/day. A drug given once/day offers much better patient convenience and compliance than does a twice/day drug, a factor that translates into a major advantage in the marketplace.

   b. Niaspan did not show the liver enzyme elevations[16] seen with Niacor-SR.

The advantages of Niaspan over Niacor-SR were acknowledged by Ms. Denise Dolan, a Product Manager for Upsher-Smith: "Kos is expected to launch Niaspan, a once-daily, controlled release formulation of niacin in late 1997 with superior cholesterol level results and side effects profile."[17]

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[13] USL 11401-2 and USL 11406
[14] Deposition of Daniel Bell, page 63
[15] SPCID2 1A 00109
[16] Elevations in the blood levels of the enzymes, SGOT and SGPT, are strongly suggestive of damage to liver cells.
[17] USL 13190.

## G. Unsuccessful Attempts by Upsher-Smith (Prior to the Schering-Upshe Agreement) to Find a European Licensee for Niacor-SR

1. David Pettit, a consultant hired by Upsher-Smith, tried unsuccessfully fo over six months to find a licensee for the European rights to Niacor-SR. A contact summary produced by Mr. Pettit listed 41 companies, **including Schering-Plough Limited** (Schering's United Kingdom operation), that had rejected the opportunity to license Niacor-SR.[18]

2. Ms. Victoria O'Neill, Upsher-Smith's Vice President of Business Development and Project Management, wrote that the company would have been willing to license Niacor-SR "in exchange for initial or 'up-front' payments *(which may be in the form of milestones against pre-agreed criteria)* and they would seek royalties on net trade sales if the product is sourced within the EU or built into transfer pricing if the product is manufactured for Upsher-Smith in the USA."[19] This argues that Upsher-Smith would not have required *non-contingent* up-front payments, particularly payments as large as $60 million, for the rights to Niacor-SR.

## H. Summary of My Perception of Niacor-SR Based on Information Readily Available to Schering at the Time of the Schering-Upsher Agreement

1. The drug had clinical efficacy similar to that of immediate-release niacin in lowering LDL cholesterol and triglycerides and raising HDL cholesterol.

2. The drug showed clear evidence of hepatotoxicity that, unless mitigated, would be unacceptable.

3. The drug decreased, but not sufficiently, the flushing caused by immediate-release niacin.

4. Patent protection for the drug, particularly in the EU, was weak or even non-existent.



[18] USL 11507-9

[19] USL 11361. Italics added to emphasize part of the quotation.

5. The drug faced direct competition from Niaspan, which was at least eighteen months ahead in development and had a better safety profile and superior dosing schedule.

## IV. Analysis of Schering's Due-diligence on Niacor-SR

### A. Personnel

1. Mr. Raman Kapur was an unusual choice as the internal "champion" and principal negotiator for Niacor-SR. He was the head of Schering's U.S. generic pharmaceutical business, a position that would not typically find him leading the deal for a branded pharmaceutical product to be sold principally in the EU.

2. Mr. James M. Audibert carried out almost all the due-diligence on Niacor-SR. Audibert testified that he could recall no one, other than his boss, Mr. Thomas Lauda, with whom he discussed the project during his assessment of Niacor-SR.[20] It is my opinion that Mr. Audibert was quite junior to handle by himself the due-diligence on a project that the company valued so highly as to pay a $60 million non-contingent licensing fee.

3. It was strange to me that David Poorvin, Ph.D., Schering's Vice President of Worldwide Licensing, did not seem to be involved at all with the licensing of Niacor-SR. Dr. Poorvin is a very experienced licensing executive, who signed most of the other in-licensing agreements for branded pharmaceuticals that were executed at or around the time of the Schering-Upsher Agreement.

### B. A Multitude of Routine Efforts Were Missing from Schering's Due-diligence on Niacor-SR

1. Safety assessment by the Schering-Plough Research Institute (SPRI).

**a. Mr. Thomas Lauda, Schering's Executive Vice President for Global Marketing, under whom were Audibert and the company's entire licensing effort, said, in discussing the requisite due-diligence on an in-licensing candidate: "In all cases he has to have a safety**

[20] Deposition of James M. Audibert, pages 31-32

review. The product has to be reviewed by the Institute to agree with its safety."[21] By "institute" he is referring to SPRI.

There was no evidence that such a safety review was performed by SPRI or any other persons or groups with professional qualifications to review the safety of Niacor-SR. Indeed, it is inconceivable to me that any such review would have missed the hepatotoxicity data and other adverse effects of Niacor-SR described in previous sections of this report.

2. Analysis of pre-clinical (animal) and clinical data on efficacy and safety of the in-licensing candidate by R & D personnel, in addition to the aforementioned safety assessment.

a. Mr. Martin Driscoll, Vice President of Marketing and Sales for Schering's Primary Care Business Unit, said: "Well, importantly one element of due diligence that's essential is if, for example, you're looking to license a product, we want to ensure that the clinical profile is what the other party has stated it is in terms of safety and efficacy. Our research people will evaluate it to determine whether the product is safe and effective under our standards, the standards of the federal government or the various regulatory agencies. That's one element of the due diligence."[22]

3. Input from top managers in the EU regarding the market potential of Niacor-SR in their territories.

a. It is almost inconceivable to me that any company would pay $60 million for the rights to a drug without checking with, and getting the enthusiastic support of, the persons directly responsible for selling it, including:

i. Mr. H.-J. Kummer, Schering's President of Europe/Canada

ii. Managers of individual countries in the EU. (Indeed, Niacor-SR had already been rejected by Schering-Plough Limited, Schering's United Kingdom subsidiary.)[23]

[21] Deposition of Thomas Lauda, page 64
[22] Deposition of Martin Driscoll, page 44
[23] USL 11509

b. Mr. Jeffrey A. Wasserstein, who, at the time of the Schering-Upsher Agreement, was Schering's Staff Vice President, Corporate Business Development, reporting to the Vice Chairman of the company, and who was involved with the presentation regarding Niacor-SR and the Schering-Upsher Agreement made to Schering's Board of Directors, said in his deposition that he had "no personal knowledge of anyone in international who was or was not interested"[24] in Niacor-SR.

4. Input from Regulatory Affairs, particularly those individuals responsible for the EU and Japan, regarding the likelihood, timing, etc. of regulatory approval in the various jurisdictions.

a. For instance, an assessment of what studies would be required in the EU in addition to those conducted for the U.S. NDA filing.

b. Regulatory authorities in many countries of the EU impose pricing restrictions on new pharmaceutical products. The opinions of individuals with expertise on such authorities would be vital to an assessment of the revenue potential of Niacor-SR in the EU. Such was a particularly important issue in view of the presence of very cheap over-the-counter niacin products in several markets of the EU.

c. Examination of the minutes of Upsher-Smith's Niacor-SR project team meetings would have shown to Schering that Upsher-Smith was very likely to encounter difficulties at the FDA regarding the conduct of it pharmacokinetic studies and, probably, its general data management as well.[25] Since so much of Schering's regulatory strategy involved leveraging FDA's acceptance of Upsher-Smith's U.S. clinical data in the EU, it would have been important to secure the opinion of individuals with expertise on U.S. regulatory matters regarding the FDA's probable response to Upsher-Smith's data.

5. Intellectual property review.

a. The entire prosecution file on each of the patents and patent applications covered under the prospective license typically would be

[24] Deposition of Jeffrey A. Wasserstein, page 59
[25] USL 12588, USL 12591, USL 12598

reviewed by patent counsel. It is important to examine the prosecution history of a patent to ascertain the likelihood of the patent's sustaining a challenge.

b. Detailed examination of any interferences that may have been provoked against any of the patent applications.

c. Examination of any pre-existent cross-licenses or other encumbrances involving the patent rights being licensed. Certainly, the aforementioned cross-license agreement with Kos would have greatly influenced the valuation of Upsher-Smith's patent position on Niacor-SR.

6. Input from Manufacturing.

a. A pharmaceutical company typically would have sought an assessment by its manufacturing personnel regarding whether Upsher-Smith would be able to supply product for the EU and Japan, particularly since Upsher-Smith was principally a U.S. company and had almost no non-NAFTA experience.

b. A pharmaceutical company also typically would have assured that alternate manufacturing sites were available and able to manufacture the product in case of a failure, regulatory closure, etc. affecting Upsher-Smith's manufacturing capability.

7. Financial analysis of Niacor-SR. This seems only to have been done by James Audibert, who was perhaps qualified to do a preliminary analysis but did not have the background, nor did he secure the input, to perform the detailed financial analysis requisite to an informed decision regarding a prospective in-licensing opportunity.

## C. The Financial Projections in Audibert's Evaluation of Niacor-SR Were Based on At Least Five Spurious Assumptions[26]

1. He assumed that Niacor-SR would have labeling for co-administration with a statin.[27] BUT Upsher-Smith had no clinical trials anywhere testing the efficacy

[26] SP16 00040-47
[27] SP16 00045

and safety of the co-administration of Niacor-SR with a statin, and there were no plans for Schering to conduct such trials. Such co-administration, therefore, could not have been promoted.

a. This contrasts sharply with Schering's own on-going efforts with ezetimibe, Schering's new cholesterol-lowering drug, which is being tested in clinical trials both as a single agent and in combination with a statin.

2. He assumed that Niacor-SR would be the only sustained-release niacin in the EU until 2002. BUT Kos's Niaspan was about to be approved in the U.S. and could have been approved in the EU well before Niacor-SR.

3. He assumed that Niacor-SR would have a selling price in the EU of 50% of that of Lipitor® (the top-selling statin.) Audibert's assumptions, however, did not consider a number of factors that very likely would have led to very low pricing for Niacor-SR in the EU:

a. Very inexpensive over-the-counter niacin was available in several EU countries, a fact that would certainly have influenced the market, as well as the regulatory authorities that set the pricing for pharmaceuticals in many EU countries. Indeed, some countries in the EU set the price at the level of the lowest price charged for the active ingredient in a product, in the case of Niacor-SR, the price of niacin.

b. Niacin is an old drug, and the EU regulatory authorities do not typically give premium pricing to old drugs in new formulations.

c. Inexpensive generic cholestyramine (a bile acid sequestrant) was widely available throughout the EU and was utilized clinically in a manner very similar to the use of niacin and the projected use of Niacor-SR (i.e., as an adjunct to diet and statin therapy.) Accordingly, I believe that generic cholestyramine might have been used by EU regulatory authorities as a pricing comparator for Niacor-SR.

4. He assumed that Niacor-SR would have minimal side effects. BUT the documents that he reviewed showed clearly that Upsher-Smith's clinical trials had shown:

a. Elevated liver enzymes;

b. A high incidence of drop-outs and dose-reductions among subjects taking Niacor-SR;

c. Flushing in 87% of patients.

5. He neglected to include the 10-15% royalty expense in his calculations and projections of profits from the sale of Niacor-SR.[28]

## D. Audibert's Financial Projections for Niacor-SR Were Significantly Higher Than Those of Other Individuals

1. Audibert projected that Schering's sales of Niacor-SR would be $45 million in year 1, reach $114 million by year 3, $126 million by year 4 and then flatten, resulting in profits of $345 million in the first 5 years of sales.[29] These figures were based on Niacor-SR's capturing 1.5%[30] of the non-NAFTA market for cholesterol-lowering agents by year 3. I think the 1.5% market share projected by Audibert was an arbitrary and ambitious figure for two reasons:

a. Sales of niacin products in 1996 represented less than 0.1% of the non-NAFTA sales for cholesterol-lowering agents, with sales of not just the statins, but the fibrates and bile acid sequestrants as well, dwarfing those of niacin products.[31]

b. Japan and the EU comprise the bulk of the non-NAFTA pharmaceutical market. While Audibert did project plans to register Niacor-SR in the EU, he made no mention of Japan. This is consistent with Lauda's statement that Schering derived 80% of its non-U.S. sales from the EU.[32] The absence of Niacor-SR sales in Japan, or even the sublicensing of Niacor-SR to a company with a strong presence in Japan,

[28] SP16 00035-36
[29] *Ibid*
[30] SP16 00046-47
[31] SP16 00447-52
[32] Deposition of Thomas C. Lauda, page 102

would mean that Schering would have to achieve greater than a 2% market share in the EU to approach the 1.5% figure projected by Audibert.

2. Ms. Denise Dolan, a marketing specialist for Upsher-Smith itself, estimated that her company would achieve, in the U.S., Niacor-SR sales of only $5.7 million in year 1, rising to about $7.5 million by year 4.[33]

3. Mr. James J. Egan, the Director of Licensing for G. D. Searle, evaluated both Niacor-SR and Niaspan and opined that the market for a sustained-release niacin product in the EU would have been $25-30 million. He also expressed the concerns noted above about low pricing of the product in the EU.[34]

4. Mr. Martin Driscoll, who had been closely involved in Schering's consideration of Niaspan, said he had projected the total U.S. market for Niaspan at a maximum of $60-70 million[35] (and the EU market is considerably smaller than that of the U.S.)

**E. Audibert Maintained That Prior Due-diligence on Kos's Niaspan, Because of Its Similarity to Niacor-SR, Obviated the Need for Much of the Due-diligence That Normally Would have Been Performed on Niacor-SR**

1. BUT Driscoll noted, in discussing Schering's interactions with Kos regarding Niaspan: "...we simply didn't get into a substantive due diligence." And he said that the only documents provided by Kos were "summaries of their pivotal clinical trials."[36]

2. Driscoll had rejected Niaspan, in large part because it caused flushing in 88% of patients during Kos's clinical trials: "First and foremost as I reviewed the clinical information on the product, I felt they had too high a rate of flushing, and I remember – I remember this number, it's just in my memory, that they had an 88 percent incidence of flushing in their pivotal clinical trial."[37]

[33] USL 13190-7
[34] Deposition of James J. Egan, pages 60-61
[35] Deposition of Martin Driscoll, page 90
[36] Deposition of Martin Driscoll, page 89
[37] *Ibid*, page 85

3. The deposition (and associated exhibits) of Mr. Mukesh Patel, Kos's Vice President of Licensing, suggested that Audibert was not a central figure in Schering's discussions with Kos:[38]

a. Ms. Karin Gast, Senior Director, Business Development, at Schering, led the interactions with Kos.

b. Conference calls on April 9, 1997 and April 25, 1997 included, among the Schering participants, Ms. Gast, Mr. Ray Russo and Ms. Antonia De Mola, but not Audibert.

c. The only mention that I could find of Audibert's involvement in the Kos discussions was the log of a phone call on March 13, 1997 between Gast, Russo and Audibert from Schering and Bell and Heatherman from Kos [39]

### F. Summary of My Opinion on Schering's Due-diligence Efforts Prior to the Schering-Upsher Agreement

1. The due-diligence effort conducted by Schering did not reach what I would consider even a minimal level for the in-licensing of a pharmaceutical product.

2. There was no apparent reason for the hasty (5 days) and sub-minimal effort, since neither Audibert nor Lauda "recalls that there was any particular urgency to complete the assessment in an unusually short time frame."[40]

## V. Analysis of the Schering-Upsher Agreement

### A. Description of the Agreement[41]

The Schering-Upsher Agreement is a three-page letter, with an eight-page Exhibit A, sent on June 17, 1997 by Mr. Raman Kapur of Schering to Mr. Ian Troup, President of Upsher-Smith, and executed by him on June 19, 1997, though the effective

[38] Deposition of Mukesh Patel, Exhibits 2, 3, 4, 5, 6, 7
[39] SPCID2 1A 00109-10
[40] *Memorandum of Schering-Plough Corporation to the Federal Trade Commission Concerning File No. 9910256* from Howrey Simon Arnold & White, LLP, March 23, 2001, page 19
[41] USL 03183-93

date is stated as June 17, 1997. The Schering-Upsher Agreement anticipated the subsequent execution of a Detailed Agreement but, nevertheless, was binding upon the parties, contingent only upon the approval of the Schering-Upsher Agreement by the Schering Board of Directors on or about June 24, 1997. The Schering-Upsher Agreement dealt with two disparate issues: 1) settlement of a dispute between Upsher-Smith and Schering concerning Schering's extended-release potassium chloride product, K-Dur, and Upsher-Smith's desire to market a like product; 2) licensing by Upsher-Smith to Schering of six products, most notably Niacor-SR. This report is only directly concerned with the latter issue, and the analysis that follows in this Section deals only with the latter issue.

## B. Schering's Stated Rationale for Licensing Niacor-SR Was Ezetimibe

A major theme of Schering's explanation[42] for its licensing of Niacor-SR involved ezetimibe, a drug being developed by Schering and currently in Phase III clinical trials. Ezetimibe is a new class of drug that inhibits cholesterol absorption and could become one of Schering's major products. Schering has stated that, in order to maximize the sales potential of ezetimibe, it must build a major presence in the cardiovascular drug marketplace. Accordingly, Schering has argued that Niacor-SR would have given it the basis on which to begin the building of such a presence. As proof-principle of this argument, Schering has stated that, because of the failure of Niacor-SR, the company now has been forced to seek an alliance with Merck to co-market ezetimibe.[43] I did not find Schering's rationale for the Niacor-SR deal convincing for a number of reasons:

1. The Schering-Merck agreement is only for the U.S.,[44,45] a territory where Schering never had rights to Niacor-SR; so how could the failure of Niacor-SR have necessitated the Merck agreement?

2. Ezetimibe is now in Phase III clinical trials in the U.S., with approval expected in 2003. Schering projected EU approval of Niacor-SR for late 1998. It does not seem reasonable to me that Schering would have built, around a minimal product like Niacor-SR, a marketing organization capable of handling a

[42] *Memorandum of Schering-Plough Corporation to the Federal Trade Commission Concerning File No. 9910256* from Howrey Simon Arnold & White, LLP, March 23, 2001, page 19
[43] *Ibid*, page 20
[44] Reuters Limited, "Schering-Plough, Merck Forge Pact," *Yahoo.com*, May 23, 2000
[45] Harris, Gardiner, "Drug Makers Pair Up to Fight Key Patent Losses," *Wall Street Journal*, May 24, 2000, page B1

potential blockbuster like ezetimibe, especially without the U.S. market and with at least five years' hiatus between the drugs.

3. Schering said that it did not do the earlier deal with Kos Pharmaceuticals for Niaspan (a once/day product almost two years ahead of Niacor-SR and for which U.S. rights were available) primarily because Kos demanded that Schering commit to giving Niaspan considerable primary detailing activity (i.e., salespersons would promote Niaspan before other products.) Such contradicts the deposition of Driscoll, who said that he rejected Niaspan largely because of its high incidence of flushing.[46] Driscoll's opinion notwithstanding, if Schering's rationale for in-licensing a sustained-release niacin product really was to provide a foundation for the building of a sales force for ezetimibe, then Schering would have had no difficulty in providing primary detailing for Niaspan during the prolonged period between the launch of Niaspan and that of ezetimibe. What else would the specialty sales force for ezetimibe have done while waiting for the approval of ezetimibe?

## C. Terms of the Schering-Upsher Agreement

1. Licensed products and their respective territories are listed in Section III.A. An exclusive, paid-up, royalty-free license, with the right to grant sublicenses, was granted to Schering for all the products, except Niacor-SR. The license grant for Niacor-SR was also exclusive, with the right to grant sublicenses, but bore the royalty and milestone payment obligations described below.

2. Unconditional, non-refundable fees, totaling $60 million, were to be paid to Upsher-Smith by Schering as follows:

   a. $28 million immediately (actually within 48 hours of the date of approval of the Schering-Upsher Agreement by the Schering Board, the "Approval Date");

   b. $20 million upon the first anniversary of the Approval Date;

   c. $12 million upon the second anniversary of the approval Date.

[46] Deposition of Martin Driscoll, page 85

3. Milestone payments upon the first commercial sale of Niacor-SR by Schering or its sublicensee in each of the following countries were to be paid to Upsher-Smith by Schering:

| | | |
|---|---|---|
| a. | United Kingdom | $1 million; |
| b. | Germany | $1 million; |
| c. | France | $1 million; |
| d. | Spain | $1 million; |
| e. | Italy | $1 million; |
| f. | Belgium/the Netherlands | $1 million; |
| g. | Japan | $2 million; |
| h. | Latin America | $1 million; |
| i. | Australia, Taiwan, Korea or South Africa | $1 million. |

4. Royalties on aggregate net sales of Niacor-SR by Schering and its sublicensees equal to 10% of net sales up to $50 million and 15% of net sales in excess of $50 million were to be paid to Upsher-Smith by Schering.

**D. Unusual Features of, and Items Missing from, the Schering-Upsher Agreement**

I recognize that the Schering-Upsher Agreement anticipated the execution of a Detailed Agreement to supercede the June 17, 1997 agreement, but this Detailed Agreement was never executed. The comments in this section are not meant to enumerate the myriad detailed clauses, definitions and protections that are typically found in a full license agreement and that, presumably, would have been found in the Detailed Agreement. Rather, my comments refer to some major items that, in my opinion, would have been covered in even a brief, but binding, letter agreement that was meant to precede a full license agreement.

1. $60 million in non-contingent payments. In my opinion and experience, it is almost unheard of for a pharmaceutical company to make such a large non-contingent cash payment for an unapproved pharmaceutical. Occasionally, such payments are made for a potential "blockbuster" drug that represents a major therapeutic advance and for which the license has been actively sought by several major pharmaceutical companies. Even the very optimistic perceptions voiced by Schering and Upsher-Smith would not put Niacor-SR even close to the "blockbuster" class, and there was no evidence that any company was seriously interested in a license for Niacor-SR, particularly for the non-U.S. market. The fact that the Upsher-Smith:Kos cross-licensing agreement in effect meant that Schering's license for Niacor-SR was non-exclusive made the $60 million payment even more unreasonable.

2. In my experience, one of the major elements of a license agreement has been the clear assurances by both licensee and licensor that they will diligently carry out the activities necessary to effectively develop and market the licensed product. The licensor almost always demands time-specific milestones, with the ability to revoke the license if the licensee has not been sufficiently assiduous in developing and marketing the licensed product. The licensee, likewise, almost always demands that the licensor explicitly agree to carry out those development and patenting activities upon which the approval and commercial success of the product depends. The Schering-Upsher Agreement had no such assurances from either party. Most glaring of these omissions was the absence of a commitment by Upsher-Smith to pursue with diligence the requirements for the filing of its U.S. NDA for Niacor-SR. Schering's entire strategy for the development of Niacor-SR depended upon its use in the EU of Upsher-Smith's data and U.S. NDA filings.

3. Also in my experience, licensees have always demanded clear warranties by the licensor regarding the licensor's ownership of the products and intellectual property being licensed. The Schering-Upsher Agreement contains no such warranty from Upsher-Smith.

## E. Other Agreements Where Schering Was the Licensee

I was provided thirteen agreements executed by Schering with eleven different licensors. I read all these agreements and considered eight of them to have enough similarities to the Schering-Upsher Agreement as to be comparable. I have briefly described in Table 1 the salient features of each of these eight agreements (plus those

of the Schering-Upsher Agreement) with the emphasis on affording a comparison with the Schering-Upsher Agreement. The agreements are listed in the Table in alphabetical order of the licensor.

# Table 1: Comparison of Schering's In-licensing Agreements[1]

| Licensor<br><br>Date of the Agreement | Licensed Product and/or Intellectual Property | Non-contingent Fees | Milestone Payments | Royalties | Territory | Conditions[2] | Payer of Development Costs | Comments |
|---|---|---|---|---|---|---|---|---|
| Iherogenics, Inc.<br><br>0/21/99 | Soluble analogs of Protocol plus a Compound Library | $2.5 M | $2M: completion of CART Study<br>$5M: Start Phase III<br>$10M: Approval U.S.<br>$7.5M: sales $300M<br>$15M: sales $600M<br>$22.5M: sales $900M<br>$30M: sales $1.2B | 15% where patent<br>7.5% no patent<br>BUT<br>Total COGS (incl. royalties) capped at 25% | U.S. | S-P must file IND by 12/31/01 & NDA by 12/31/05 | S-P | Drug in late Phase II for treatment and prevention of coronary re-stenosis, a major clinical problem with no effective treatment. Secondary indications for treatment & prevention of atherosclerosis. |
| lecton Dickinson<br>nd Company<br><br>/15/99 | Use of B-D Pen delivery system with S-P's PEG Intron-A | $250K | $100K for prototypes<br>$200K for validation of mold<br>$200K at first shipment | | U.S. | S-P will purchase minimums at a price set for 12 months, which can be increased according to B-D's COGS | S-P | This agreement provided a single-dose and metered-dose injection system for use with PEG Intron-A, one of S-P's major products. |
| ritish Biotech<br>harmaceuticals,<br>td.<br><br>/6/99 | Marimastat and back-up compounds | $2M<br>$4M in stock at 2X price | $6M (total): NDA filing in US or EU for small cell lung CA<br>$5M: approval for small cell lung CA<br>$5M: 2nd approval<br>$5M: approval for advanced cancer<br>$5M: approval for colorectal cancer | Where patent:<br>12% <$200M sales<br>15% $200-400M<br>18& >$400M<br>Where no patent: 6, 7.5, 9%<br>If 3rd-party generic: 3, 3.75, 4.5% | World except U.K. and most of Far East | Many developmental & marketing demands placed on S-P.<br><br>S-P can terminate if clinical trials suggest drug to be non-approvable. | S-P | Marimastat in Phase III & is the first of a potential breakthrough class of anti-cancer drugs known as matrix metalloproteinase inhibitors. These drugs may inhibit a major mechanism whereby cancers spread. Also potentially useful in many non-cancer diseases. |
| Centocor, Inc.<br><br>4/3/98 | Infliximab (Avakine) for Crohn's Disease & Rheumatoid Arthritis | $24.5M<br>$6M 12/31/98 BUT $20M against devel. expenses | $10M: approval for Crohn's Disease in EU<br>$20M: approval for rheum. arthritis in EU<br>BUT no milestones if get | Split of 'contribution income' (~pre-tax profits w/o devel. expenses):<br>66% to S-P on sales | World except U.S. & Far East | Many developmental & marketing demands placed on S-P, incl. loss of exclusivity if sales no exceed $100M by 3 yr | Complex terms, but basically S-P pays nothing in 1998 & 1999 | Infliximab is the first of a new class of drugs that block the effects of the inflammatory mediator, TNF-alpha. Inhibition of TNF-alpha is one of the **Continued on the Next Page** |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | "Black Box" warning[3] re. certain safety issues that impact sales | <$150M; 60% to S-P on sales >$150M | | after approval. | and then parties split costs thereafter | most important recent advances in the treatment of inflammatory disease. |
| nzon, Inc<br>0/29/90 | Application of Enzon's pegylation technology to S-P's Intron A to create a new drug, PEG-Intron-A | $150K | $450K: filing IND<br>$$2.5M: 1st successful clinical trial<br>$1M: PLA filing<br>$2M: PLA approval | If no competition:<br>6% <$200M sales<br>8% >$200M sales<br>If there is a competitive interferon then 3% & 6% rate | World | Development plan defined. Enzon has manufacturing rights. | S-P | Intron A is one of Schering's major products. Pegylation is a process that makes the Intron A last longer in the circulation and makes it relatively invisible to the immune system. It has given PEG-Intron-A an advantage over competitive interferon products. |
| CN<br>harmaceuticals,<br>ic.<br>/28/95 | Ribavirin for hepatitis C; plus any improvements | $23M plus $7M stock purchase @ market price | $20M stock purchase at approval in the U.S.<br>$15M stock purchase at approval in the EU | 10% sales <$50M<br>15% sales $50-100M<br>20% sales >$100M<br>Certain minimums & royalty reductions | World, except ICN can also sell in EU & Egypt | Many development & marketing demands placed on S-P. Controls on competition with S-P from ICN selling drug for other indications. | S-P, except ICN pays 50% for EU up to $5M | Ribavirin is the first oral drug effective against hepatitis C. Use of Intron-A against hepatitis C is one of S-P's major products. Ribavirin was thus a perfect fit for S-P, especially for use in combination with Intron-A. |
| leurogen Corp.<br>/28/95 | D4 antagonists and all Neurogen's other dopamine agonists & antagonists | $14M plus $3M for Screening Agreement | $3M: end Phase II for schizophrenia<br>$3M: NDA schizophrenia<br>$3M: approval U.S.<br>$3M: approval EU<br>$5.5M total: approval for other indications for D4 antagonists<br>$11M total: other products if sales >$300M per year by year 3 | 8% on sales <$200M<br>10% on $200-500M<br>12% on >$500M | World | Many development & marketing demands placed on S-P. | S-P funds 16 scientists at Neurogen and pays for development | Neurogen was one of the leading neuroscience research companies in the world, and S-P got exclusive access to one of Neurogen's most exciting research programs, with the potential to produce major breakthrough drugs for the treatment of psychiatric and neurologic diseases. |
| .P. Scherer Corp.<br>/24/99 | Application of the Zydis technology to DCL (see comments) | $350K | $350K: 1st NDA or ANDA filed<br>$250K: foreign NDA or ANDA filed<br>$450K: U.S. approval<br>$$350K: foreign approval | 2-6% depending upon sales levels | World | Scherer had development timelines; S-P offered two $1M incentive payments if timelines were exceeded. | S-P | DCL=descarboethoxyloratadine, which is the active metabolite of Schering's major drug, Claritin. Zydis technology is a fast-dissolving drug delivery system that S-P wanted to apply to DCL to make a better, proprietary Claritin-like drug |
| | | | | | | | | **Continued on Next Page** |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| oshor-Smith<br>aboratories, Inc.<br><br>17/97 | Niacor-SR and five generic drugs | $28M<br>$20M in 1 yr<br>$12M in 2 yr | $1M each on approval in Germany, France, U.K., Italy, Spain, Benelux, Latin America & Australasia<br>$2M on approval in Japan | 10% on sales <$50M<br>15% on sales >$50M | World except U.S., Canada Mexico | None | S-P in its territories | |

Abbreviations: K=thousands, M=millions, B=billions; S-P=Schering; PLA=Product License Application (similar to an NDA but for biological drugs); COGS=cost of goods sold

Refers to performance requirements imposed on the licensors and licensees; list, of course, is not extensive and is meant merely to show the agreement's general tenor.

A "Black Box" warning refers to requirement by the FDA and/or other regulatory agencies that the package insert and other written descriptions and promotions of the product ave, in clear type contained in a black-bordered box, warnings about specific potential adverse effects, contraindications or other problems concerning the product. A "Black Box" rather unusual, is a significant warning about the product and, almost always, compromises sales of the product.

The five agreements provided by Schering but not included in the Table are:

a. Distribution agreement with Centocor, Inc. for Infliximab. The license agreement for Infliximab was included in the Table, and this distribution agreement merely spelled out details of marketing and sales issues to which allusion was made in the Table.

b. Stock purchase agreement with ICN Pharmaceuticals, Inc. The license agreement was listed in the Table, and included were the stock purchase provisions.

c. Collaboration and license agreement with Pharmacopeia, Inc. Pharmacopeia is a company that conducts a specialized form of chemical research useful for the discovery of drugs. This was really a research agreement, under which Schering made no up-front payments but funded 42 scientists at Pharmacopeia.

d. Option agreement with Silicon Microdevices, Inc. This was a research/collaboration agreement, under which Silicon Microdevices and Schering would try to combine their technologies to invent a means of delivering insulin through the skin without using injection. Schering paid a one-time "access fee" of $40,000.

e. Co-promotion agreement by and between Bristol-Myers Squibb Company (BMS) and Schering Sales Management, Inc. This was not a licensing agreement. It was a co-promotion agreement, under which Schering paid BMS for the right to co-market one of BMS's new approved drugs, the broad-spectrum fluoroquinolone antibiotic, Tequin®.

## F. Summary Comments on the Schering-Upsher Agreement

1. A non-contingent payment of $60 million was greatly in excess of non-contingent payments made by Schering, and, in my experience, other companies, for pharmaceuticals with much greater sales potential than that of Niacor-SR. Only two of the agreements listed in the table included non-contingent payments amounting to even half of $60 million. Both of these agreements were for drugs that provided entirely new classes of therapy and that had market potential much in excess of even Audibert's projections for Niacor-SR. The ICN agreement was worldwide, and the licensed product, Ribavirin, was a perfect complement to Intron-A, one of Schering's major products. The licensed product in the Centocor agreement was considered a potential breakthrough in the treatment of Crohn's Disease and rheumatoid arthritis. Moreover, of the $30.5 million in the Centocor agreement, $20 million was applied against Schering's portion of development expenses. The British Biotech agreement included only a $6 million non-contingent payment (of which $4 million was stock) and granted almost worldwide rights to what could be an enormous breakthrough in the therapy of cancer. The Enzon, Scherer and Becton Dickinson agreements each included non-contingent payments of less than $1 million but provided to Schering technologies of considerable importance to various of Schering's major marketed products.

2. Most in-licensing agreements for unapproved pharmaceuticals, including all the other agreements listed in Table 1, provide higher payments contingent upon the licensed product's achieving various milestones, most importantly, approval in major markets, than they do non-contingent payments. Such was not the case with the Schering-Upsher Agreement, this fact being particularly odd in view of the myriad factors that any informed party would have recognized as major risks to the approvability and marketability of Niacor-SR.

3. In my opinion, neither party built into the Schering-Upsher Agreement the rudimentary performance and due-diligence provisions that would have been demanded by any party serious about the development and marketing of the licensed product.

## VI. Activities of the Parties After the Schering-Upsher Agreement

### A. Upsher-Smith's Activities

1. I was provided documents that appeared to be the minutes of Upsher-Smith's Niacor-SR project meetings:

8/14/97: They seemed to be making some progress on the development of assays requisite to the pharmacokinetic studies demanded by the FDA and with which the company had been struggling since early in the year, but questions were raised about the impact of the study delays on the development timeline. Also noted that Niaspan had been approved and indicated a consequent need to revise and update their marketing plans.[47]

10/21/97: Assay development for pharmacokinetic studies still progressing; samples collected. Team has decided to develop an ANDA[48] strategy and conduct only minimal activity on the NDA strategy while this plan is being developed and evaluated.[49] **I find it incredible that Upsher-Smith would take such steps without at least conferring with Schering unless they knew that Schering was not very serious about developing Niacor-SR.**

11/13/97: No mention of pharmacokinetic studies. Repeated plan to develop an ANDA strategy. The ANDA (generic) product now seems to have been given a name, Niacin ER.[50]

1/15/98: Niacor-SR project has been put on hold.[51]

**There are considerable inconsistencies in the record regarding when Upsher-Smith actually terminated its efforts to develop Niacor-SR as an**

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[47] USL 12583

[48] ANDA = Abbreviated New Drug Application. An ANDA is an application made to the FDA for the approval of a generic drug and is based on the concept that the generic drug is equivalent to a marketed drug that is no longer covered by patents. In this case, Upsher-Smith intended to maintain that Niacor-SR was a generic version of Kos' Niaspan. Unlike an NDA, an ANDA does not require clinical trials demonstrating the safety and efficacy of the drug and, accordingly, is a much simpler filing. But an ANDA would be of no use to Schering's effort to register Niacor-SR in the EU or any other country, and Upsher-Smith's change to an ANDA strategy would have had very deleterious effects on any of Schering's marketing plans, pricing assumptions and financial projections for Niacor-SR.

[49] USL 12581

[50] USL 12580

[51] USL 12579

NDA product (10/97[52] or 1/15/98[53]). Regardless, it was almost a year (9/12/98) until they notified Schering.[54]

**B. Schering Gave No Indication of Being Serious About the Development of Niacor-SR in its Territories**

1. No evidence of a project team's having been formed.

2. No clinical trials were begun in the EU.

3. Upsher-Smith was having difficulty developing assay methodology for the conduct of pharmacokinetic studies mandated by the FDA. The pharmacokinetic studies were essential to Upsher-Smith's NDA filing on Niacor-SR and thus directly impacted the timelines for Schering's own development of the product. Such assay development is routine for the R&D departments of major pharmaceutical companies, and thus it seemed strange to me that Schering did not provide help to Upsher-Smith on this matter (or that Upsher-Smith did not ask for such help.)

[52] *White Paper of Upsher-Smith Laboratories, Inc.*, pages 27-28
[53] USL 12579
[54] SP16 00057

August 15, 2001 (10:03AM)

DOCUMENT LOG- Dr. Nelson Levy

| Document Title | Bates Number Begin | Bates Number E |
|---|---|---|
| | FTC 0015138<br>Schering et al., D-9297 | FTC 00151<br>Schering et al., D92 |
| Complaint Counsel's Identification of Trial Experts | | |
| Audibert investigational hearing transcript and exhibits | | |
| Bell investigational hearing transcript and exhibits | | |
| Driscoll investigational hearing transcript and exhibits | | |
| Hoffman investigational hearing transcript and exhibits | | |
| Kapur investigational hearing transcript and exhibits | | |
| Kralovec investigational hearing transcript and exhibits | | |
| Lauda investigational hearing transcript and exhibits | | |
| O'Neill investigational hearing transcript and exhibits | | |
| Patel investigational hearing transcript and exhibits | | |
| Robbins investigational hearing transcript and exhibits | | |
| Troup investigational hearing transcript and exhibits | | |

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| | USL 12841 | USL 12 |
| | USL 15473 | USL 15 |
| | USL 15534 | USL 15 |
| | USL 21232 | USL 21 |
| 03/23/01, White Paper of Schering-Plough Corporation | | |
| | SP 05 00011 | SP 05 00 |
| | SP 16 00057 | SP 16 00 |
| | SP 16 00236 | SP 16 00 |
| | SP 18 00004 | SP 18 00 |
| | Schering-Plough White Paper Exhibits 0000189, Schering et al., 9910256 | Schering-Plough Wh Paper Exhibits 00001 Schering et al., 9910 |
| 06/28/95, Collaboration and Licensing Agreement by and between Neurogen Corporation, Schering Corporation and Schering-Plough Ltd. | | |
| 07/28/95, Exclusive License and Supply Agreement between ICN Pharmaceuticals, Inc. and Schering-Plough Ltd. | | |
| 07/28/95, Stock Purchase Agreement by and between ICN Pharmaceuticals, Inc. and Schering-Plough Corporation | | |
| 04/03/98, Distribution Agreement by and Between Centocor, Inc. and Schering-Plough Ltd. | Schering-Plough 0000390, Schering et al., 991-0256 | Schering-Plough 00005 Schering et al., 991-02 |
| Co-promotion Agreement by and between Bristol-Myers Squibb Company and Schering Sales Management, Inc. | Schering-Plough 0000538, Schering et al., 991-0256 | Schering-Plough 00006 Schering et al., 991-02 |

| 06/17/97, Key Pharmaceuticals, Inc. v. Upsher-Smith Laboratories, Inc. U.S.D.C., D.N.J. (Civil Action No. 956281 (WHW)) | Schering-Plough 0000002, Schering et al., 991-0256 | Schering-Plough 00000 Schering et al., 991-02 |
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| | SPCID 00090 | SPCID 001 |
| | SPCID 00138 | SPCID 002 |
| | SPCID 00442 | SPCID 005 |
| | SPCID 00255 | SPCID 003 |
| | SPCID 00695 | SPCID 007 |
| | SPCID 00631 | SPCID 006 |
| | FTC 0015038 Schering et al., D-9297 | FTC 00150 Schering et al., D-92 |
| | FTC 0015011 Schering et al., D-9297 | FTC 00150 Schering et al., D-92 |
| | FTC 0015024 Schering et al., D-9297 | FTC 00150 Schering et al., D-92 |
| | AAA 0000378 | AAA 00003 |
| | Moreton 0000001 | Moreton 00007 |
| | SP 12 00075 | SP 12 001 |
| | USL 02008 | USL 020 |
| | USL 09122 | USL 091 |
| | USL 09883 | USL 098 |
| | USL 11367 | USL 113 |
| | USL 11396 | USL 114 |
| | USL 11931 | USL 119 |
| | USL 11946 | USL 119 |
| | USL 12577 | USL 126 |

| | FTC 0015000<br>Schering et al., D9297 | FTC 001501<br>Schering et al., D929 |
|---|---|---|

## CERTIFICATE OF SERVICE

I hereby certify that this 3rd day of January, 2002, I caused an original, one paper copy and an electronic copy of the foregoing Respondents' Joint Motion to Exclude the Expert Testimony of Dr. Nelson Levy and accompanying memorandum, to be filed with the Secretary of the Commission, and that two paper copies were served by hand upon:

Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
Room 104
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

and one paper copy was hand delivered upon:

Karen Bokat
Bureau of Competition
Federal Trade Commission
Washington, D.C.
601 Pennsylvania Ave, N.W.
Washington, D.C. 20580

Christopher Curran
White & Case LLP
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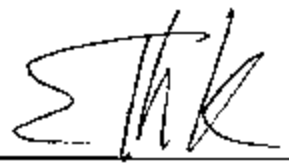

Erik T. Koons