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The Honorable Sandra Mazer Moss Philadelphia Court of Common Pleas

Litigation)

Room 653 City Hall Philadelphia, PA 19107 January 19, 2010

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In Re: Avandia Litigation; February Term 2008, No. 2733 (Avandia Mass Tort Re:

**Opposing Counsel:** Christopher Wasson, Esquire and Joseph Crawford, Esquire of Pepper Hamilton, LLP

Filing Date: January 19, 2010

Response Date: February 1, 2010

Plaintiffs' Motion re: Defendant's Ex Parte Contacts with Plaintiffs' Treating Physicians

Case ID: 080202733

IN THE COURT OF COMMON PLEAS PHILADELPHIA COUNTY, PENNSYLVANIA						
IN RE: AVANDIA LITIGATION	:	February Term 2008				
	:	No. 2733				
<u>ORDER</u>						
AND NOW, this	day of	, 2010, it is				
hereby ORDERED AND DECREED that defendants and defense counsel are prohibited from						
communicating ex parte with plaintiffs' treating physicians. In addition, it is hereby ORDERED AND						
DECREED that defendant GSK's sales representatives are prohibited from having ex parte contact						
with plaintiffs' treating physicians dur	ring the pendency	of this litigation.				

Sandra Mazer Moss, J.

Case ID: 080202733

#### Dear Judge Moss:

Plaintiffs respectfully request by and through liaison counsel, Anapol Schwartz, that this Honorable Court hereby enter an Order directing defendant, GlaxoSmithKline (hereinafter "GSK") to cease and desist communicating *ex parte* with plaintiffs' treating physicians. It has come to plaintiffs' counsel's attention during the course of several depositions that defense counsel or defendant, through its sales representatives, have been communicating ex parte with plaintiffs' treating physicians prior to depositions in an attempt to either create bias and influence the physician's testimony or to gather information that will influence the course of the deposition and thereby the litigation.

It has recently come to light that GSK has engaged in *ex parte* communications with plaintiffs' treating physicians without the plaintiffs' knowledge or consent prior to the treating physicians' depositions. Specifically, Dr. Andrew G. Polakovsky, a treating physician for plaintiff Samuel Thomas, testified that a GSK representative informed him sometime before his scheduled deposition that he "was going to get papers or something like that regarding one of [his] patients."

See the deposition of Dr. Andrew G. Polakovsky taken October 20, 2009 at lines 85:3-14 and attached hereto as Exhibit A:

- Q. Have you spoken to any representative from GlaxoSmithKline prior to this deposition with regard to this lawsuit?
- A. There was a representative that stopped in my office some time in August, and I can't recall the date, who stated that I was going to get papers or something like that regarding one of my patients. She did not mention the patient specifically, and she told me, "don't shoot the messenger," and that was –
- Q. So this was a sales rep?
- A. This was one of the sales reps, yes.

Similarly, Dr. Francis X. Perna, treating physician for plaintiff Frank Schreffler, testified that a GSK sales representative gave him studies related to Avandia before his scheduled deposition seemingly in anticipation of the deposition. The studies in question are favorable to GSK's position that Avandia does not cause an increased risk for myocardial infarction and Dr. Perna, a thought leader for GSK, based his testimony on causation on the studies in question.

See the deposition of Dr. Francis X. Perna taken November 5, 2009 at lines 162:24 to 163:19 and attached hereto as Exhibit B:

- Q. (By Ms. Finken) Has any GSK sales representatives spoken to you about your deposition today?
- A. No. They supplied me with a copy of RECORD and BARI-2D which I really haven't looked at. I have not prepared these -- looking at these studies for this deposition.
- Q. When did they provide you with those studies?
- A. And I suspect they had these copies made for a lot of us. Probably several weeks ago.

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- Q. Did they -- what did they say to you when they provided you with the studies?
- A. They said here are the studies, here's the studies on RECORD and BARI-2D trial. I didn't need them. I mean, I had -- by then I had already seen the subanalysis or the preliminary analysis at the ADA meeting in June.
- Q. Did they provide you with those studies in anticipation of your deposition in this case?
- A. I think they probably did. They didn't say so, but I think they probably did.

Earlier during the deposition testimony, Dr. Perna testified as follows:

- Q. (By Ms. Finken) I believe you stated that recently you have put some patients back on Avandia, is that correct?
- A. Yes.
- Q. And I believe you said one of the studies was ADOPT, is that right?
- A. ADOPT was one of the first, yes.
- Q. And, RECORD was one of the other ones?
- A. RECORD.
- Q. And then there was a third study that I didn't catch the name on.
- A. Called the BARI-2D trial. B-A-R-I.

See Exhibit B, page 314:16-315:6.

In addition, during the deposition of Muhamed Saleh Fauor, M.D., treating physician for Plaintiff Joe Self, Dr. Fauor admitted that he spoke to Attorney for GSK, Anthony Vale, and another representative of GSK named "Pete" prior to his deposition and during this conversation he disclosed to them that his uncle still takes Avandia.

See the deposition of Dr. Muhamed Saleh Fauor taken on November 25, 2009, at lines 40:21 to 42:20 and attached hereto as Exhibit C:

- Q. Okay. Doctor, prior to your deposition today, did you speak with anyone at GlaxoSmithKline about this deposition?
- A. Only with Mr. Vale and Pete.

By Mr. Vale: Pete, just to set up the deposition.

- Q. (By Mr. Dickens) What was the substance of that conversation?
- A. Well, you know, setting up the time and date and I asked them I need the medical record before the date. That's all.
- Q. Did you ever tell anyone at GlaxoSmithKline that you had a family member on Avandia?
- A. Did I tell him? Yes I did.
- Q. You told who?
- A. I told Mr. Vale.
- Q. When did you tell Mr. Vale that?
- A. When I talked I spoke with him only one time.

During GSK's direct examination of Dr. Fauor, Mr. Vale, already knowing the answer from his *ex parte* communication with the doctor, asked Dr. Fauor whether he had any family members who take Avandia. See Exhibit C, 10:9-25.

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Plaintiffs had no knowledge of GSK's *ex parte* contacts until after they occurred. Furthermore, Plaintiffs do not know the extent or manner of defendant's *ex parte* contacts with other treating physicians related to the Avandia litigation.

The practice of communicating *ex parte* with plaintiffs' treating physicians infringes on Pennsylvania law, and the law of many other jurisdictions, which prohibits contact with a plaintiff's treating physician without the plaintiff's consent. For all of the following reasons, plaintiffs request the Court's intervention to prohibit defendants from contacting plaintiffs' treating physicians *ex parte*.

## PENNSYLVANIA POLICY, LAW, AND RULES OF CIVIL PROCEDURE PROHIBIT CONTACT WITH PLAINTIFF'S TREATING PHYSICIAN WITHOUT CONSENT

Pennsylvania law prohibits contact with a plaintiff's treating physician without the plaintiff's consent or by method of discovery authorized in the Pennsylvania Rules of Civil Procedure. *See* Pa. R.C.P. 4003.6. Before the Pennsylvania Supreme Court formally adopted this rule, courts relied on the public policy that a physician's professional and fiduciary duty to her patients bars her from participating in *ex parte* interviews with defense counsel. *See Hoffmeyer v. Pell*, 23 Pa. D. & C.3d 448, 453 (Pa. C.P. 1982); *Manion v. N.P.W. Medical Center*, 676 F. Supp. 585 (M.D. Pa. 1987). Further, the courts found that the potential for doctors to be exposed to tort liability for breach of a patient's right to privacy or to professional discipline provides a significant reason for refusing to allow private *ex parte* interviews between defendants and plaintiffs' treating physicians. *See Alexander v. Knight*, 25 D.&C.2d 649, 655 (Phila. Cty. 1961), *aff'd per curiam on opinion below*, 177 A.2d 142 (Pa. Super. 1962) (reasoning that members of the medical profession owe "a duty to aid the patient in litigation" and "a duty to refuse affirmative assistance to the patient's antagonist in litigation," subject to the physician's obligation "to speak the truth... only at the proper time.").

The Pennsylvania Supreme Court expressly codified Pennsylvania's policy of protecting the confidential nature of the of the physician-patient relationship by enacting Pennsylvania Rule of Civil Procedure 4003.6, Discovery of Treating Physician, in 1991.<sup>1</sup> In the pertinent part the rule provides:

## Information may be obtained from the treating physician of a party only upon written consent of that party or through a

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<sup>&</sup>lt;sup>1</sup> Rule 4003.6 was anticipated by Chief Judge William J. Nealon in *Manion v. N.P. Medical Center of N.E. Pennsylvania Inc.*, 676 F. Supp. 585 (M.D. Pa. 1987). In *Manion*, counsel for a Defendant doctor spoke to Plaintiff's treating physician without telling opposing counsel. The court said: "The public policy favoring confidentiality between a physician and his patient compels this court to preclude defense counsel from calling [the treating physicians] as expert witnesses at trial." Chief Judge Nealon continued: "[T]his court believes that the Pennsylvania Supreme Court, if confronted with the issue, would at least require reasonable notice to a plaintiff or his counsel before defense counsel may communicate with plaintiff's treating physician." *Id.* at 595.

method of discovery authorized by this chapter. This rule shall not prevent an attorney from obtaining information from

- (1) the attorney's client,
- (2) an employee of the attorney's client, or
- (3) an ostensible employee of the attorney's client.

See Pa. R.C.P. No. 4003.6 (emphasis added). The Rule effectively recognized a defendant's duty to refrain from ex parte contacts with a plaintiff's treating physician. It was designed to reasonably limit a defendant's communications with a plaintiff's treating physician in the wake of Moses v. McWilliams, the Superior Court decision condoning the use of private discussions between defense counsel and plaintiffs' treating physician as a cost-efficient alternative to formal discovery. See White v. Behlke, 65 Pa. D. & C.4th 479, 486 (Lackawanna Cty. 2004) referring to Moses v. McWilliams, 549 A.2d 950 (1988), appeal denied, 558 A.2d 532 (Pa. 1989). In promulgating Rule 4003.6, the Supreme Court upheld the formal discovery process and strictly limited defendants' communications with treating physicians to filed discovery. See Jakobi v. Ager, 45 Pa. D. & C.4th 189, 193 (Phila. Cty. 2000). The plain language of Rule 4003.6 clearly indicates that unless defense counsel secures the written consent of the patient, [s]he may only obtain information from a treating physician by way of written interrogatories, requests for production of documents or depositions which require advance notice to the patient and afford the patient an opportunity to object prior to the disclosure of irrelevant or privileged matter. See White, 65 Pa. D. & C.4th at 487. The dual purpose behind the Rule is to preclude a treating physician from acting in an adverse capacity to a patient, while protecting the right of the defense and the court to obtain full access to truthful testimony concerning past medical care. Jakobi, 45 Pa. D. & C.4th at 193.

After the adoption of Pa.R.C.P. 4003.6, the Superior Court in *Marek v. Ketyer*, examined the breadth of the *ex parte* proscription. 733 A.2d 1268 (Pa. Super. 1999), *allocatur denied*, 749 A.2d 471 (Pa. 2000).<sup>2</sup> In *Marek*, the court held that Pa.R.C.P. 4003.6:

[D]oes not limit a treating physician from disclosing only that information learned in confidence. Rather, it prohibits a treating physician from providing the opposing party with any information without written consent of the patient .... Courts have recognized the value of a rule prohibiting ex parte communications between treating physicians and patients' opposing counsel. Among the concerns prompting the development of rules, regulations and legislative enactments is the recognized privacy interest underlying the physician patient relationship and the physician's duty of loyalty to the patient.... Also of concern is the potential tort liability physicians may face for breach of privacy, as well as the potential that

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<sup>&</sup>lt;sup>2</sup> The Supreme Court of Pennsylvania has not specifically addressed *ex parte* contacts with treating physicians since the adoption of Pa. R.C.P. 4003.6.

defense counsel may seek to improperly influence the physician or to dissuade the doctor from testifying.

*Id.* at 1269-70 (emphasis added). The *Marek* Court, which granted a new trial where the plaintiff's treating physician communicated with defense counsel *ex parte* and testified as a defense expert on liability without plaintiff's consent in violation of Rule 4003.6, also found that:

Rule 4003.6 is clear in its directive. Only upon consent or through a method of authorized discovery may information be obtained from a party's treating physician. These procedures protect both the patient and the physician by ensuring that adverse counsel will not abuse the opportunity to contact or interrogate the physician privately. When formal discovery is undertaken in the presence of a patient's counsel it can be assured that irrelevant medical testimony will not be elicited and confidences will not be breached, preserving the trust which exists between doctor and patient.

Id. at 1270(emphasis added).

The only other appellate decision discussing Rule 4003.6 did not specifically address whether an *ex parte* communication between the treating physician and opposing counsel was in violation of Rule 4003.6. *See Alwine v. Sugar Creek Rest, Inc.*, 883 A.2d 605 (Pa. Super. 2005). Rather, based on its heightened appellate review for abuse of discretion, the *Alwine* Court did not grant a new trial where the trial court admitted testimony from the treating physician despite alleged *ex parte* communications. *Id.* "[A]Ithough any *ex parte* communication between [the treating physician] and Appellee's counsel may have been a violation of Rule 4003.6, the record does not suggest, nor does Appellant argue, that the testimony prejudiced Appellant or improperly affected the verdict in any way. *Id.* at 611.

Pennsylvania trial courts have also strictly enforced the ban against *ex parte* contact with plaintiffs' treating physicians and have shown little tolerance for violations of Rule 4003.6. *See e.g. White*, 65 Pa. D. & C.4th at 487(precluding the defendants and their counsel and representatives from engaging in *ex parte* communications with the plaintiff's treating physician); *Jakobi*, 45 D.&C.4th at 194-95 (disqualifying defense counsel from representing the defendant because defense counsel conversed with the plaintiff's treating physician in violation of Rule 4003.6 after the doctor had been subpoenaed for a deposition); *Tollari v. General Motors Corp.*, 40 D.&C.4th 339, 346-48 (Allegheny Cty. 1998) (ordering defense counsel to return a letter sent by plaintiff's treating

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<sup>&</sup>lt;sup>3</sup> The procedural posture of the case required the court to review of a trial court's evidentiary determinations and "reverse only upon a finding that the trial court abused its discretion or committed an error of law." 883 A.2d at 610 *citing Miller v. Ginsberg*, 874 A.2d 93, 97 (Pa. Super. 2005). Further, in order to constitute reversible error the "evidentiary ruling must not only be erroneous, but also harmful or prejudicial to the complaining party. Evidentiary rulings which do not affect the verdict will not provide a basis for disturbing the jury's judgment." *Id*.

physician and prohibiting defense counsel from referencing the substance of the letter during trial where plaintiff provided defense counsel with a signed authorization for release of medical records but did not consent to *ex parte* discussions or solicitation of further reports from his treating physician); but see Bernick v. Inglis House, 2008 Phila. Ct. Com. Pl. LEXIS 155 (Pa. C.P. 2008)(permitting *ex parte* communications with plaintiff's treating physician where it was undisputed that the treating doctor was an agent of the defendant in the case).

#### PENNSYLVANIA STATE AND FEDERAL COURTS ARTICULATE PUBLIC POLICY CONCERNS RESULTING FROM EX PARTE COMMUNICATIONS

Ex parte communications between a defendant and plaintiff create a probability of collusion and unintentional waivers of privilege. The Middle District of Pennsylvania has expressed fear that ex parte communications could encourage improper discussions or collusion between doctors, namely plaintiffs' treating physicians, and the attorneys defending the doctors' colleagues. Manion, 676 F. Supp. at 593. "Ex parte interviews could develop into a discussion of the impact of a jury's award upon a physician's professional reputation, or the rising cost of malpractice insurance premiums." Without knowing the nature of the confidential information beforehand, a defendant may unknowingly elicit a response containing information outside the scope of the plaintiff's waiver of privilege. Thus, no ex parte contact can be permitted.

Similarly, as discussed *supra*, *ex parte* communications could expose physicians to civil liability. *See Alexander*, 177 A.2d 142. The potential for doctors to be exposed to tort liability for breach of a patient's right to privacy or to professional discipline for unprofessional conduct provides this Court with a significant reason for refusing to allow private *ex parte* communication between the defendants and plaintiffs' treating physicians.

### COURTS AROUND THE COUNTRY HAVE DENIED DEFENDANTS' REQUESTS FOR EX PARTE COMMUNICATIONS WITH PLAINTIFFS' TREATING PHYSICIANS

Many courts around the country have held that a defense attorney who contracts a plaintiff's treating physician without the plaintiff's express consent violates state law, professional ethics, or the physician-patient privilege of confidentiality. *See e.g. Harlan v. Lewis*, 982 F.2d 1255 (8th Cir.) *cert. denied*, 114 S. Ct. 94 (1993). In the *Vioxx* New Jersey state litigation, the court would not permit *ex parte* communications between the defendant and the plaintiffs' treating physicians. *See In re Vioxx*, New Jersey Superior Court Case No. 619, Memorandum of Decision on Motion dated November 17, 2004. The court recognized that "given the large number of cases involved in this mass tort and even the larger number of doctors involved, the court would be unduly burdened by hearings to determine the permissible scope of each interview." Likewise, other courts have denied defendants the right to engage in *ex parte* contact with plaintiffs' treating physicians. *See e.g. Horner v. Rowan Companies, Inc.*, 153 F.R.D. 597, 602 (S.D. Tex. 1994); *Alston v. Greater S.E. Cmty. Hosp.*, 107 F.R.D. 35 (D.D.C. 1985); *Duquette v. Superior Court*, 778 P.2d 634 (Arz. Ct. App. 1989); *Torres v. Superior Court*, 221 Cal. App. 3d 181 (Cal. Ct. App. 1990); *Neal v. Boulder*, 142 F.R.D. 325 (D. Colo. 1992); *Gobuty v. Kavanagh*, 795 F. Supp. 281 (D. Minn. 1992); *Pourchot v. Commonwealth* 

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Edison Co., 587 N.E.2d 589, 591 (III. App. Ct. 1992); Loudon v. Mhyre, 756 P.2d 138 (Wash. 1988); Johns v. United States, 1997 U.S. Dist. LEXIS 17979 (ED. La. Nov. 6, 1997). A prohibition on ex parte interviews, these courts assert, does not prevent defense counsel from obtaining relevant material; it simply insures that only privileged information will be acquired. E.g., Harlan, 141 F.RD. at 111.

Similarly, MDL courts have determined that *ex parte* communications between defendants and plaintiffs' physicians are not appropriate. *See e.g. In re Human Tissue Prods. Liab. Litig.*, No. 2:06-135 (D.NJ.), MDL No. 1763, Order of September 11, 2006; *In re Prempro Prods. Liab. Litig.*, MDL No. 4:03-CV-1507, Superseding Order re *Ex Parte* Physician Interview, September 16, 2005(prohibiting *ex parte* interviews of Arkansas residents under Arkansas privilege law); and *In re Vioxx Prods. Liab. Litig.*, 230 F.RD. 473 (E.D. La. 2005) (Judge Fallon issued an order preventing defendants from having *ex parte* communications with treating physicians relating to plaintiffs' claims on a uniform basis).

These courts have recognized that permitting *ex parte* contacts in complex cases raises a host of management and discovery problems for the parties and the court. This management problem is even more acute in the context of mass tort proceedings where the court must manage hundreds (if not thousands) of cases.

In closing, it is important to remember that this Court has wide discretion in deciding case management and discovery issues in considering plaintiffs' instant request. Based on the foregoing, and in keeping with the public policy of our Commonwealth, the intent of the Pennsylvania Supreme Court, the directive of other states and MDL courts around the country, and in order to protect the rights of the plaintiffs in upholding the physician-patient privilege, this Court should enter an Order prohibiting defendants and defense counsel from communicating *ex parte* with plaintiffs' treating physicians. In addition, plaintiffs respectfully request that this Honorable Court enter an Order prohibiting any contact between sales representatives from GSK and plaintiffs' treating physicians during the pendency of this litigation.

Respectfully submitted,

Law & Weiss

Søi H. Weiss Tracy A. Finken

cc: Christopher W. Wasson, Esquire Joseph C. Crawford, Esquire Joseph Roda, Esquire Jerome Shestack, Esquire

<sup>4</sup> In supervising discovery, the trial court has broad discretion to take such action as it deems appropriate to insure prompt and adequate discovery. *Kerns v. Methodist Hosp.*, 393 Pa. Super. 533, 544 (Pa. Super. Ct. 1990)(Citations omitted).

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# **EXHIBIT A**

Case ID: 080202733

#### In Re:

Avandia/Thomas v. GSK

Andrew G. Polakovsky, M.D. October 20, 2009

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17	14654		17	
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22			22	
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24	Notary	y Public ence No. JB15262	24	
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1	VIDEOTAPE DEPOSITION OF ANDREW (	. POLAKOVSKY, M.D.,		
	a witness, called by the Plaintiffs for examination, in accordance with the Pennsylvania Rules of Civil Procedure, taken by and before JoAnn M. Brown, RMR, CRR, a Court Reporter and Notary Public in and for the Commonwealth of Pennsylvania, at the offices of Davies, McFarland & Carroll, P.C., One Gateway Center, 10th Floor, Pittsburgh, Pennsylvania, on		1	
			2	P-R-O-C-E-E-D-I-N-G-S
			3	
4			4	THE VIDEOGRAPHER: We are now on the
5	Tuesday, October 20, 2009, commo	encing at 1:02 p.m.	5	record.
6	ADDEAD ANGEG		6	My name is Brad Coble, and I'm the
7	APPEARANCES:			videographer for Golkow Technologies.
8	FOR THE PLAINTIFFS:  THE LANIER LAW FIRM, P.C. Catherine T. Heacox, Esquire			Today's date is October 20, 2009,
9			8	
	cth@lanierlawfirm.com Paul R. Cordella, Esquire			and the time is 1:02 p.m. This video
10	prc@lanierlawfirm.com 126 East 56th Street, 6th Floo	or	10	deposition is being held in Pittsburgh,
11	New York, New York 10022 P 212-421-2800			Pennsylvania in the matter of Avandia, Thomas
12	F 212-421-2878		12	versus SmithKline for the Court of Common
13	BOD THE DESERVE AND		13	Pleas, Philadelphia, Pennsylvania. The
14	FOR THE DEFENDANT: PEPPER HAMILTON, LLP			deponent is Dr. Andrew Polakovsky.
15	Christopher W. Wasson, Esquire wassonc@pepperlaw.com	Э	15	Counsel, please identify yourselves.
16	3000 Two Logan Square		16	MS. HEACOX: My name is Catherine
17	Phīladelphia, Pennsylvania 19103 P 215-981-4000 F 215-981-4750			Heacox. I'm with the Lanier Law Firm, and I'm
				representing the plaintiff, Samuel Thomas, in
18			19	this action against the manufacturers of
19			20	Avandia for Mr. Thomas' claims that the
	DAVIES, MCFARLAND & CARROLL, I Daniel P. Carroll, Esquire			
19	DAVIES, MCFARLAND & CARROLL, 1 Daniel P. Carroll, Esquire dcarroll@dmcpc.com One Gateway Center, 10th Floo:			ingestion of Avandia caused his heart attack.
19 20	DAVIES, MCFARLAND & CARROLL, Daniel P. Carroll, Esquire dcarroll@dmcpc.com			ingestion of Avandia caused his heart attack.
19 20 21 22	DAVIES, MCFARLAND & CARROLL, I Daniel P. Carroll, Esquire dcarroll@dmcpc.com One Gateway Center, 10th Floo: Pittsburgh, PA 15222		21	ingestion of Avandia caused his heart attack. MR. CORDELLA: Also appearing on
19 20 21 22 23	DAVIES, MCFARLAND & CARROLL, In Daniel P. Carroll, Esquire dcarroll@dmcpc.com One Gateway Center, 10th Floor Pittsburgh, PA 15222 P 412-338-4740 F 412-261-7251		21 22 23	ingestion of Avandia caused his heart attack. MR. CORDELLA: Also appearing on behalf of the plaintiff is Paul Cordella,
19 20 21 22 23 24	DAVIES, MCFARLAND & CARROLL, In Daniel P. Carroll, Esquire dcarroll@dmcpc.com One Gateway Center, 10th Floor Pittsburgh, PA 15222 P 412-338-4740		21 22 23 24	ingestion of Avandia caused his heart attack. MR. CORDELLA: Also appearing on behalf of the plaintiff is Paul Cordella, C-O-R-D-E-L-L-A, Lanier Law Firm.
19 20 21 22 23	DAVIES, MCFARLAND & CARROLL, I Daniel P. Carroll, Esquire dcarroll@dmcpc.com One Gateway Center, 10th Floor Pittsburgh, PA 15222 P 412-338-4740 F 412-261-7251		21 22 23	ingestion of Avandia caused his heart attack. MR. CORDELLA: Also appearing on behalf of the plaintiff is Paul Cordella,

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- 1 Pepper Hamilton on behalf of GlaxoSmithKline.
- MR. CARROLL: And Dan Carroll on
- 3 behalf of Dr. Polakovsky.
- 4 THE VIDEOGRAPHER: The court
- 5 reporter is JoAnn Brown and will now swear in
- 6 the witness.
- 7 ----
- 8 ANDREW G. POLAKOVSKY, M.D.
- 9 having been duly sworn,
- 10 was examined and testified as follows:
- 11
- 12 ----
- THE VIDEOGRAPHER: Proceed.
- 14 ----
- 15 EXAMINATION
- 16 ---
- 17 BY MS. HEACOX:
- 18 Q. Hi, Dr. Polakovsky.
- 19 A. Hi.
- 20 Q. Thanks for joining us here today.
- You're here today on the basis of
- 22 this Subpoena; is that correct?
- 23 A. That's correct.
- MS. HEACOX: I'd like to mark this
- 25 as Polakovsky 1.

- 1 Q. And you brought one additional piece of paper,
- 2 is that correct, Dr. Polakovsky?
- 3 A. That's correct. This is the backside of the
- 4 one page in the chart that listed Mr. Thomas'
- 5 initial medications when he first came to the
- 6 office.
- 7 Q. Okay.
- 8 MS. HEACOX: And so I guess we'll
- 9 just mark this as Polakovsky 4.
- 10 ----
- 11 (Exhibit No. 4 was marked for identification.)
- 12 ----
- BY MS. HEACOX:
- 14 Q. And this being a piece of paper that says, in
- handwriting, Zetia, 10 milligrams and
- 16 Simvastatin, 20 milligrams?
- 17 A. Yes.
- 18 Q. That's your handwriting or --
- 19 A. That's Mr. Thomas' handwriting.
- 20 Q. Oh, okay.
- Understanding that you brought your
- 22 CV, thank you very much, could you tell me a
- 23 little bit about yourself?
- Let's start with where is your
- 25 office located?

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- . .
- 1 (Exhibit No. 1 was marked for identification.)
- 2 ----
- 3 BY MS. HEACOX:
- 4 Q. Did you bring any materials with you today?
- 5 A. Yes, I did.
- 6 Q. In response to the deposition Subpoena?
- 7 A. Correct.
- 8 Q. What did you bring?
- 9 A. I brought a copy of -- well, I actually
- brought the actual chart, Mr. Thomas' chart
- 11 from my office, and I brought a curriculum
- 12 vitae.
- 13 Q. Okay. Thank you. I think you handed that out
- 14 earlier.
- MS. HEACOX: You can mark that, the
- 16 CV, as Polakovsky 2.
- 17 ----
- 18 (Exhibit No. 2 was marked for identification.)
- 19 ----
- MS. HEACOX: And then if we can mark
- your chart as Polakovsky 3.
- 22 ---
- (Exhibit No. 3 was marked for identification.)
- 24 ----
- BY MS. HEACOX:

- 1 A. It's in Scottdale, Pennsylvania, 310 Mulberry
- 2 Street.

7

- 3 Q. And where do you live, Dr. Polakovsky?
- 4 A. I also live in Scottdale, Pennsylvania. 202
- 5 North Chestnut Street is my home address.
- 6 Q. Thank you.
  - Maybe you could tell me a little bit
- 8 about your background, your educational
- 9 background?
- 10 A. Okay. I graduated from the University of
- 11 Pittsburgh in 1975. I was a chemistry major
- at that point, with the intentions of going on
- to medical school. I applied to medical
- school and dental school, as a backup, in
- 15 1975. I was accepted into Temple dental
- program and was also on an alternates list for
- 17 medical school but decided to pursue the
- 18 dental career.
- 19 Q. Mm-hmm.
- 20 A. I went to Temple Dental School in 1976.
- 21 Graduated in 1980 from Temple Dental School
- and set up a private practice in Scottdale. I
- practiced as a dentist until about 1988. At
- that point, I decided that I wasn't happy
- being a dentist, I wanted to be a physician,

Page 8

Page 9

- and went to medical school in Ohio. So I
- 2 applied to several medical schools. I was
- 3 accepted at Northeastern Ohio University's
- 4 College of Medicine and entered that school in
- 5 1988. Graduated from that school in 1992.
- 6 Did a residency -- actually, when I graduated
- 7 from medical school, I thought I was going to
- 8 do anesthesia, so I applied to anesthesia
- 9 residency programs. I did an internship year
- at Ruby Hospital in Morgantown, West Virginia,
- and then entered Mercy Hospital anesthesiology
- residency program in 1993, because you have to
- do a preliminary year before you enter the
- 14 anesthesia program.
- 15 Q. Mm-hmm.
- 16 A. I was an anesthesia resident until, I want to
- say, about -- thank you.
- 18 Q. Yeah, it's not a memory test.
- 19 A. I know. It's just these dates in the remote
- 20 past.
- 21 Q. Yes.
- 22 A. Thank you.
- Yeah, 1995 at Mercy Hospital. At
- that point, I decided that anesthesia wasn't
- 25 the proper field for me. I didn't follow the

- 1 Is that like internal medicine or is
- 2 that a little different from --
- з A. It's a little different.
- 4 Family practice is a separate
- 5 specialty of medicine, as is internal
- 6 medicine, that's another separate boarded area
- 7 in medicine, so my certification is in family
- 8 practice.
- 9 Q. Is there a different focus?
- 10 A. I believe so.
- 11 Q. Could you describe what's different about
- 12 family practice?
- 13 A. Okay. In family practice, you're treating the
- entire family from children to adults. You
- deal more with less complex problems, I would
- say, more with the growth and development of
- young children through their adolescence into
- early childhood into adulthood. You do treat
- middle-age and geriatric patients as well, but
- 20 in family practice, we don't do much in terms
- of chemotherapy or certain conditions, such as
- 22 end-stage renal disease where people need to
- be on dialysis, some of the more complex
- 24 problems. Those are the ones that internal
- 25 medicine physicians are more equipped to

Page 10

- patients, and I felt more of an interest in
- the patients than just being an
- 3 anesthesiologist, because, at that point, I
- 4 felt that patient contact is better in the
- 5 primary care field.
- 6 O. Mm-hmm.
- 7 A. So I applied to the family practice residency
- 8 program at Wheeling, West Virginia and did my
- 9 family practice residency there in Wheeling
- 10 Hospital.
- 11 O. Mm-hmm.
- 12 A. I graduated from Wheeling family practice
- residency program in 1997.
- 14 Q. Mm-hmm.
- 15 A. I was chief resident in my senior year, and
- opened up the private practice in Scottdale,
- Pennsylvania in 1998.
- 18 Q. And have you been practicing there ever
- 19 since?
- 20 A. Yes, I have.
- 21 Q. Are you board certified?
- 22 A. Yes, I am.
- 23 Q. What are you board certified in?
- 24 A. In family practice.
- 25 Q. Family practice.

1 train -- or more equipped to treat. I'm

- 2 SOTTV
- 3 Q. Do you need to get recertified at any time?
- 4 A. Yes.
- 5 Q. When would that be?
- 6 A. Okay. Recertification in family practice runs
- on a cycle. It's typically a seven-year
- 8 cycle. They've recently extended it to a
- 9 10-year cycle if you keep with certain
- 10 requirements for continuing education. My
- next recertification will be due in 2013.
- 12 Q. Okay. And are you licensed to practice in the
- 13 State of Pennsylvania?
- 14 A. Yes, I am.
- 15 Q. Are you licensed to practice in any other
- 16 state?
- 17 A. No.
- 18 Q. Do you have an independent recollection of
- 19 Mr. Samuel Thomas?
- 20 A. Somewhat, yes.
- 21 Q. Can you describe your recollection of your
- 22 treatment of him?
- 23 A. My treatment of him? I would say I first was
- called -- I was covering for Mr. Thomas' usual
- physician. Mr. Thomas came to Frick

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Page 13

- Hospital. He was in congestive heart failure,
- and I was called to see him because he was in 2
- the emergency room. 3
- 4 Q. Were you attending or --
- A. Yes, I was an attending physician at Frick
- Hospital at that point.
- So I saw Mr. Thomas at Frick 7
- Hospital. We also consulted the cardiologist, 8
- as I recall, who was also familiar with
- Mr. Thomas, and Mr. Thomas was in the hospital 10
- for a few days. I would say three or four 11
- days. At that point, he recovered. He was 12
- discharged to home, and Mr. Thomas, who was a 13
- patient of Dr. Timothy Saloom, decided that he
- would rather have me care for him instead of 15
- Dr. Saloom. 16
- O. Mm-hmm. 17
- A. He called and asked if he could be my
- patient. I did mention that to Dr. Tim Saloom 19
- back then, and Dr. Saloom was not 20
- objectionable to that, so Mr. Thomas came to 21
- me as a patient I assume it was in the month 22
- of September of 2006.
- 24 Q. Mm-hmm. Okay.
- 25 A. Okay?

- reasonably good control, some people can get
- by with once-daily injecting.
- Q. Mm-hmm. 3
- A. Some people need to go to a twice-daily
- schedule, and then supplement with a different
- type of insulin for the meal coverage as well. 6
- 7 O. I see.
- And so when do you typically inject 8
- yourself? Is it before meals or after meals
- or is there any --
- A. Typically, it's before meals. 11
- Q. Mm-hmm. Okay. So, like, before breakfast and
- before dinner, something like that?
- A. Before -- correct. Before breakfast and
- before dinner would be a good schedule, and, 15
- typically, you need to check your sugars on a 16
- regular basis so that you can determine the 17
- amount of insulin that you need to inject for
- each meal. 19
- Q. Okay. Did you prescribe any other diabetes 20
- medication? 21
- Q. Okay. Did you prescribe any other medications
- for Mr. Thomas --
- 25 A. Yes.

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- 1 Q. And you treated him for some period of time?
- 2 A. Yes, I treated him for approximately two
- years.
- 4 Q. And during that time, did you prescribe to him
- any diabetic -- diabetes medicine?
- A. Yes.
- Q. What is it you prescribed to him?
- A. We prescribed insulin, 70/30 Insulin.
- 9 Q. Is that -- can you describe is that a pill or
- is that -- how is that administered? 10
- A. Okay. That's an injection. It comes in a
- syringe, and it's injected, a certain number 12
- of units per day. The 70/30 has two parts: A 13
- short-acting part and a long-acting part of 14
- the insulin.
- O. Mm-hmm.
- A. And, typically, patients are on a twice-daily 17
- schedule with injections of the 70/30 Insulin.
- Q. Okay. And so is that -- is that something 19
- that -- do you always inject it twice a day or
- do you do that, like, as-needed basis or --21
- 22 A. Well, there are different ways to inject the
- 70/30 Insulin.
- 24 Q. Mm-hmm.

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25 A. Typically, it's twice daily, but if you have

- 1 Q. -- while he was under your care?
- 2 A. Yes, I did.
- 3 Q. What would that be?
- A. The other medications that Mr. Thomas was on
- was Furosemide.
- Q. Why? What's that for?
- That is a, quote, water pill. It is a
- diuretic.
- 9 Q. Mm-hmm. What's the purpose of that?
- A. Oh, I'm sorry. 10
- The purpose of that medication is to 11
- treat hypertension, and it can also be used to 12
- treat heart failure.
- 14 Q. Okay.
- 15 A. Okay?
- Q. And Mr. Thomas had heart failure?
- 17 A. Mr. Thomas was admitted to the hospital with
- heart failure when I first met him. That was
- treated, and at that point, you know, he
- had -- no longer had symptoms of the heart 20
- failure. I believe, as long as he was taking 21
- his medications, it seemed things were under 22
- 23 control.
- Q. Perhaps you could describe for me what that
  - means exactly, heart failure.

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- 1 A. Heart failure is a condition where the heart
- is not adequately pumping the blood.
- з Q. Mm-hmm.
- 4 A. At that point, you can develop swelling of
- your lower extremities, you can develop
- shortness of breath, you can feel tired.
- 7 Q. Why would the swelling occur?
- A. Because the blood is not being circulated well
- enough and the kidneys can't extract the
- excess fluid.
- 11 Q. Okay. And could congestive heart failure lead
- to any more serious consequences if left 12
- untreated? 13
- MR. WASSON: Object to form. 14
- A. If left untreated, congestive heart failure, I 15
- believe, can lead to more serious conditions, 16
- probably including death. 17
- Q. What are the treatments for congestive heart
- failure? 19
- 20 A. Treatments for congestive heart failure are
- diuretics such as Furosemide. 21
- O. Mm-hmm. 22
- A. Classes of medications known as ACE inhibitors
- or ARBs, which are drugs which are used to
- treat hypertension. Beta blockers are also

- heart -- in between beats is when the heart
- gets its oxygen and blood supply, so as the
- heart beats slower, the heart has more time to 3
- 4 accumulate the oxygen and the blood supply
- that it needs for the next -- the next cycle.
- Q. Okay. And did you prescribe anything else?
- 7 A. Yes. We prescribed Diovan.
- Q. And what is that? 8
- A. Diovan is an angiotensin receptor blocker, and
- it is also used to treat patients with heart 10
- failure, that class of medications. That 11
- class of drugs blocks the enzyme from the 12
- kidneys which causes the blood pressure to be 13
- increased, so by blocking the enzyme from the
- kidneys, the blood pressure tends to remain 15
- lower. 16
- Q. Okay. So it's, in essence, a blood pressure 17
- medication? 18
- A. Yes, it can be used to treat blood pressure. 19
- Yes. 20
- 21 Q. Okay. Is there anything else that you
- prescribed?
- A. Yes. He was also on Lotrel, which is a
- combination drug.
- 25 Q. Mm-hmm.

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- used to treat heart failure. So those are
- your standards for treating heart failure.
- 3 Q. Do you need to take all of those drugs?
- 4 A. Usually, there's a combination of drugs that
- would include ACEs or ARBs, diuretics and beta
- Q. So you discussed that you had prescribed for 7
- Mr. Thomas, I'm sorry, the water pill which
- was -- was it HCTZ or --
- A. It was Furosemide. 10
- O. Furosemide. 11
- And so I kind of derailed the 12
- conversation, but what else did you prescribe? 13
- A. The other medications were Metoprolol, which
- is a beta blocker.
- O. And what does that do?
- A. That controls the heart rate. 17
- 18 Q. Uh-huh.
- A. It also --
- 20 Q. Does it make your heart beat faster or slower?
- A. It makes the heart beat slower. It actually
- makes the heart beat slower.
- Q. And how does that help congestive heart 23
- failure?
- 25 A. When the heart is beating more slowly, the

- 1 A. Lotrel has an ACE inhibitor, which is
- Benazepril, which works similar to an
- angiotensin receptor blocker, it just works a 3
- little further up in the cascade, and there's 4
- also a calcium channel blocker in Lotrel as 5
- well, which tends to cause dilation of the
- small arterials and, therefore, lower the 7
- blood pressure.
- Q. Okay. Is there anything else?
- A. Yes. He was on Plavix, 75 milligrams a day.
- That's a medication that is used when you've
- had a cardiac event. Its purpose is to 12
- prevent or to help reduce the chance of blood 13
- 14
- Q. Okay. Would you need to take that on a daily
- basis --16
- A. Yes. 17
- Q. -- for the rest of your life after you've had
- a heart attack?
- 20 A. There's some discussion about that point.
- Initially, when Plavix came out, 21
- they were treating people for a shorter period 22
- of time, maybe up to a year. Some of the 23
- later research on this medication and the
- later studies is indicating that it would 25

Page 20

Page 24

Page 21

- benefit to treat the patients for a longer
- period of time.
- 3 Q. Okay. Did you prescribe anything else?
- 4 A. Yes. Mr. Thomas was also on Simvastatin,
- which is a cholesterol medication and lowers
- cholesterol, and a medication called Zetia,
- which is a cholesterol medication as well.
- They work in combination together. 8
- Q. So he was on two cholesterol medications?
- A. Yes. 10
- Q. Did you test his cholesterol levels when you 11
- first started treating him? 12
- A. Yes, we did. I believe he had -- the initial
- cholesterol work-up was done in the hospital,
- and then it was tested on a regular basis as 15
- he was a patient. 16
- Q. Do you know what those levels were in the 17
- hospital?
- A. I can't recall them off the top of my head, 19
- 20
- 21 Q. Do you remember, generally, whether they were
- high or low? 22
- A. I don't recall.
- 24 Q. Okay. So would we assume that they were high
- for you to have prescribed the cholesterol or

- 1 A. Yes.
- 2 Q. Or is congestive heart failure also considered
- an event or is that a different category of
- heart injury?
- MR. WASSON: Object to form. 5
- A. I'm not sure if congestive heart failure would
- 7 be considered the same as a cardiac event. In
- my mind, I would say that they are very close, 8
- 9
- Q. So do you believe that increasing the LDL 10
- cholesterol is a risk factor for heart
- attacks? 12
- A. Yes, I believe that an elevated LDL
- cholesterol level can be a risk factor for
- heart attacks, sure. 15
- Q. How about decreasing HDL level, is that a risk
- factor for heart attack?
- A. Yes.
- Q. How about increasing the triglycerides, is
- that a risk factor for heart attack?
- Yes, it is. 21
- Q. Do you have any idea of what would be a
- clinically significant increase? 23
- MR. WASSON: Object to form. 24
- 25 A. In which one?

Page 22

- 1 O. We'll start with LDL cholesterol.
  - A. LDL cholesterol greater than 130 in an average
  - person, I think, would be a risk, and someone
  - such as Mr. Thomas, LDL greater than 70 would
  - be a risk. 5
  - Q. Okay. And then when you say "such as
  - Mr. Thomas," is that because he has had the
  - prior heart attack or because he has diabetes
  - 9 or both?
  - A. Both 10
  - MR. WASSON: Object to form.
  - Q. So any increase over 70 could increase
  - 13 someone's risk potentially to have a heart
  - attack? 14
  - 15 A. I would think so.
  - MR. WASSON: Object to form. 16
  - Q. Can you tell me what some of the causes of 17
  - congestive heart failure would be? 18
  - A. Congestive heart failure can arise from a
  - cardiac event such as a myocardial 20
  - infarction. It can also arise from such 21
  - things as renal insufficiency which would be 22
  - 23 due to a heart attack or something on that
  - order. It can also arise from damage to the
  - heart valves where the heart is not pumping a 25

did you do that as a prophylactic measure or

- some other reason? 2
- MR. WASSON: Object to form. 3
- 4 Q. If you recall?
- 5 A. Typically, patients that have had a cardiac
- history are treated with cholesterol
- medications more so as a prophylactic basis 7
- than as a treatment for high cholesterol.
- 9 That's pretty much a standard of care, I would
- think. 10
- O. Okay. And is it necessary to be on both of
- those cholesterol medications? 12
- 13 A. The addition of the second medication is to have the cholesterol numbers more ideal. 14
- There are standards where they like to see the 15
- LDL cholesterol less than a hundred in some 16 patients and less than 70 in patients that 17
- have had an event, and in order to get the 18
- numbers to that point, you sometimes need to 19
- add a second medication, such as the Zetia, to 20
- the Simvastatin. 21
- 22 Q. Okay. And by "an event," do you mean a
- cardiac event?
- 24 A. Yes.
- 25 O. Such as a heart attack?

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- sufficient amount of blood.
- 2 O. Can you describe the process by which a heart
- attack could cause renal insufficiency and/or
- congestive heart failure?
- 5 A. When someone has a heart attack, the cardiac
- muscle is weakened and is stunted, and when
- that occurs, the heart does not pump a 7
- sufficient quantity of blood. At that point, 8
- 9 the kidneys may not receive sufficient blood
- flow, and so they may not do their job 10
- properly, and the patient may go into heart 11
- failure because of the fact that the kidneys 12
- are unable to eliminate the waste products. 13
- Q. Okay. So that's pretty much the whole process 15 right there.
- If you don't have renal 16
- insufficiency, could a heart attack still 17
- cause you to have congestive heart failure?
- A. Yes. 19
- 20 Q. How would that happen?
- A. The cardiac output would be reduced to a point 21
- where the heart could not pump enough blood to
- be sufficiently filtered by the kidneys and
- you can go into heart failure.
- 25 Q. Did you -- I don't know, maybe this wasn't

- thing.
- Q. In your treatment of Mr. Thomas, did you 2
- notice any of those symptoms or did you notice
- him complaining or having any problems related
- to his heart condition?
- MR. WASSON: Object to form. 6
- A. I -- in reviewing my chart of Mr. Thomas, the
- only thing that I would notice that he 8
- occasionally complained of was some shortness 9
- of breath. When he was in the office, as far 10
- as walking from the waiting room to the exam 11
- room, seating at the exam table, he appeared 12
- quite comfortable and appeared to be doing 13
- quite well.
- Q. Did you give Mr. Thomas any samples? 15
- A. Yes, I did.
- Q. What kind of -- maybe you can describe to me 17
- what is a sample, first of all? 18
- A. Okay. Samples are small quantities of 19
- medications that -- the drug manufacturers 20
- will send a representative to the office, 21
- they'll discuss a product, and they'll 22
- typically leave us samples of certain 23
- medications. They're, typically, as I said, 24
- small quantities of whatever medications that

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- something that you did, but did you happen to
- take note of Mr. Thomas' ejection fraction
- while you were treating him?
- 4 A. I noticed from the note from Mr. Olivenstein,
- the cardiologist, where they had mentioned
- Mr. Thomas' ejection fraction, yes.
- Q. And was it abnormal? 7
- A. It was low. I can look at the note exactly.
- 9 Q. Mm-hmm.
- A. They mention a 20 to 25 percent ejection

10

- Q. Can you explain what the ejection fraction is? 12
- A. Yes. The ejection fraction is the amount of
- blood that the heart pumps during each stroke, 14
- and normal ejection fraction is probably in 15
- the neighborhood of 50 percent, something like 16
- 17
- Q. Mm-hmm. So if his ejection fraction was 20 to 18
- 25 percent, it was -- can you describe what 19
- that means? 20
- 21 A. That means that the heart is pumping much less
- than a typical healthy heart would be pumping, 22
- 23 and you would probably have symptoms such as
- shortness of breath or fatigue or swelling of 24
- your lower extremities, and that type of

- the drug company happens to be promoting.
- Q. Okay. And what samples did you prescribe for
- or did you give to Mr. Thomas?
- 4 A. Well, let me look through my notes.
- Q. Yeah, if you recall?
- A. Yeah, it's been a little while, so -- I gave
- him samples of Zetia, samples of Lotrel,
- samples of Diovan, and that was on his first
- 9 visit to the office which was September 5,
- 2006. 10
- O. Mm-hmm.
- 12 A. October 2006, I gave him samples of Levitra.
- 13 November of 2006, I don't notice any samples
- 14
- Q. Do you always write down the samples that you
- give or do sometimes you or your nurses give
- samples that don't make their way into the 17
- chart? 18
- 19 A. No, we always write down what samples we give.
- 20 Q. Okay.
- 21 A. Diovan samples were given in January of '07,
- Lotrel samples also on that day, and Zetia
- 23 samples on that day, as well as Levitra
- samples on that day.
- 25 Q. Now, when you give samples, do you typically

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- give, you know, one week, two week, a month?
- 2 A. No, we write the numbers down of the amount of
- samples, and typically it's a month or two if
- I have that quantity on hand. So if you're
- interested in the exact samples, they're
- listed in the chart, but I can go over those,
- too, if you would like.
- Q. Sure, I guess, if they're listed in the
- chart.
- Does it say -- does it indicate next 10
- to it -- does it say sample or how do you --11
- A. Yes, it does. 12
- On Mr. Thomas' first visit, 13
- September 5, 2006, Zetia, 10 milligram, 14
- samples number 56, one daily. The next line, 15
- Lotrel 5/20, samples number 56.
- Q. Does number 56 mean you gave 56 pills? 17
- Q. Would that last 56 days?
- 20 A. Yes, and it says one daily.
- 21 Q. Okay.
- A. And next is Diovan, 320 milligram, samples 22
- number 56, one daily.
- If I go to October 12, '06, Levitra, 24
- 20 milligram, samples number 6, one as

- December of '07, Plavix, 75
- milligram, number 56 samples. 2
- March 6, 2008 I gave him a sample of 3
- a 7/30 pen device, which is insulin.
- Q. Now, is that the actual insulin or is it just
- the --6
- A. No, it's the actual -- that pen device would
- have contained 300 units of insulin.
- Q. Uh-huh. And then, the pen, would that be good
- for one day or for multiple days?
- A. Multiple days.
- Q. How many?
- A. He was taking 24 units in the morning and a
- sliding scale in the evening.
- Q. What does that mean "a sliding scale"? 15
- A. Well, a sliding scale means that you check
- your sugar, and depending on what the value of
- your sugar is, you give yourself a certain
- amount of insulin. 19
- 20 Q. Mm-hmm. Okay.
- 21 A. So it can vary.
- I would assume, you know, his dose
- may be 30 units a day.
- 24 Q. Mm-hmm.
- 25 A. So if there were 300 units in a syringe,

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- directed. A prescription was also written.
- 2 Q. And Levitra is a drug for --
- 3 A. That's for erectile dysfunction.
- 4 Q. Okay.
- 5 A. November 20 of '06, again, no samples there.
- January of '07, Diovan, 320
- milligram, samples number 56, one daily. 7
- Lotrel 5/20, samples number 48, one daily. 8
- 9 Zetia, 10 milligram, samples number 28, one
- daily, and Levitra, 20 milligram, number 6, 10
- one as directed. 11
- Let's see. April of '07, Zetia, 10 12
- milligrams, number 56 samples. Diovan, 320, 13
- number 56 samples, plus Lotrel 5/20, number 56 14
- samples, and Plavix, 75 milligram, number 30. 15
- Apparently, that was a prescription. I'm 16
- sorry, Plavix was not a sample, that was a 17
- prescription. 18
- 19 O. Okav.
- 20 A. October 9, '07, Plavix, 75 milligram, number
- 44 samples, one daily. Zetia, 10 milligram, 21
- number 56 samples, one daily. Lotrel 10/20, 22
- number 16, daily -- one daily, sorry, and
- Diovan, 160 milligrams, number 56 samples, and
- that's one daily.

- that's about a 10-day supply.
- Q. Okay.
- A. I also gave him samples of Plavix that day,
- number 36.
- 5 Q. And that day, again, is?
- A. That was March 6, 2008.
- 7 Q. Thank you.
- A. And then I gave him samples also of a drug
- called Vytorin, which is Zetia with
- Simvastatin. 10
- Q. Uh-huh.
- 12 A. And samples number 56 were given to him that
- 13 day.
- 14 Q. That's for cholesterol?
- A. Yes. 15
- Q. 56 pills?
- A. Yes. That was the samples on that day. 17
- I believe that's all the samples 18
- that I supplied to Mr. Thomas. 19
- Q. Thank you, Dr. Polakovsky. 20
- Do you know why you were giving 21
- samples to Mr. Thomas? 22
- 23 A. Yes. Mr. Thomas told me that he was unable to
- afford his medications and asked if I could
- help him with samples. 25

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Page 33

- 1 Q. Are there a lot of patients that -- in your
- office that ask for samples?
- 3 A. There are, I would say, probably, maybe, a
- third to -- yeah, probably about 30 percent.
- 5 Q. Has that number increased at all with the
- recent economic downturn?
- A. Well, actually --7
- MR. WASSON: Object to form. 8
- A. -- it probably has, yes.
- Q. Do you practice in a rural area?
- A. Yes, I do. 11
- 12 Q. Did there come a time -- let's see.
- Let's back up and say -- you said, 13
- as a family practitioner, you don't usually 14
- deal with the hard cases or the more difficult 15
- cases; is that correct? 16
- MR. WASSON: Object to form. 17
- A. Could you rephrase that question? 18
- Q. Yeah. Sorry about that. 19
- Do you have any specialization in 20
- treating diabetes? 21
- A. My treatment of diabetes is what I was taught 22
- in family practice residency, so we are taught
- to treat diabetes. The more-difficult-to-24
- treat diabetic patients, I usually refer to an

- THE VIDEOGRAPHER: We are now back
- on the record. The time is 1:58 p.m. 2
- Please proceed. 3
- 4 BY MS. HEACOX:
- Q. Dr. Polakovsky, did you test Mr. Thomas'
- cholesterol levels while he was under your
- care from time to time? 7
- A. Yes, I did. 8
- Q. And do you know whether those -- whether he
- was -- had high cholesterol or low cholesterol
- or normal or what were the results? 11
- A. His cholesterol numbers were low. His
- triglyceride numbers were high. I have the
- exact numbers here if you're interested.
- Q. Sure. 15
- A. June 27, 2007, total cholesterol was 112;
- triglycerides, 287; LDL, 25; HDL, 30.
- Was that 125 for the LDL or 25?
- A. 25. 19

23

- 20 Q. Wow!
- So that's very low. 21 A.
- Q. That's very low. 22
  - MR. WASSON: I'm sorry, Doctor, what
- date was that were you reading from? 24
- THE WITNESS: Sorry. June 27, 2007. 25

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MR. WASSON: Thank you.

- A. The next I have here is October 7, 2006. I'm
- sorry they're out of order.
- 4 Q. Mm-hmm.
- A. Total cholesterol, 133; triglycerides, 183;
- LDL, 68; HDL, 28.
- Q. LDL is also very low, right? 7
- A. Yes, it is. Yeah, 68, so that's good.
- 9 March 25, 2008, cholesterol, 95;
- triglycerides, 209; LDL, 28; and HDL, 25. And 10
- I believe that's all I have.
- Q. And during the time that you treated
- Mr. Thomas, he was not using Avandia to
- regulate his diabetes, correct?
- A. Correct.
- Q. Do you ever prescribe Avandia in your
- practice? 17
- A. Occasionally, I have prescribed Avandia, yes.
- Q. Do you continue to prescribe Avandia?
- A. I can't recall if my patients are still on
- Avandia at this point. I don't -- I don't
- recall if I continue to prescribe it. I don't 22
- 23 believe so. I don't believe I have any new
- starts on Avandia, but the people that are on
- Avandia, I believe, are continuing on Avandia. 25

endocrinologist.

- 2 Q. Did there come a time when you felt that
- Mr. Thomas could use the services of someone
- who is more specialized in diabetes?
- 5 A. Yes.
- 6 Q. And did you refer him to someone else?
- A. Yes, I did. 7
- I recall sending Mr. Thomas a 8
- certified letter in March of 2008 asking him
- to see an endocrinologist. 10
- Q. And have you -- have you seen Mr. Thomas since
- then? 12
- A. Yes. Mr. Thomas was back to see me in August of 2008. 14
- 15 Q. Was that the last time you treated him?
- A. Yes, it was.
- Q. And you parted ways on amicable terms? 17
- A. I believe so. 18
- MS. HEACOX: Can we go off the 19
- record for a minute? 20
- THE VIDEOGRAPHER: We're going off 21
- 22 the record. The time is 1:41 p.m.
- 23
- (There was a recess in the proceedings.) 24
- 25

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- 1 Q. Do you prescribe Actos?
- 2 A. Yes, I do occasionally. Yes.
- 3 Q. Are you familiar with the term detail men or
- being detailed?
- 5 A. Yes.
- Q. Can you describe what that means?
- 7 A. From my understanding, what you're asking me
- is these are men that are employed by the drug
- companies, and they'll come to the office and
- they have literature on their products. They 10
- usually stop in, and they'll leave samples of 11
- the drug if they have, and they'll go over the 12
- pertinent literature that they want to 13
- describe, you know, the drug products.
- Q. Do you ever get visited by drug 15
- representatives from GlaxoSmithKline?
- A. Yes. 17
- O. How often?
- A. Maybe once every six weeks or so.
- Q. Do you recall ever being detailed or, you 20
- know, sold on the drug Avandia by 21
- representatives from GlaxoSmithKline? 22
- A. Well, Avandia, as I remember, was introduced
- around the year 2000, and at the time when it
- was first introduced, I remember some of the

- would be local to my area, so, typically, in
- my area. They may have a program in
- Greensburg, Pennsylvania or Uniontown, 3
- Pennsylvania. There's not much in Scottdale,
- I'm sorry, so, typically, I have to drive 10
- or 15 miles to get to a program.
- Q. I don't suppose you have any literature in
- your office from the program --
- Q. -- that you could share with us? 10
- A. No. We get so much literature, that if I kept
- every piece of literature that those reps left
- me, I wouldn't have room to walk around in my 13
- office.
- Q. It would be awash? 15
- A. Mm-hmm. So, typically, after the rep leaves,
- you know, I'll read it and then throw it away
- in the trash.
- Q. Do you happen to recall the names of the -- or
- the name of the endocrinologist who came to 20
- speak about Avandia? 21
- A. Dr. Kowalik is -- to my best recollection,
- Steven Kowalik.
- 24 Q. Is he a local endocrinologist?
- 25 A. He's a local endocrinologist. He has a

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- reps coming to the office to detail me on that
- product. I can't specifically remember back
- that far who they were, but I'm sure I've 3
- attended a program or two on Avandia when it
- first was introduced. Lately, I really 5
- haven't seen any reps that have Avandia. I
- don't know if they're still detailing it or 7
- what's going on there. 8
- Q. When you said you attended a program, can you
- describe what you mean by that? 10
- A. Usually, what they'll have is an
- endocrinologist, typically, will give you a 12
- lecture to a group of family practice doctors 13
- or internal medicine physicians. They'll 14
- have, maybe, four or five doctors at a dinner 15
- meeting. The specialist, usually the 16
- endocrinologist, will show a series of slides 17
- and describe the medication, the risks, the 18
- benefits, the side effects, that type of 19
- 20 thing.
- 21 Q. Mm-hmm. Do you remember, you know, where the
- location -- what restaurant or what town? Was 22
- it in Pittsburgh?
- A. No. I usually don't go to Pittsburgh. It's
- just too far from where I live. No, these

- practice in Greensburg, Pennsylvania.
- Q. Mm-hmm.
- A. There may have been another endocrinologist, a
- Dr. Shawn Nolan. I don't know if he spoke for
- Avandia, however. 5
- O. Mm-hmm.
- A. And Dr. Timothy Jackson, who is another
- endocrinologist in the Uniontown area.
- 9 But, again, it's been so many years
- that I can't recall if they specifically spoke 10
- for Avandia, but those are the local 11
- endocrinologists that were giving programs at 12
- that time. 13
- Q. Okay. Do you recall what was said about
- Avandia in the programs or anything about the
- slide deck? 16
- A. What I can recall about Avandia was the 17
- mechanism of action where it's an insulin 18
- sensitizer so that it gets the -- it helps the 19
- glucose to go into the cell, such as the 20
- muscle cells, the adipose tissue, the liver, 21
- places where we need to get the insulin into 22
- 23 these cells. So it sensitizes. That's,
- basically, it's mechanism of action. 24
- As I recall, during the 25

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- presentation, there was mention of peripheral
- edema being listed as one of the side effects 2
- of that medication. They may have mentioned 3
- drug-to-drug interactions, but I really
- specifically can't recall them. As I recall,
- though, there weren't very many drug-to-drug
- interactions with that class of medications.
- Q. Do you recall hearing that Avandia has a
- favorable lipid profile?
- 10 A. I remember lipid profiles being discussed with
- Avandia and Actos as well, and the lipid 11
- profile benefits were touted by both 12
- companies, as I recall. 13
- Q. Do you remember specifically what they said
- 15 about what Avandia would do for your lipid
- profile? 16

3

17

- A. I can't remember specifically, no. 17
- Q. Do you remember if any sales representative
- from GlaxoSmithKline described to you the 19
- advantages of Avandia over Actos? 20
- 21 A. As I recall -- and, again, this is a long time
- ago -- it was the benefits in the lipid 22
- profile, and it seemed to be that one company
- would tout one portion of the lipid profile 24
- and the other company would tout another

portion of the lipid profile, and, again,

- plaintiff, not to be questioned about a drug
- he did not prescribe your client. 2
- MS. HEACOX: Okay. Well, can he 3
- 4 answer the last question, and then I'll move
- 5 on?
- MR. CARROLL: Thanks. 6
- A. I don't recall them saying anything about it 7
- being cardio-protective. 8
- 9 Q. Okay. Fair enough.
- MS. HEACOX: That's all I have right 10
- now. 11

13

- 12 Thank you very much.
- EXAMINATION 14
- 15
- BY MR. WASSON: 16
- Q. Good afternoon, Dr. Polakovsky. 17
- My name is Chris Wasson, and I 18
- represent GlaxoSmithKline. I have a few 19
- questions for you as well. 20
- A. Okay. 21
- Q. The first time you met or treated Mr. Thomas
- was in Frick Hospital; is that correct?
- A. Yes. 24
- 25 Q. I'm going to show you what we'll mark as

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- Exhibit 5, I believe we're up to.
- 2
- (Exhibit No. 5 was marked for identification.) 3
- BY MR. WASSON: 5
- 6 Q. Have you had a chance to look at that, Doctor?
- A. Yes. 7
- Q. And is that the admission record from Frick
- 9 Hospital from August 10th of 2006 relating to
- Mr. Samuel Thomas? 10
- A. Yes, it is. It's my history and physical
- examination, yes.
- Q. And you were -- did you have -- were you an
- attending physician at Frick at that time?
- Yes. 15 A.
- Q. Would you cover patients in the hospital?
- A. Yes, I do. 17
- Q. And that's how you came to treat Mr. Thomas? 18
- That's correct. 19
- Q. You took a history from Mr. Thomas, correct? 20
- A. Yes, I did. 21
- Q. And you have, in your note here, under Past 22
- 23 Medical History -- well, actually, under Chief
- Complaints, you say: The patient has a known
- cardiac history, however, he stopped his 25

their specific product was better for.

- 5 Q. So, you know, if I'm correct, what you're
- saying is that both companies were telling you

being so many years ago, I just don't recall

which one was saying about, you know, which

- their drug was better for the lipid profile 7
- than the other drug --8
- 9 MR. WASSON: Objection to form.
- 10 Q. -- in essence?
- A. Yes, in essence. Yes.
- 12 Q. Okay. Do you remember any other specific
- message that the GlaxoSmithKline sales 13
- representative had about their drug Avandia? 14
- Specifically, did they tell you it 15
- was -- it had cardio-protective effects? 16 MR. WASSON: Objection to form and,
- really, relevance --18
- MR. CARROLL: Yeah, I'm going to --19
- 20 MR. WASSON: -- at this point.
- MR. CARROLL: Yeah, I'm going to, 21
- sort of, interpose an objection here as his 22 23 counsel.
- My understanding is he was here to 24 talk about his care and treatment of the 25

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- 1 cardiac meds and his diabetic meds
- 2 approximately six months ago for cost issues.
- 3 Do you see that?
- 4 A. That's correct. Yes.
- 5 Q. Is that something that Mr. Thomas told you?
- 6 A. Yes, it is.
- 7 Q. And you also put that in the past medical
- 8 history: Mr. Thomas' other past medical
- 9 history is significant for non-insulin-
- 10 dependent diabetes mellitus for which he has
- 11 not taken medications for approximately six
- 12 months.
- Again, is that something Mr. Thomas
- 14 told you?
- 15 A. Yes, it is.
- 16 Q. Part of your assessment and plan from that
- 17 record, Doctor, is -- the last one is anemia.
- Do you see that?
- 19 A. Mm-hmm.
- 20 Q. Did you make a diagnosis of anemia for
- 21 Mr. Thomas?
- 22 A. Yes, I believe so.
- 23 Q. Do you remember what the basis for your
- 24 diagnosis was?
- 25 A. It was the initial set of labs that were drawn

- 1 A. Yes.
- 2 Q. And you also noted a positive family history
- 3 for coronary artery disease and hypertension;
- 4 is that right?
- 5 A. Yes.
- 6 Q. Is that something you would have gotten from
- 7 Mr. Thomas as well?
- 8 A. Yes.
- 9 Q. And you also note that his blood pressure was
- 10 elevated?
- 11 A. Yes.
- 12 Q. I think you said after -- it was after this
- meeting or encounter with Mr. Thomas that he
- became your patient afterwards; is that
- 15 correct?
- 16 A. Yes, it is.
- 17 Q. And did you talk to Dr. Timothy Saloom about
- 18 Mr. Thomas before the care was transferred to
- 19 you?
- 20 A. Yes, I did.
- Normally, when we have a patient in
- 22 the hospital -- I was covering for Dr. Saloom,
- 23 who was away that weekend, so when we have a
- patient in the hospital, when Dr. Saloom came
- back Sunday, the typical routine is to call

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. 3

- 1 when he was admitted to the hospital.
- 2 Q. Which specific labs would those be?
- 3 A. That would be his hemoglobin and hematocrit.
- 4 Q. And so based on his hemoglobin and hematocrit
- 5 findings or levels, you determined that he had
- 6 anemia?
- 7 A. I believe so.
- 8 Q. Did you talk to Dr. -- Mr. Thomas about how
- 9 long he had had anemia?
- 10 A. I don't recall talking to him about how long
- 11 he had anemia.
- 12 Q. Okay. And, also, in the past medical history,
- you note that -- at least at this time or from
- October of 2003, that he had a 36 percent
- ejection fraction; is that right?
- 16 A. Yes. Yes.
- 17 Q. Do you remember where you got that information
- 18 from?
- 19 A. That ejection fraction must have come from his
- 20 previous medical chart which would have been
- available to me at the time that I examined
- 22 him at the hospital.
- 23 Q. So based on your treatment of Mr. Thomas at
- 24 this time, August 10th of 2006, he hadn't been
- on any meds for six months; is that right?

- 1 Dr. Saloom and let him know which of his
- 2 patients I've seen and what exactly is going
- on with them, so I'm sure that I discussed
- 4 Mr. Thomas with Dr. Saloom.
- 5 Q. Do you remember any specifics of the
- 6 discussions that you had with Dr. Saloom about
- 7 Mr. Thomas at the time in the transition?
- 8 A. No, I can't remember any specifics other than
- 9 the fact to say that he was in the hospital
- and he was being treated. I believe
- 11 Dr. Saloom discharged the patient.
- 12 Q. From Frick Hospital?
- 13 A. From Frick Hospital, correct.
- 14 Q. Did you come to know that Dr. Saloom actually
- had to terminate his care of Mr. Thomas?
- 16 A. No, I did not know that.
- 17 Q. Did you ever talk to Dr. Saloom about the fact
- that Mr. Thomas wouldn't follow Dr. Saloom's
- medical advice or take his medications?
- MS. HEACOX: Objection to the form
- of the question.
- 22 A. No, I wasn't aware of that.
- 23 Q. Do you remember any discussions like that?
- 24 A. No. The discussion I had with Dr. Saloom was
- when Mr. Thomas called me and asked if I would

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- 1 assume him as a patient, and I remember
- 2 calling Dr. Saloom and asked if that would be
- 3 okay with him, and Dr. Saloom said it was
- 4 okay.
- 5 Q. Did Mr. Thomas tell you that he had been
- 6 terminated from Dr. Saloom's care?
- 7 A. No.
- 8 MS. HEACOX: Objection to the form
- 9 of the question.
- 10 Q. Your first office visit was September 5th of
- 2006, is that right, if you can find that page
- of your chart?
- 13 A. Yes, September 5 of 2006. Correct.
- 14 Q. Did you take a weight of Mr. Thomas?
- 15 A. Yes.
- 16 Q. What was his weight?
- 17 A. 223 pounds.
- 18 Q. And how tall was he?
- 19 A. 65 inches.
- 20 Q. Five-five?
- 21 A. Five-five.
- 22 Q. So that was -- that's a BMI of about 37,
- 23 right?
- 24 A. Yes.
- 25 Q. That's severely obese?

- 1 A. Yes, it is.
- 2 Q. What is right after that?
- 3 A. He states that cost is a problem. I advised
- 4 him that there could be serious consequences
- 5 or even death from not taking his
- 6 medications. Okay.
- 7 Q. And go ahead.
- 8 A. Well, after that, it said: He switched to me
- 9 because he was not happy with Dr. Tim Saloom.
- 10 Q. Did Mr. Thomas tell you why he wasn't happy
- 11 with Dr. Saloom?
- 12 A. No.
- 13 Q. What specifically did you advise Mr. Thomas
- about the serious consequences or even death
- that could result from him not taking his
- 16 medications?
- 17 A. I explained that diabetes needs to be
- 18 controlled with diet and exercise, and
- 19 coronary disease as well needs to be
- 20 controlled with diet and exercise, and that
- that's important in the treatment of these
- 22 conditions as well as, you know, other
- 23 factors.
- 24 Q. How about for his high blood pressure, did you
- 25 talk about that?

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- 1 A. Yes. Well, it's obese, yes.
- 2 Q. Did you have any discussions with Mr. Thomas
- 3 about his obesity during that first visit
- 4 about addressing that condition?
- 5 A. I don't believe I had a specific discussion
- 6 about his obesity. I'm looking at my note in
- 7 the chart, and I don't have that marked --
- 8 well, wait, I'm sorry, I do. I do have
- 9 mention of a low-calorie/low-salt consistent
- 10 carbohydrate diet, so I must have mentioned
- something to him because I did mark that under
- 12 diet.
- 13 Q. Is it important for patient care to address a
- 14 condition like that of obesity?
- 15 A. Yes.
- 16 Q. You also made a note in your -- I guess your
- office notes. At the top of your first page
- of the September 5, '06 record, you make
- reference to patient had not been taking any
- of his medications since February of 2006,
- with an exclamation point.
- Do you see that?
- 23 A. Yes, I do.
- MS. HEACOX: Objection.
- 25 Q. Is that your handwriting?

- 1 A. Yes. I advised him to use a low-salt diet,
- 2 and that's about it.
- 3 Q. Did you talk to him about problems of not
- 4 taking his blood pressure medication?
- 5 A. Yes.
- 6 Q. What did you tell him about that?
- 7 A. I explained that the blood pressure
- 8 medications needed to be taken on a regular
- 9 basis. Certain medications can cause problems
- if you are not consistent with taking those
- medications, such as a beta blocker.
- 12 Q. How about for his cholesterol problems, did
- you talk to him about not taking medication
- 14 for that?
- 15 A. Yes, I believe so.
- 16 Q. And what did you tell him about that?
- 17 A. I explained that he needs to take the
- 18 cholesterol medications to help reduce his
- 19 chances of cardiac events.
- 20 Q. The first labs you did were after that visit
- on October -- or the first labs you
- 22 received --
- 23 A. Mm-hmm.
- 24 Q. -- I should say, were on October 7th of 2006
- 25 after that first office visit; is that

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- 1 correct?
- 2 A. Yes. Yes, they were.
- 3 Q. And what was Mr. Thomas' glucose at that
- 4 time -- fasting glucose?
- 5 A. Fasting glucose was 169.
- 6 Q. Is that high?
- 7 A. Yes, it is.
- 8 Q. What was his HpA1c?
- 9 A. 7.3.
- 10 Q. Is that high as well?
- 11 A. Yes, it is.
- 12 Q. And his HDL at the time?
- That's the good cholesterol, right?
- 14 A. Mm-hmm.
- 15 Q. What was his HDL?
- 16 A. His HDL was 28.
- 17 Q. Is that low?
- 18 A. That's very low, yes.
- 19 Q. What's normal?
- 20 A. Normal HDL we like to see greater than 60.
- 21 Q. So 28 is very low?
- 22 A. 28 is very low.
- 23 Q. Is low HDL a risk factor for cardiac events?
- 24 A. Yes, it is.
- 25 Q. Did you do anything specific in treating

- MR. WASSON: Okay. Can we take a
- 2 short break? We just need to change the tape.
- 3 THE VIDEOGRAPHER: This is the end
- 4 of tape number 1. We're going off the
- 5 record. The time is 2:21 p.m.
- 6 ----

8

13

- 7 (There was a recess in the proceedings.)
  - - -.
- 9 THE VIDEOGRAPHER: This is the
- beginning of tape number 2. We're going back
- on the record. The time is 2:23 p.m.
- 12 Please proceed.
  - BY MR. WASSON:
- 14 Q. Thank you. Thank you, Doctor. We just took a
- short break to change the tape.
- We were talking about the first lab
- 17 results you got in October 7th of 2006 for
- 18 Mr. Thomas, and I just want to back up and ask
- 19 you, as of that time, as of those labs, he had
- 20 been on those meds that you prescribed back in
- 21 September for about a month; is that right?
- 22 A. Yes.
- 23 Q. So how did you feel that the medication was
- addressing his cholesterol and diabetes
- problem, as of those labs, after a month?

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- Mr. Thomas after you reviewed these initial 1 A
- 2 laboratory results?
- What was your plan after seeing
- 4 these?
- 5 A. Well, the plan after seeing these -- I'm going
- 6 to turn my page to get to -- to get to his
- 7 office visit just to refresh my memory.
- 8 For his coronary disease, I wanted
- 9 him to see Dr. Olivenstein, the cardiologist.
- 10 We were keeping his medications the same as
- when he first came in, but I felt that the
- cardiologist, you know, was appropriate at
- this point because of his cardiac disease.
- 14 Q. Any other specific recommendations or plans
- that you had to treat Mr. Thomas after those
- initial lab results?
- 17 A. To be on the 70/30 Insulin and the sliding
- scale at supper time, which I would have
- 19 discussed with him. He mentioned about an
- 20 impotence problem, and I asked him to see a
- urologist. That's what I can, you know, gain
- from reading this note from October 12th of
- 23 '06
- THE VIDEOGRAPHER: I need to change
- 25 the tape.

- 1 A. I wasn't happy with his blood sugar level, and
- 2 I wasn't happy with the cholesterol profile.
- 3 Q. Did you make any adjustments in those
- 4 medications, after he got the labs, in your
- 5 next office visit in October of '06?
- 6 A. No.
- 7 Q. When he came back to you, it was October 12th
- 8 of 2006, I believe; is that right?
- 9 A. He came November 20 of 2006.
- 10 Q. Oh, I'm sorry. I had -- is that not an office
- visit at the top of that page?
- 12 A. Yes. Yes, it is. I'm sorry.
- 13 Q. Okay.
- 14 A. October 12, 2006. Correct.
- 15 Q. And did you see him on that visit?
- 16 A. Yes, I did.
- 17 Q. And it was at that point that you prescribed
- 18 or gave him samples for Levitra?
- 19 A. Yes.
- 20 Q. Now, Mr. Thomas told you his sugars were
- averaging 140 during that visit?
- 22 A. Yes.
- 23 Q. Is that consistent with the labs you got?
- 24 A. His labs were higher than what he told me, so

it's not consistent.

igiit.

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- 1 Q. And that was a fasting lab, right?
- 2 A. Yes, it was.
- 3 Q. And his tests at home weren't fasting, were
- they?
- 5 A. I would assume his tests at home should be
- fasting.
- 7 Q. He was instructed to do fasting tests?
- A. Yes.
- 9 Q. Okay. And your next visit was in November 20;
- is that correct?
- 11 A. Yes.
- 12 Q. And his weight is 228 at that point, right?
- 13 A. Yes.
- 14 Q. That's still -- that's more weight than he had
- the first time he saw you, right?
- A. That's right.
- O. And that's still obese? 17
- A. Yes, it is.
- 19 Q. Is that the -- that's the visit where you
- first prescribed Levitra for him or gave him 20
- samples? 21
- A. The Levitra was -- samples were provided
- October 12 --
- 24 Q. Oh, I'm sorry, you're correct.
- 25 A. -- 2006.

- earlier?
- A. Yes, I did.
- I don't believe I supplied any
- samples on the November 20th visit, however.
- I don't have anything documented on that date.
- Q. Okay. You had previously provided him with
- samples?
- A. Yes. Previously I had, yes.
- Q. And the next visit you saw him was January 11
- of 2007; is that right?
- A. Yes. 11
- Q. And his weight at that time is 233 pounds, 12
- 13
- A. That's correct.
- 15 Q. So he's continuing to gain weight?
- A. Yes, he is.
- Q. And you have a reference here, and you've had
- in other places, to ESSHTN as a diagnosis.
- What does that mean?
- A. Oh, essential hypertension. 20
- Q. And what is essential hypertension?
- A. That's hypertension for no known cause.
- O. On this visit of January 11, '07, there's also
- a reference to you giving him Levitra samples, 24
- correct? 25

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- 1 Q. I apologize.
- And then it was in the November
- visit that, I think, did you instruct him not
- to use the Levitra?
- 5 A. Yes.
- 6 Q. And why was it specifically that you
- instructed him not to use the Levitra?
- 8 A. The reason I didn't want him to use the
- Levitra was because I felt that in his
- situation, if he had to use nitrates, it could 10
- be a dangerous situation. He was not on 11
- nitrates, he had no symptoms, but I felt that 12
- if he -- if he was in that position where he 13
- would have to use that, that that wouldn't be 14
- a wise choice.
- 16 Q. Do you know whether he, in fact, stopped using
- it or if he kept using it? 17
- 18 A. I don't know if he stopped using it. I know
- he had asked for samples, and that's as much
- as I know. 20
- 21 Q. And then in the November 20 visit, there's
- also reference to him having an issue with
- cost and requesting samples, correct?
- 24 A. Yes.
- 25 Q. And you provided samples as you testified

- 2 Q. And how many samples did you give him?
- A. Number 6.
- 4 Q. Do you know if he continued to take Levitra?
- A. I don't know.
- Q. You had previously instructed him not to,
- correct? 7
- A. That's right.
- 9 Q. Your next visit is April 3rd of 2007, correct?
- A. Yes, it is.
- Q. At that point, he weighs 242 pounds, right?
- A. Mm-hmm. 12
- Q. Gained another 9 pounds? 13
- 14 A. Yes.
- 15 Q. Do you recall having any discussions with him
- at this point about his weight or efforts to
- lose weight?
- A. I mentioned to him about the ADA diet, the
- diabetic diet on that visit, and so, yeah, I
- must have had a discussion about his weight 20
- since I mentioned the diet, yes. 21
- Q. Do you know whether he was compliant with your
  - 23 advice?
- A. I can't say whether he was compliant because
- I'm not Mr. Thomas, but it appears that he's

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- 1 not being compliant.
- 2 Q. Based on your --
- 3 A. Based on, you know, the numbers and what I was
- 4 seeing in the office.
- 5 Q. And one of the other diagnoses you had here
- 6 on -- actually, I think you've had it a couple
- times. Is that hypercholesterolemia? Is that
- 8 correct?
- 9 A. Yes.
- 10 O. What does that mean?
- 11 A. That means his cholesterol is elevated, it is
- under treatment, and, again, I recommended a
- 13 low-cholesterol diet and the medications.
- 14 Q. And he had that elevated cholesterol from the
- day he began treating with you, correct?
- 16 A. Yes.
- 17 Q. The next labs you got, Doctor, were from June
- 18 of 2007; is that right?
- 19 A. Yes.
- 20 Q. And these were -- these labs from June --
- 21 actually, June 27th of 2007; is that correct?
- 22 A. Yes, correct.
- 23 Q. These lab results that you got were the next
- in line that you got after those from October
- of 2006 that we already went over, correct?

- 1 A. Yes.
- 2 Q. And what was Mr. Thomas' HDL, the good
- 3 cholesterol, from these labs?
- 4 A. The HDL, good cholesterol, was 29.
- 5 Q. Again, that's very low, correct?
- 6 A. Yes, it is.
- 7 Q. So how would you describe his lipid profile at
- 8 this time?
- 9 A. It's not good at all. It's not a good lipid
- 10 profile to have.
- 11 Q. And his HpA1c was what at this point?
- 12 A. 9.3
- 13 Q. That's higher than -- that's higher than the
- 7.3 we saw last time, right?
- 15 A. Yes, it is.
- 16 Q. Was that a concern to you?
- 17 A. Yes.
- 18 Q. He also had urine -- he also had glucose in
- 19 his urine; is that correct?
- 20 A. Yes, he did.
- 21 Q. That's the first time you saw that?
- 22 A. Yes.
- 23 O. And it had been negative before?
- 24 A. It had been negative before. I believe,
- because of the fact that his blood glucose was

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- 1 A. Correct.
- 2 Q. And his glucose at that point -- his fasting
- 3 glucose was what?
- 4 A. It was 244.
- 5 Q. Is that high?
- 6 A. Yes, it is.
- 7 Q. It's a lot higher than 169, isn't it?
- 8 A. Yes, it is.
- 9 Q. Is that your handwriting there that says:
- Needs to be referred to endocrinologist?
- 11 A. Yes, that's my handwriting. Yes.
- 12 Q. And did you refer him, Mr. Thomas, to an
- endocrinologist in June of 2007?
- 14 A. Yes, I did.
- 15 Q. Do you know if he went?
- 16 A. I don't believe he went.
- 17 Q. So he didn't follow your advice?
- 18 A. I don't think so.
- 19 Q. What was Mr. Thomas' triglyceride level from
- these labs?
- 21 A. His triglycerides were 277.
- 22 Q. Is that high?
- 23 A. Yes, very high.
- 24 Q. It's a lot higher than the last ones, isn't
- 25 it?

- 1 so high, that he was spilling glucose into the
- 2 urine at this point, yes.
- 3 Q. Do you think Mr. Thomas was taking his
- 4 insulin?
- 5 MS. HEACOX: Objection. Calls for
- 6 speculation.
- 7 Q. If you can?
- 8 A. He may not have been taking the insulin as
- 9 prescribed or may not have been taking a
- sufficient amount. I mean, I can't say he
- 11 didn't take any. It would be a guess.
- 12 Q. Okay. Are these the sort of lipid levels and
- 13 glucose levels you would expect to see from a
- 14 patient taking the medications you prescribed
- 15 for Mr. Thomas?
- 16 A. No, they're not.
- 17 Q. What does it mean to have glucose in your
- 18 urine?
- 19 A. That means that the blood glucose is so high
- 20 that the kidneys can't -- they're spilling
- 21 urine -- I'm sorry, they're spilling glucose
- into the urine, so, generally, we see that when the glucose is greater than 160 or so.
- 24 Q. What, if anything, did you do -- other than
- your note to refer him specifically to see an

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- endocrinologist, what other steps did you take
- in response to reviewing these lab results for 2
- Mr. Thomas? 3
- 4 A. Well, I know I asked him to see an
- endocrinologist.
- Let me check my note from July of 6
- '07 here. 7
- Q. Did you have a visit with him the next day on 8
- June 28th of 2007?
- 10 A. June 28th, 2007, yes.
- 11 Q. And from that record, can you tell what it was
- that you did in addition to referring 12
- Mr. Thomas to an endocrinologist? 13
- A. Well, I asked him to have a diabetic eye exam
- and a foot exam. I advised him to have a 15
- colonoscopy and a rectal prostate exam on that 16
- visit. I continued him on the 70/30 Insulin 17
- until -- you know, until he could see an 18
- endocrinologist. I asked him to follow up 19
- with Dr. Olivenstein, the cardiologist. I 20
- advised him to follow a low-cholesterol diet 21
- because I wasn't happy with the lipid numbers, 22
- and he had another problem where he had
- injured his thumb and I asked him to see a 24
- hand specialist for the thumb. 25

- 1 Q. And under HPI --
- What is that, health physical 2
- information? 3
- 4 A. It's history of present illness.
- Q. History of present illness.
- -- there's a notation that patient 6
- 7 does not always check sugars.
- Do you see that? 8
- A. Yes, I do.
- Q. Is that something you advised him to do?
- A. I do advise him to check sugars daily, yes, at
- least twice daily, and he told me he was not
- always checking his sugars. 13
- Q. So he wasn't following your advice?
- A. That's right. 15
- Q. On the visit of October 9th of 2007, Doctor, I
- think it might be on the second page of your
- records, there's a reference to -- at the
- bottom, under A/P, do you see that section? 19
- A. Yes. 20
- Q. There's a reference to IDDM poor control. Do
- you see that?
- A. Yes, I do.
- Q. Is that your reference to the laboratory
- results that you had?

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- 1 Q. And the lipid levels and the glucose levels
- you saw from the October -- I'm sorry, the
- June '07 lab results, did those give you
- concern for Mr. Thomas' cardiovascular health?
- 5 A. Yes.
- 6 Q. Is that why you referred him to the
- cardiologist?
- 8 A. That's why I referred him to the cardiologist,
- 10 Q. And on that June 28th, '07 visit, he was up to
- 245, right?
- 12 A. Yes.
- 13 Q. So he gained another 3 pounds?
- 14 A. Yes.
- Q. Do you remember having any discussions with
- him about his weight during that visit?
- 17 A. I don't remember discussing his weight. I'm
- looking to see if I have something noted in my 18
- note about it. It's just hard to remember 19
- specifics that far ago.
- 21 Q. Nothing specific in your notes that you see?
- 22 A. No.
- Q. Your next visit was on October 9th of 2007; is
- that correct?
- 25 A. Yes.

- Q. And is this -- and I see here -- maybe you
- could help me read this.
- 4 A. Okay.
- Q. Does it say refer to --
- A. Refer to Dr. Kowalik.
- Q. Okay. And is he an endocrinologist?
- A. He's an endocrinologist locally, and then I
- noted recheck labs, recheck blood pressure in
- two months. 10
- Q. So this was the second time you specifically
- referred Mr. Thomas to an endocrinologist?
- 13 A. Yes.
- 14 Q. Do you know if he went?
- A. I don't believe he went.
- Q. I don't see any records from Dr. Kowalik in
- yours. Are there? 17
- A. No, I have no records from Dr. Kowalik, and
- that's the reason why I don't believe he went,
- because, typically, I'll get a letter back 20
- from the endocrinologist saying that they saw 21
- the patient and this was what they were going
- to do to treat the patient, yes.
- Q. You also have a reference there to written
- RX. Is that Prandia? 25

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- 1 A. Written -- no.
- 2 Q. I'm sorry. What does that say?
- 3 A. I'm sorry. No, no. It means written referral
- provided. Okay?
- 5 Q. Oh, okay. Sorry.
- 6 A. Now, if I go back on 10-7 -- let me find
- the -- that means written referral provided,
- but let me go back and see -- okay. I wrote
- him, on a prescription form: See Dr. Kowalik
- or Dr. Basham -- I'm sorry, part of this thing
- is cut off -- and I wrote their phone number 11
- down, for diabetes management. Your A1c is 12
- 9.3, and I wrote too high. Sugars are 13
- averaging over 220. Call for appointment.
- Have blood work and tests done first. And 15
- this was a paper that I handed Mr. Thomas, 16
- along with his prescriptions. 17
- Q. During that meeting?
- A. During that meeting, correct.
- 20 Q. Your next visit was December 11th of 2007; is
- that right? 21

3 A. His lab slip.

4 Q. What did that mean?

- A. Yes.
- Q. At this point he weighs, what, 237; is that

1 Q. You said -- also, under HPI here, it says:

Patient states he lost -- what does that say?

5 A. I give the patient a written prescription to

hospital, and that way they can have their

have blood work done, and they take it to the

cholesterol checked, their hemoglobin, A1c,

whatever, and then I'll get the results back,

On that lab slip, I do have copy to

Dr. Kowalik, and this is the lab slip -- this

is my copy of the lab slip that I gave him

Q. And he didn't have any lab work done?

20 Q. Also, down there on the -- I guess, three-

24 Q. Denies seeing endocrinologist as he was

back on, you know, December -- or October 9th

quarters of the way down that page from 12-11-

and apparently he lost the lab slip.

Q. That you gave Mr. Thomas?

07, under endo, do you see that?

right?

9

10

11

12

13

14

17

of '07.

A. Yes.

A. That's right.

25 A. Yes. He had lost some weight.

- Is that what that says?
- A. Yes.
- Q. So Mr. Thomas told you he didn't go see the 3
- endocrinologist?
- That's right.
- Q. So, again, he's not following your advice?
- A. That's right.
- Q. The next thing you had were more lab results
- from February of 2008; is that right?
- 10 A. Yes, February 25.
- Q. And do you have those in front of you?
- A. Yes, I do. 12
- Q. Okay. What was Mr. Thomas' fasting glucose in
- February -- on February 25, 2008?
- A. It was 285.
- Q. So that's even higher than the June labs; is
- that right?
- A. Yes.
- Q. And did that concern you?
- 20 A. Yes, it did.
- Q. And then there's some handwriting at the
- bottom of that page.
- A. Mm-hmm.
- Q. On the left-hand side, I think I can read
- that, but what does the writing on the right-

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- hand bottom say?
- A. On the right-hand, it says: Needs seen.
- Dyslipidemia. Poor glycemic control.
- 4 Q. Say that first part again. Something seen?
- A. Well, needs seen.
- O. Needs seen?
- A. Yes.
- Q. What does that mean?
- A. When I write that on the labs, on the slip,
- that's given to the receptionist, and the
- receptionist will call the patient for an
- appointment.
- Q. Okay. Is that glucose -- fasting glucose
- level consistent with a patient who is taking
- insulin?
- A. I don't believe so.
- Q. What was Mr. Thomas' triglyceride level?
- A. They were 209.
- 19 Q. Is that high?
- 20 A. Yes.
- Q. And what was Mr. Thomas' HDL level, the good
- cholesterol?
- A. His HDL was 25.
- Q. So that's dropped even lower than the last
- labs, right?

advised.

23 A. Yes.

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- 1 A. Yes, it has. Yes.
- 2 Q. Did that concern you?
- 3 A. Yes, it did.
- 4 Q. And what was Mr. Thomas' HpA1c on February
- 25th of 2008?
- 6 A. It was 10.4.
- 7 Q. So higher than the 9.3 from June, correct?
- 8 A. Yes.
- 9 Q. Did that concern you as well?
- 10 A. Yes, it did.
- 11 Q. Other than, again, your referral of Mr. Thomas
- to an endocrinologist, what other -- what
- steps did you take to address these lab
- results with Mr. Thomas?
- 15 A. Well --
- Q. Oh, I'm sorry, before we get there, Doctor,
- can we go back to the second last page of the 17
- 18
- Again, there was glucose in 19
- Mr. Thomas' urine, right? 20
- 21 A. Yes.
- 22 Q. And this time it's up to a thousand?
- 23 A. Yes.
- 24 Q. Last time, it was 300?
- 25 A. Yes.

1 Q. Is that against your advice?

- 2 A. Yes.
- 3 Q. How many times is he supposed to use it a day?
- 4 A. Twice a day.
- Q. And you observed that his sugars were not
- well-controlled again?
- A. Yes.
- Q. Did you make another referral to an
- endocrinologist for Mr. Thomas?
- A. Yes, we spoke with him for a long time on that
- visit and asked him again to see the
- endocrinologist.
- O. Do you know if he ever went?
- A. I don't believe so.
- 15 Q. You also, I think, wrote him -- I think you
- mentioned earlier you wrote him a certified
- letter --17
- A. Yes.
- Q. -- on March 8th of 2008; is that right?
- A. Yes, I did.
- Q. What was your reason in writing Mr. Thomas a
- certified letter?
- A. I wanted to reinforce what we had discussed at
- the office visit.
- 25 Q. Is there some reason you did it by certified

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- mail?
  - 2 A. Yes.
  - з Q. Why?
  - A. I felt that Mr. Thomas was not following my
  - medical advice at this time, and I felt that
  - if I sent him a certified letter, at least
  - everything would be spelled out in front of 7
  - him and my reasoning would be clear to him and
  - 9 perhaps he would, you know, follow the medical
  - advice. 10
  - Q. Were you considering terminating your care of
  - Mr. Thomas at this point?
  - A. At this point, I was considering referring him
  - beyond my care to an internal medicine
  - specialist, yes.
  - Q. Because he wasn't following your advice?
  - A. Well, because we weren't controlling his
  - problem, so I felt that at this point, maybe
  - another doctor could impress on him the
  - importance of his care, so that was my 20

  - reasoning. 21
  - Q. A big part of the problem you weren't
  - controlling his problem was he wasn't
  - following your advice, correct?
  - 25 A. I think so.

1 Q. And now we've also got, what, hemoglobin in

- his urine as well?
- 3 A. Yes, there's a trace of hemoglobin, 1 plus.
- 4 Q. What's the significance of that?
- 5 A. I'm not sure what the significance of the 1
- plus trace hemoglobin. There can be several
- causes, and I would be speculating if I would
- say as to what it was.
- 9 Q. We don't want you to speculate.
- What's the significance of the 1,000 10
- reading for glucose in his urine?
- A. That means that his glucose control is very 12
- 14 Q. Your next visit was March 6th of 2008; is that
- right?
- A. Yes.
- 17 Q. And you actually have some -- the handwritten
- pages that we've seen before, but you also
- have a typewritten note for this visit as
- well? 20
- 21 A. Yes. Correct.
- 22 Q. And you make reference to the fact that
- Mr. Thomas is only using the 70/30 once a day;
- is that correct?
- 25 A. Yes.

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- 1 Q. And there was a call to your office, it looks
- 2 like, June 30th of 2008 regarding some
- 3 medications. That's the next event that I
- 4 see; is that correct?
- 5 A. Yes.
- 6 O. And what was that about?
- 7 A. He wanted a refill on his Lasix and his Zocor,
- 8 and I called him a 30-day prescription with
- one refill and asked him to call the office
- 10 for a follow-up appointment.
- 11 Q. Did you actually talk to him during that June
- call, do you know?
- 13 A. I believe so. You know, from what it says in
- 14 my note, I did.
- 15 Q. And your last visit with Mr. Thomas was August
- 16 4th --
- 17 A. Yes.
- 18 Q. -- of 2008; is that correct?
- 19 A. Yes.
- 20 Q. You made reference in that visit that he
- wasn't taking his blood pressure medication;
- 22 is that correct?
- 23 A. Mm-hmm. Yes.
- 24 Q. And you had advised him to take his blood
- 25 pressure medication, correct?

- prescribing Zoloft for blood pressure?
- 2 A. No.
- 3 Q. You then sent Mr. Thomas another -- I think,
- another certified letter on August 8th of
- 5 2008; is that right?
- 6 A. Yes.
- Q. What was your purpose in sending this letter?
- 8 A. At this point, I asked Mr. Thomas to see an
- 9 internal medicine specialist. I was
- 10 dismissing him from my practice.
- 11 Q. Was part of the reason you dismissed him
- because he wasn't following your advice?
- 13 A. Yes, I believe so.
- MR. WASSON: Thank you, Doctor. I
- don't think I have any other questions. Thank
- 16 you.
- 17 ----
- 18 EXAMINATION
- 19 ----
- BY MS. HEACOX:
- 21 Q. I have a few follow-up questions.
- 22 A. Okay.
- 23 Q. Dr. Polakovsky, we talked a lot about Dr. -- I
- 24 mean Mr. Thomas' hypercholesterolemia or high
- 25 cholesterol.

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- 1 A. Yes
- 2 Q. You provided -- as you testified earlier, you
- 3 provided Mr. Thomas with a lot of samples,
- 4 didn't you?
- 5 A. Yes, I did.
- 6 Q. So there was no problem with Mr. Thomas
- 7 getting those medications, was there, because
- 8 you gave them to him for free?
- 9 A. That's true.
- 10 Q. He didn't have a -- he didn't have to pay for
- 11 those samples, did he?
- 12 A. No.
- 13 Q. He also requested Zoloft; is that right?
- 14 A. Yes, he asked me for Zoloft.
- 15 Q. Why did he request Zoloft, do you know?
- 16 A. He explained to me that he was robbed at
- gunpoint recently before this visit and his
- nerves were upset, so that's why -- and he
- said that he was on Zoloft in the past and it
- 20 had worked for him.
- 21 Q. Did he tell you that he was taking Zoloft in
- 22 the past for his high blood pressure?
- 23 A. No, Zoloft would not be a blood pressure
- 24 medication.
- 25 Q. Have you ever heard that, a physician

- 1 A Yes
- 2 Q. And you detailed for us earlier his
- 3 cholesterol readings, correct?
- 4 A. Mm-hmm.
- 5 Q. And his LDL was always very low, correct?
- c Δ Ves
- 7 Q. So when you said he had, you know, cholesterol
- 8 problems, are you talking about the
- 9 triglycerides and the HDL?
- MR. WASSON: Object to form.
- 11 A. You need to talk about the whole picture of
- cholesterol, the total cholesterol, the LDL,
- the HDL, and the triglycerides, and so you try
- to optimize each of those four separate
- 15 values.
- One can have a good profile with the
- 17 LDL, "bad cholesterol," and still have a low
- 18 HDL which can give you a risk for heart attack
- and cardiac events or stroke. Triglycerides
- are also an independent risk factor, and so
- you have to look at the whole picture of all
- these numbers.
- 23 Q. And in Mr. Thomas' picture, was it the HDL and
- the triglycerides only that were out of range?
- MR. WASSON: Object to form.

raye o

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- 1 A. For the most part, yes, it was the
- triglycerides and the HDL that were out of
- range, yes. 3
- 4 Q. Can you tell me, with regard to the HDL, what
- Mr. Thomas could have done to control his
- HDL? 6
- For example, is there -- if he had 7
- stayed on an ADA diet, would that have 8
- increased his HDL?
- 10 A. The things that are known to increase HDL are
- exercise and products such as the Omega 3 oils 11
- 12 and niacin.
- O. Is that fish oil? 13
- A. Yes.
- 15 Q. And the vitamin niacin?
- A. Yes.
- O. And exercise? 17
- A. Yes. 18
- Q. Okay. So the cholesterol medications that you
- had prescribed to him would not have increased 20
- his HDL? 21
- MR. WASSON: Object to form. 22
- A. Those cholesterol medicines have some effect
- on the HDL, but I don't know the full extent 24
- of how much they would change his HDL.

- 1 A. I don't know.
- O. You detailed for us the many samples that you
- gave to Mr. Thomas, correct?
- 4 A. Yes.
- Q. And there was one pen that you gave him of the
- insulin --
- 7 A. Yes.
- Q. -- that he was taking? 8
- Is there a reason why you only gave
- him one sample of that?
- A. Probably because that's all I had. 11
- Q. So is that insulin especially expensive? 12
- MR. WASSON: Object to form. 13
- A. I don't know the cost of insulin.
- Q. Do you know whether it costs money to test 15
- your blood sugar at home? 16
- MR. WASSON: Object to form. 17
- A. I believe it does.
- Q. Do you know how much that would cost? 19
- A. No, I don't. 20
- Q. Do you know what's entailed? 21
- A. You need a strip and a lancet to puncture the
  - finger, and you puncture the finger, get a
- drop of blood, put it on the strip in the 24
- glucometer, and it will give you a glucose

- reading.
  - Q. So you also need a glucometer?
  - A. Yes.
  - 4 Q. Is that a machine that reads the blood glucose
  - level?
  - A. Yes, it is.
  - Q. And you need the little -- you need one strip
  - for each time that you test your blood
  - glucose?
  - 10 A. Yes.
  - Q. And you have to purchase those at a pharmacy?
  - 12 A. You do purchase those at a pharmacy. I don't
  - know the cost or whether they're covered by
  - Mr. Thomas' insurance as part of his benefits.
  - Q. Did Mr. Thomas ever tell you that he was
  - having trouble covering the cost of his

  - medications? 17
  - A. Yes. 18
  - Q. In fact, I see that you noted more than once
  - in your records that he told you he was having
  - trouble with keeping up with the payments, 21
  - correct? 22
  - MR. WASSON: Object to form. 23
  - A. He noted that there was a problem with the
  - cost of his medications. 25

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1 Q. How about the triglycerides, is there

- something that he could have done
- independently to lower his triglycerides?
- 4 A. Losing weight, maintaining a low-fat diet,
- obtaining exercise. Those would be the main
- things I would think of.
- Q. And the medications that you prescribed to
- him, were they -- would they have reduced his 8
- 9 triglycerides?
- MR. WASSON: Object to form. 10
- A. I believe they would have some effect on the
- triglycerides, but I don't know to what extent 12
- they would lower his triglycerides. There are 13
- specific medications that are directed at 14
- triglycerides. 15
- O. Such as?
- A. Such as the fibrates. 17
- Q. You referred Mr. Thomas to a diabetes
- specialist, correct? 19
- 20 A. Yes.
- 21 Q. Do you know, in your general experience,
- whether that generally costs more on a co-pay 22
- 23 basis --
- MR. WASSON: Object to form.
- 25 Q. -- seeing a specialist?

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- 1 Q. Did you know what Mr. Thomas did for a living?
- 2 A. I can't recall.
- 3 Q. Have you spoken to any representative from
- 4 GlaxoSmithKline prior to this deposition with
- 5 regard to this lawsuit?
- 6 A. There was a representative that stopped in my
- office some time in August, and I can't recall
- the date, who stated that I was going to get
- 9 papers or something like that regarding one of
- my patients. She did not mention the patient
- specifically, and she told me, "don't shoot
- the messenger," and that was --
- 13 Q. So this was a sales rep?
- 14 A. This was one of the sales reps, yes.
- 15 Q. Do you remember her name?
- 16 A. Her first name was Hemel. I cannot recall her
- last name because I don't see her very often.
- 18 Q. Did she talk to you at all about the basis of
- 19 the lawsuit?
- 20 A. No, not that I can think of. No.
- 21 Q. Did she talk to you at all about Avandia at
- 22 the time?
- 23 A. No.
- 24 Q. Did she talk to you at all about Mr. Thomas?
- 25 A. No, she never mentioned a name.

- 1 Middle Eastern. It was an odd name.
- 2 Probably less than a minute.
- 3 Q. Do you see her often?
- 4 A. No.
- 5 Q. Is that the first time you've seen her?
- 6 A. No, it would not be the first time. She
- 7 comes, maybe, once ever two months or so,
- 8 something on that order, and she hasn't -- I
- 9 mean, she was one of the newer reps that comes
- to my office, so she hasn't been, you know,
- calling on me in the past, you know, for any
- 12 length of time.
- 13 Q. Do you know what she -- what products she's
- 14 usually there detailing?
- 15 A. She has Lovaza.
- 16 Q. Which is?
- 17 A. That's a fish oil product that they use to
- 18 lower triglycerides.
- 19 Q. Anything else?
- 20 A. That's all I can think of. She may have
- another product, but I associate her with
- 22 Lovaza.
- 23 Q. Now, when she said to you "don't shoot the
- 24 messenger," what did you make out of that?
- MR. WASSON: Object to form.

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. . . .

- 1 Q. Did she tell you how she came to know about
- 2 the fact that you'd be subpoenaed?
- 3 A. No, she didn't tell me how she came to know
- 4 about it and, honestly, I didn't ask.
- 5 Q. Have you spoken to any other representatives
- 6 of GlaxoSmithKline about the lawsuit --
- 7 A. No.
- 8 Q. -- or about anything to do with the matters
- 9 herein?
- 10 A. No.
- 11 O. Any lawyers?
- 12 A. Mr. Carroll.
- 13 Q. That's right.
- Any lawyers from the Pepper Hamilton
- 15 law firm or any other law firm representing
- 16 GlaxoSmithKline?
- 17 A. Not representing GlaxoSmithKline or Pepper
- 18 Hamilton, no.
- 19 Q. Okay. How long do you think that conversation
- 20 took between you and the sales representative,
- 21 Ms. -- I'm sorry?
- 22 A. Her first name was Hemel. I can't recall her
- 23 last name.
- 24 Q. Hemel?
- 25 A. Hemel. I think it's -- I don't know if she's

- 1 A. I don't know if she was just afraid that I
- 2 would be upset. I don't know.
- 3 Q. What did you do when she told you?
- 4 A. I basically -- I basically just went on with
- 5 the rest of the visit. I said, well, I
- 6 haven't heard anything, and that's okay, and,
- 7 you know, what can I say?
- 8 I mean, my mother used to tell me
- 9 don't borrow trouble, so I try to follow her
- 10 advice on that.
- 11 Q. Did you call your lawyer?
- 12 A. No.
- MS. HEACOX: Okay. I have no
- 14 further questions.
- 15 ----

17

- 16 EXAMINATION
  - ----
- 18 BY MR. WASSON:
- 19 Q. I just have two questions.
- Can you tell from your chart what
- insurance coverage Mr. Thomas had?
- 22 A. Yes.
- 23 Q. Can you tell me?
- 24 A. He had UPMC Health Plan.
- 25 Q. Is that a local Pittsburgh area plan?

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	Page 89		Page 91
	A Vos it is through the University of	1	COMMONWEALTH OF PENNSYLVANIA) CERTIFICATE
	A. Yes, it is, through the University of	2	COUNTY OF ALLEGHENY ) SS:
2	Pittsburgh.	3	I, JoAnn M. Brown, RMR, CRR, a Court Reporter
3	And, actually, yeah, it lists, you	4	and Notary Public in and for the Commonwealth of
4	know, the co-payments on here. Office visits	5	Pennsylvania, do hereby certify that the witness,
5	are listed as \$15, and specialists are listed	6	ANDREW G. POLAKOVSKY, M.D., was by me first duly
6	as \$25, and ER visits are listed as \$50.	7	sworn to testify to the truth; that the foregoing
7	MS. HEACOX: Am I still on the	8	deposition was taken at the time and place stated
8	record, I guess?	9	herein; and that the said deposition was recorded
9	MR. WASSON: No, I'm asking	10	stenographically by me and then reduced to printing
10	questions.	11	under my direction, and constitutes a true record of
11	MS. HEACOX: Oh, yeah, sorry about	12	-
12	that. Yeah, sorry. Sorry, Chris.	13	the testimony given by said witness.
13	BY MR. WASSON:		I further certify that the inspection, reading
14	Q. Finally, I guess Exhibit 5, which was your	14	and signing of said deposition were NOT waived by
15	hospital admission note concerning your	15	counsel for the respective parties and by the
16	treatment of Mr. Thomas	16	witness.
17	A. Yes.	17	I further certify that I am not a relative or
18	Q the episode of congestive heart failure	18	employee of any of the parties, or a relative or
19	that he had, could that have been caused in	19	employee of either counsel, and that I am in no way
20	any way by his failure to take his meds for	20	interested directly or indirectly in this action.
21	six months?	21	IN WITNESS WHEREOF, I have hereunto set my
22		22	hand and affixed my seal of office this 28th day of
23	MR. WASSON: I have no further	23	October, 2009.
24	questions.	24	Notary Public
25		25	Notary rabite
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1	Page 90 EXAMINATION	1	Page 92
1 2	EXAMINATION	2	E R R A T A
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2	EXAMINATION  BY MS. HEACOX: Q. I just have one more question.	2 3 4	PAGE LINE CHANGE
2 3	EXAMINATION  BY MS. HEACOX:  Q. I just have one more question.  When you sent him to get the blood	2 3 4 5	E R R A T A
2 3 4	EXAMINATION  BY MS. HEACOX:  Q. I just have one more question.  When you sent him to get the blood work done, that was to the emergency room?	2 3 4 5 6	PAGE LINE CHANGE  REASON:
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1	ACKNOWLEDGMENT OF DEPONENT		
2			
3	hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.		
4	foregoing pages, and that the same		
	given by me to the questions therein		
5	propounded, except for the corrections or changes in form or substance, if any,		
6	noted in the attached Errata Sheet.		
7			
8	ANDREW G. POLAKOVSKY, M.D. DATE		
9			
10			
11			
12			
13			
14	Subscribed and sworn		
15	to before me this day of, 20		
16			
17	My commission expires:		
18			
19	Notary Public		
20			
21			
22			
23			
24			
25			

Case ID: **(09/02/927**33

# **EXHIBIT B**

Case ID: 080202733

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5 : FRANK SCHREFFLER, JR., : JURY TRIAL DEMANDED 6 PLAINTIFF, : APRIL TERM, 2008	6 7 8
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Page 5	Page 7
1 DIRECT EXAMINATION 1 A Yes, it is.	r ago r
2 Q Did you do anythir	ng to prepare for
3 BY MS. FISHER: 3 today's deposition, Doctor?	
4 Q Good afternoon, Doctor. 4 A No. No.	
5 A Hi. 5 Q Did you look at an	y records, any medical
6 Q My name is Donna Fisher and I'm here 6 files?	
7 today on behalf of GlaxoSmithKline to ask you some 7 A No. I had none av	ailable.
8 questions about your treatment of the plaintiff in a 8 Q Did you review an	y medical literature or
9 litigation that brought against GlaxoSmithKline 9 any news releases or news	oress releases or anything
10 involving the drug Avandia. 10 like that?	
11 I am going to show you a document that 11 A No.	
	nyone in preparation
13 the subpoena, the notice of deposition for this 13 of today's deposition?	
14 deposition. The court reporter will mark it as 14 A No.	
	conversations with Frank
16 (Notice of Videotaped Deposition marked 16 Schreffler, the plaintiff, abou	t this deposition or
17 Osevala Exhibit No. 1.) 17 this lawsuit?	
18 BY MS. FISHER: 18 A No.	
	ken to anyone in his
20 at it, if you need to. 20 family about the lawsuit?	
21 A Yes. Okay. 21 A No.	
	2, which is your CV, I
23 for your deposition. Have you seen this document 23 just want to ask you a few quantum of the control of the	-
24 before? 24 background, your education	-
25 A Yes. 25 You attended Penn	sylvania State
Page 6  1 Q If you turn to Exhibit A of the Exhibit 1 University?	Page 8
1 Q If you turn to Exhibit A of the Exhibit 1 University? 2 1, it lists certain documents that you were asked to 2 A Correct.	
3 bring, look for and bring with you.  3 Q And graduated fro	m there in 1977?
4 A I do see that, yes. 4 A Yes.	in there in 1977:
	CV, Exhibit 2, you then
6 emergency, presumably at the hospital 6 went to Pennsylvania State	-
7 A Yes. 7 medical school, is that corre	
8 Q so you did not come in with any 8 A That's correct.	
9 documents. 9 Q And what degree of	did vou get there?
10 We did receive documents from the medical 10 A A master's degree	, ,
11 records service. I will show them to you in a minute. 11 Q In?	
12 And when we do that, I would like you to be able to 12 A Physiology.	
, , ,	Philadelphia College of
14 your files, original files, that you can remember of 14 Osteopathic Medicine?	
15 that would not be there. 15 A Correct.	
16 A Okay. 16 Q And what years we	ere you there?
17 Q We've also asked for your CV. And we 17 A 1981 to 1985.	· ·
	duated, what degree did
	duated, what degree did
18 have been provided with a current version of your CV, 18 Q And when you gra	duated, what degree did
<ul> <li>18 have been provided with a current version of your CV,</li> <li>19 which I am going to have marked as Osevala Exhibit 2.</li> <li>18 Q And when you gra</li> <li>19 you receive?</li> </ul>	
18 have been provided with a current version of your CV, 19 which I am going to have marked as Osevala Exhibit 2. 20 (Curriculum vitae marked Osevala Exhibit 2. 20 A D.O.	-
18 have been provided with a current version of your CV, 19 which I am going to have marked as Osevala Exhibit 2. 20 (Curriculum vitae marked Osevala Exhibit 21 No. 2.)  18 Q And when you gra 19 you receive? 20 A D.O. 21 Q Did you then do an	n internship?
18 have been provided with a current version of your CV, 19 which I am going to have marked as Osevala Exhibit 2. 20 (Curriculum vitae marked Osevala Exhibit 20 A D.O. 21 No. 2.) 22 BY MS. FISHER: 28 A Yes.	n internship? e internship?

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1		Page 9			Page 11
1	Α	One year.	1	Q ,	According to your resumé, you then moved
2	Q	And what was that in?	2		or you moved to Central Pennsylvania?
3	Α	A rotating internship.	3	Α `	Yes.
4	Q	You then did a general surgery residency?	4	Q ·	To Lemoyne
5	Α	Yes.	5		Yes.
6	Q	And where was that?	6	Q ·	Pennsylvania, in July of 2000?
7	Α	At Suburban General Hospital.	7		Yes.
8	Q	And how long did that last?	8		And have you been in this area since
9	Α	Four years.	9	then?	•
10	Q	And that was just general surgery?	10	Α `	Yes.
11	Α	Yes.	11		You are not with, obviously, Shaffer
12	Q	You then did a fellowship?	12		cular Surgical Institute anymore, is that
13	Α	Yes.	13		, i i, i
14	Q	Can you describe that, please.	14		Correct, yes.
15	A	Cardiothoracic surgical fellowship.	15		When did you leave Shaffer Cardiovascular
16	Q	Was that two years?			
17	A	Two years, correct.	17	• •	The practice closed in December of 2003.
18	Q	Is that the end of your formal	18		Did you then come to this practice, or
19		•	19		rm this practice at that time?
20	Α	Yes.	20	-	No; I came to this practice at that time.
21	Q	institutional with an institution?	21		And the name of the practice you're
22	Ā	Yes.	22	currently in	
23	Q	What did you do next?	23	-	The Capital Area Cardiovascular Surgical
24	A	I stayed on to work at Jersey Shore Heart			The Suphar Area Surdievassarar Surgical
	Institute.	Total out to Work at Goldey Chord Hourt	25		And how many surgeons do you have are
		Davis 40			
1	Q	Page 10  Did you develop a specialty there of any	1	there in the	Page 12 e group, Doctor?
	sorts?	Did you develop a specially there of any	2		Currently there are five.
3	A	Cardiothoracic surgery, yes.	3		What states do you hold medical licenses
4	Q	And you stayed there for how long?		in?	What states do you hold medical licenses
5	A	Thirteen months initially.	5		Pennsylvania.
6	Q	I look at your resumé, and it looks like	6		You at one point held licenses in
1		went West to South Dakota.			ey and South Dakota?
8	A	Yes.	8		Correct.
9	Q	Why did you go to South Dakota?	9		And you no longer keep those licenses
1 3	Q			Q /	And you no longer keep those licenses
	Λ	A job opportunity	10		, , ,
10	A	And you were out there for a year almost?		active?	
10 11	Q	And you were out there for a year almost?	11	active?	Correct.
10 11 12	Q A	And you were out there for a year almost? One year, yes.	11 12	active?  A (	Correct. Could you just give us name the
10 11 12 13	Q A Q	And you were out there for a year almost? One year, yes. Was that a did you only plan to stay a	11 12 13	active?  A ( Q (  profession	Correct. Could you just give us name the al associations you belong to.
10 11 12 13 14	Q A Q year the	And you were out there for a year almost? One year, yes. Was that a did you only plan to stay a re or	11 12 13 14	active?  A C Q C profession A F	Correct. Could you just give us name the al associations you belong to. Pennsylvania Osteopathic Medical
10 11 12 13 14 15	Q A Q year then A	And you were out there for a year almost? One year, yes. Was that a did you only plan to stay a re or No, no.	11 12 13 14 15	active?  A (Q (profession A F Associatio	Correct. Could you just give us name the al associations you belong to. Pennsylvania Osteopathic Medical n, the American College of Osteopathic
10 11 12 13 14 15 16	Q A Q year then A Q	And you were out there for a year almost? One year, yes. Was that a did you only plan to stay a re or No, no. You planned to stay longer?	11 12 13 14 15 16	active?  A (Q)  profession  A F  Associatio  Surgeons,	Correct. Could you just give us name the al associations you belong to. Pennsylvania Osteopathic Medical n, the American College of Osteopathic the American Osteopathic Association, the
10 11 12 13 14 15 16 17	Q A Q year then A Q A	And you were out there for a year almost? One year, yes. Was that a did you only plan to stay a re or No, no. You planned to stay longer? Yes.	11 12 13 14 15 16 17	active?  A C Q C profession A F Associatio Surgeons, Society of	Correct. Could you just give us name the al associations you belong to. Pennsylvania Osteopathic Medical n, the American College of Osteopathic the American Osteopathic Association, the Thoracic Surgeons, Dauphin County Medical
10 11 12 13 14 15 16 17	Q A Q year then A Q A	And you were out there for a year almost? One year, yes. Was that a did you only plan to stay a re or No, no. You planned to stay longer? Yes. You then moved back East	11 12 13 14 15 16 17 18	active?  A C Q C profession A F Associatio Surgeons, Society of Society, th	Correct. Could you just give us name the al associations you belong to. Pennsylvania Osteopathic Medical n, the American College of Osteopathic the American Osteopathic Association, the Thoracic Surgeons, Dauphin County Medical the Pennsylvania Society of Thoracic
10 11 12 13 14 15 16 17 18	Q A Q year then A Q A Q A	And you were out there for a year almost? One year, yes. Was that a did you only plan to stay a re or No, no. You planned to stay longer? Yes. You then moved back East Yes.	11 12 13 14 15 16 17 18 19	active?  A (Q)  Q (profession  A F  Associatio  Surgeons,  Society of  Society, th  Surgeons,	Correct. Could you just give us name the al associations you belong to. Pennsylvania Osteopathic Medical n, the American College of Osteopathic the American Osteopathic Association, the Thoracic Surgeons, Dauphin County Medical the Pennsylvania Society of Thoracic and a former member of the New Jersey
10 11 12 13 14 15 16 17 18 19 20	Q A Q year then A Q A Q A	And you were out there for a year almost? One year, yes. Was that a did you only plan to stay a re or No, no. You planned to stay longer? Yes. You then moved back East Yes back to Neptune?	11 12 13 14 15 16 17 18 19 20	active?  A C Q C profession A F Associatio Surgeons, Society of Society, th Surgeons, Society of	Correct. Could you just give us name the al associations you belong to. Pennsylvania Osteopathic Medical n, the American College of Osteopathic the American Osteopathic Association, the Thoracic Surgeons, Dauphin County Medical the Pennsylvania Society of Thoracic and a former member of the New Jersey Thoracic Surgeons.
10 11 12 13 14 15 16 17 18 19 20 21	Q A Q year then A Q A Q A	And you were out there for a year almost? One year, yes. Was that a did you only plan to stay a re or No, no. You planned to stay longer? Yes. You then moved back East Yes back to Neptune? And why was that?	11 12 13 14 15 16 17 18 19 20 21	active?  A C Q C Profession  A F Associatio Surgeons, Society of Society, the Surgeons, Society of Q C C C C C C C C C C C C C C C C C C	Correct. Could you just give us name the al associations you belong to. Pennsylvania Osteopathic Medical n, the American College of Osteopathic the American Osteopathic Association, the Thoracic Surgeons, Dauphin County Medical the Pennsylvania Society of Thoracic and a former member of the New Jersey Thoracic Surgeons. When I look at your resumé, your CV/ your
10 11 12 13 14 15 16 17 18 19 20 21 22	Q A Q year then A Q A Q A Q	And you were out there for a year almost? One year, yes. Was that a did you only plan to stay a re or No, no. You planned to stay longer? Yes. You then moved back East Yes back to Neptune? And why was that? Primarily illness in my wife's family.	11 12 13 14 15 16 17 18 19 20 21 22	active?  A C Q 0 profession A F Associatio Surgeons, Society of Society, th Surgeons, Society of Q V resumé, th	Correct. Could you just give us name the al associations you belong to. Pennsylvania Osteopathic Medical n, the American College of Osteopathic the American Osteopathic Association, the Thoracic Surgeons, Dauphin County Medical the Pennsylvania Society of Thoracic and a former member of the New Jersey Thoracic Surgeons. When I look at your resumé, your CV/ your the hospital staff positions, it appears that
10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q A Q year then A Q A Q A Q	And you were out there for a year almost? One year, yes. Was that a did you only plan to stay a re or No, no. You planned to stay longer? Yes. You then moved back East Yes back to Neptune? And why was that? Primarily illness in my wife's family. And you stayed in Neptune, New Jersey,	11 12 13 14 15 16 17 18 19 20 21 22 23	active?  A C Q C Profession  A F Associatio  Surgeons, Society of Society, th Surgeons, Society of Q V  resumé, th you have t	Correct. Could you just give us name the al associations you belong to. Pennsylvania Osteopathic Medical n, the American College of Osteopathic the American Osteopathic Association, the Thoracic Surgeons, Dauphin County Medical the Pennsylvania Society of Thoracic and a former member of the New Jersey Thoracic Surgeons. When I look at your resumé, your CV/ your the hospital staff positions, it appears that the treating privileges at five local hospitals;
10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q A Q year then A Q A Q A Q	And you were out there for a year almost? One year, yes. Was that a did you only plan to stay a re or No, no. You planned to stay longer? Yes. You then moved back East Yes back to Neptune? And why was that? Primarily illness in my wife's family. And you stayed in Neptune, New Jersey,	11 12 13 14 15 16 17 18 19 20 21 22 23	active?  A C Q C O Profession  A F Associatio Surgeons, Society of Society, the Surgeons, Society of Q C C Presumé, the you have the is that corrections and the society of	Correct. Could you just give us name the al associations you belong to. Pennsylvania Osteopathic Medical n, the American College of Osteopathic the American Osteopathic Association, the Thoracic Surgeons, Dauphin County Medical the Pennsylvania Society of Thoracic and a former member of the New Jersey Thoracic Surgeons. When I look at your resumé, your CV/ your the hospital staff positions, it appears that the treating privileges at five local hospitals;

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	Page 13			Page 15
1	exact number.	1	•	ations on your CV.
2	Q Do you conduct your surgery primarily at	2	Α	Yes.
3	one or two hospitals?	3	Q	Those were all done while you were in
4	A At two hospitals.	4		sey as well?
5	Q And what hospitals are they?	5	Α	Yes.
6	A Holy Spirit Hospital and Harrisburg	6	Q	Thank you.
	Hospital, the PinnacleHealth system.	7		Have you ever been deposed before?
8	Q So even though you have, it looks like,	8	A	Yes.
	treating privileges at Carlisle Regional Medical	9	Q	In what circumstance? What type of case?
	Center, you tend not to go there for surgery, to do	10	Α	A medical malpractice case.
11	surgery?	11	Q	Were you a party in that case?
12	A That's correct.	12	A	Yes.
13	Q Do you are you at one hospital more	13	Q	And did the case go to trial?
	than the other? Are you at Pinnacle more than at Holy	14	A	Yes.
1	Spirit, or do you split your time fairly equally?	15	Q	In Dauphin County?
16	A Fairly equally.	16	A	No.
17	Q And is that the same for most of the	17	Q	Where was that?
	doctors in your practice?	18	A	New Jersey.
19	A I think it is, yes.	19	Q	Where did the case go to trial? New
20	Q Your business address is 423 North 21st	20	Jersey?	
21		21		Is that the only time you were deposed?
22	A Yes.	22	A	No.
23	Q Camp Hill?	23	. Q	When else what other cases were you
24	Since coming to the Central Pennsylvania		deposed	
25	area, have you written any publications or online	25	Α	Other times in New Jersey.
4	Page 14	,	0	Page 16
1	or A No.	1	Q	Since coming to Central Pennsylvania,
2			-	u been deposed?
3 4	Q hard copy?	3	A	Yes. In what type of case have they been in?
5	Are you on any editorial boards?  A No.	4	Q	in what type of case have they been in?
6		[	Λ	* '
		5	A	Medical malpractice.
-	Q Have you done any presentations or any	6	Q	Medical malpractice. Were you the defendant in that case?
7	Q Have you done any presentations or any speaking?	6 7	Q A	Medical malpractice. Were you the defendant in that case? Yes.
7 8	Q Have you done any presentations or any speaking? A No.	6 7 8	Q A Q	Medical malpractice. Were you the defendant in that case? Yes. And did it go to trial?
7 8 9	Q Have you done any presentations or any speaking?  A No.  Q And have you participated in any clinical	6 7 8 9	Q A Q A	Medical malpractice. Were you the defendant in that case? Yes. And did it go to trial? No.
7 8 9 10	Q Have you done any presentations or any speaking?  A No. Q And have you participated in any clinical studies or trials?	6 7 8 9 10	Q A Q A Q	Medical malpractice. Were you the defendant in that case? Yes. And did it go to trial? No. It was resolved before going to trial?
7 8 9 10 11	Q Have you done any presentations or any speaking? A No. Q And have you participated in any clinical studies or trials? A No.	6 7 8 9 10 11	Q A Q A Q A	Medical malpractice. Were you the defendant in that case? Yes. And did it go to trial? No. It was resolved before going to trial? It's in the process.
7 8 9 10 11 12	Q Have you done any presentations or any speaking?  A No. Q And have you participated in any clinical studies or trials? A No. Q Prior to coming to Central Pennsylvania,	6 7 8 9 10 11 12	Q A Q A Q	Medical malpractice. Were you the defendant in that case? Yes. And did it go to trial? No. It was resolved before going to trial? It's in the process. All right.
7 8 9 10 11 12 13	Q Have you done any presentations or any speaking?  A No. Q And have you participated in any clinical studies or trials? A No. Q Prior to coming to Central Pennsylvania, did you do any of those activities?	6 7 8 9 10 11 12 13	Q A Q A Q A	Medical malpractice. Were you the defendant in that case? Yes. And did it go to trial? No. It was resolved before going to trial? It's in the process. All right. So you've been deposed more than once,
7 8 9 10 11 12 13 14	Q Have you done any presentations or any speaking?  A No. Q And have you participated in any clinical studies or trials? A No. Q Prior to coming to Central Pennsylvania, did you do any of those activities? A Yes.	6 7 8 9 10 11 12 13 14	Q A Q A Q A Q	Medical malpractice. Were you the defendant in that case? Yes. And did it go to trial? No. It was resolved before going to trial? It's in the process. All right. So you've been deposed more than once, by?
7 8 9 10 11 12 13 14 15	Q Have you done any presentations or any speaking?  A No. Q And have you participated in any clinical studies or trials? A No. Q Prior to coming to Central Pennsylvania, did you do any of those activities? A Yes. Q Was that when you were in New Jersey?	6 7 8 9 10 11 12 13 14 15	Q A Q A Q A Q obviousl A	Medical malpractice. Were you the defendant in that case? Yes. And did it go to trial? No. It was resolved before going to trial? It's in the process. All right. So you've been deposed more than once, y? Yes.
7 8 9 10 11 12 13 14 15 16	Q Have you done any presentations or any speaking?  A No. Q And have you participated in any clinical studies or trials?  A No. Q Prior to coming to Central Pennsylvania, did you do any of those activities?  A Yes. Q Was that when you were in New Jersey? A Yes.	6 7 8 9 10 11 12 13 14 15 16	Q A Q A Q A Q obviousl A Q	Medical malpractice. Were you the defendant in that case? Yes. And did it go to trial? No. It was resolved before going to trial? It's in the process. All right. So you've been deposed more than once, ly?
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7 8 9 10 11 12 13 14 15 16 17 18	Q Have you done any presentations or any speaking?  A No. Q And have you participated in any clinical studies or trials? A No. Q Prior to coming to Central Pennsylvania, did you do any of those activities? A Yes. Q Was that when you were in New Jersey? A Yes. Q And did you publish did you have something published or did you write publications?	6 7 8 9 10 11 12 13 14 15 16 17 18	Q A Q A Q Obviousl A Q times? A	Medical malpractice. Were you the defendant in that case? Yes. And did it go to trial? No. It was resolved before going to trial? It's in the process. All right. So you've been deposed more than once, y? Yes. Can you give me an approximate number of Several.
7 8 9 10 11 12 13 14 15 16 17 18	Q Have you done any presentations or any speaking?  A No. Q And have you participated in any clinical studies or trials?  A No. Q Prior to coming to Central Pennsylvania, did you do any of those activities?  A Yes. Q Was that when you were in New Jersey? A Yes. Q And did you publish did you have something published or did you write publications? A Yes.	6 7 8 9 10 11 12 13 14 15 16 17 18 19	Q A Q A Q obviousl A Q times? A	Medical malpractice. Were you the defendant in that case? Yes. And did it go to trial? No. It was resolved before going to trial? It's in the process. All right. So you've been deposed more than once, y? Yes. Can you give me an approximate number of Several. Well, you know the rules of the
7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q Have you done any presentations or any speaking?  A No. Q And have you participated in any clinical studies or trials? A No. Q Prior to coming to Central Pennsylvania, did you do any of those activities? A Yes. Q Was that when you were in New Jersey? A Yes. Q And did you publish did you have something published or did you write publications? A Yes. Q And are they listed on your CV?	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q A Q A Q Obviousl A Q times? A Q deposition	Medical malpractice. Were you the defendant in that case? Yes. And did it go to trial? No. It was resolved before going to trial? It's in the process. All right. So you've been deposed more than once, ly? Yes. Can you give me an approximate number of Several. Well, you know the rules of the on so I'm not going to explain what's going to
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q Have you done any presentations or any speaking?  A No. Q And have you participated in any clinical studies or trials? A No. Q Prior to coming to Central Pennsylvania, did you do any of those activities? A Yes. Q Was that when you were in New Jersey? A Yes. Q And did you publish did you have something published or did you write publications? A Yes. Q And are they listed on your CV? A Yes.	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q A Q A Q obviousl A Q times? A Q depositio what I	Medical malpractice. Were you the defendant in that case? Yes. And did it go to trial? No. It was resolved before going to trial? It's in the process. All right. So you've been deposed more than once, y? Yes. Can you give me an approximate number of Several. Well, you know the rules of the on so I'm not going to explain what's going to 'm going to be doing or asking questions
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q Have you done any presentations or any speaking?  A No. Q And have you participated in any clinical studies or trials? A No. Q Prior to coming to Central Pennsylvania, did you do any of those activities? A Yes. Q Was that when you were in New Jersey? A Yes. Q And did you publish did you have something published or did you write publications? A Yes. Q And are they listed on your CV? A Yes. Q Were the publications written primarily	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q A Q A Q obviousl A Q times? A Q depositio what I about. E	Medical malpractice. Were you the defendant in that case? Yes. And did it go to trial? No. It was resolved before going to trial? It's in the process. All right. So you've been deposed more than once, y? Yes. Can you give me an approximate number of Several. Well, you know the rules of the on so I'm not going to explain what's going to 'm going to be doing or asking questions But the only thing we need to remember and
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q Have you done any presentations or any speaking?  A No. Q And have you participated in any clinical studies or trials? A No. Q Prior to coming to Central Pennsylvania, did you do any of those activities? A Yes. Q Was that when you were in New Jersey? A Yes. Q And did you publish did you have something published or did you write publications? A Yes. Q And are they listed on your CV? A Yes. Q Were the publications written primarily while you were doing your education or afterwards?	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q A Q A Q obviousl A Q times? A Q depositio what I about. E you're ve	Medical malpractice.  Were you the defendant in that case?  Yes.  And did it go to trial?  No.  It was resolved before going to trial?  It's in the process.  All right.  So you've been deposed more than once,  ly?  Yes.  Can you give me an approximate number of  Several.  Well, you know the rules of the on so I'm not going to explain what's going to  'm going to be doing or asking questions  But the only thing we need to remember and ery good at this, I have to say is wait
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q Have you done any presentations or any speaking?  A No. Q And have you participated in any clinical studies or trials? A No. Q Prior to coming to Central Pennsylvania, did you do any of those activities? A Yes. Q Was that when you were in New Jersey? A Yes. Q And did you publish did you have something published or did you write publications? A Yes. Q And are they listed on your CV? A Yes. Q Were the publications written primarily	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	Q A Q A Q obviousl A Q times? A Q depositio what I about. E you're vo	Medical malpractice. Were you the defendant in that case? Yes. And did it go to trial? No. It was resolved before going to trial? It's in the process. All right. So you've been deposed more than once, y? Yes. Can you give me an approximate number of Several. Well, you know the rules of the on so I'm not going to explain what's going to 'm going to be doing or asking questions But the only thing we need to remember and

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1 for the court reporter.

- 2 If I ask an inarticulate question that
- 3 you don't understand, just tell me and I will try to
- 4 do a better job.
- Have you ever served as an expert witness in litigation?
- 7 A No.
- 8 Q Your speciality is cardiothoracic
- 9 surgery, is that correct?
- 10 A Yes.
- 11 Q Could you just generally describe your
- 12 practice.
- 13 A Personal practice or --
- 14 Q Yes, your personal practice.
- 15 A Primarily the practice -- my part of the
- 16 practice consists of coronary bypass surgery, aortic
- 17 valve replacement surgery and general thoracic
- 18 surgery, including lung surgery, esophageal surgery
- 19 and chest wall surgery, in addition to evaluating
- 20 patients for prospective surgery preoperatively and
- 21 managing and taking care of patients postoperatively
- 22 as well.
- 23 Q Let me just ask you a couple of follow-up
- 24 questions.
- 25 You referred to treating them -- meeting

Page 18

- 1 with them pre -- assessing them for surgery presurgery2 and then postsurgery as well.
- 3 Do patients tend to stay with your
- 4 practice for a long period of time or is it
- 5 surgery-specific?
- 6 A It's a surgery-specific practice.
- 7 Q Do most of your patients come to you --
- 8 when you said you meet with them to discuss potential
- 9 surgery, what percentage of your patients meet you in
- 10 the office and discuss future surgery versus
- 11 presenting themselves to the hospital and that's where
- 12 you meet them?
- 13 A Personally? For my practice?
- 14 Q Yes, for your practice.
- 15 A I would say 15 to 20 percent in the
- 16 office. The remainder are hospital.
- 17 Q When you meet them in the hospital and
- 18 you're treating them in the hospital, is that -- is
- 19 surgery usually conducted sort of on an emergency
- 20 basis?
- 21 A No.
- 22 Q So they would be discharged from the
- 23 hospital and then come back for surgery?
- 24 A Sometimes they are, yes.
- 25 Q Do you know what percentage of the

1 patients you meet in the hospital are emergency

2 versus -- is it elective, the opposite of emergency?

3 A True emergency surgery is probably 5 4 percent or less.

5 Q What about the age of your patients, if

6 you can draw any generalities? Are they over a

- 7 certain age for the most part? Can you give a
- 8 breakdown of the age of your patients?
  - A The majority of them are older, probably
- 10 over 65. The majority of patients would be in that
- 11 age category.

9

- 12 Q What percentage, if you can give me a
- 13 general percentage, of your patients that you operate
- 14 on have diabetes?
- 15 A A large percentage. 70 percent or more.
- 16 Q What percentage of your patients whom you
- 17 operate on have family histories of cardiovascular
- 18 problems?
- 19 A A large percentage. Probably 80 percent
- 20 or more.
- 21 Q We are here today, as I told you earlier,
- 22 in relation to litigation that has been brought by a
- 23 former patient, I guess, of yours, Frank Schreffler,
- 24 against GlaxoSmithKline concerning Avandia.
- 25 Do you have any recollection of

Page 20

Page 19

- ery 1 Mr. Schreffler?
  - 2 A No.
  - 3 Q The surgery you conducted was in 2006.
  - 4 So since that was three -- over three years ago, it's
  - 5 perfectly understandable.
  - 6 I am going to have the court reporter
  - 7 mark a copy of the medical records we have received
  - 8 from the medical service, medical records service.
  - 9 This will be Osevala Exhibit 3. And after she has
  - 10 marked it and hands it to you, then I would like you
  - 11 just do glance at it before I start asking you
  - 12 questions.
  - 13 (Medical records, SchrefflerF\_CSI\_0001
  - 14 through 0037, collectively marked Osevala Exhibit
  - 15 No. 3.)

20

- MS. FISHER: We can go off the record for
- 17 two minutes while he looks at that.
- 18 THE VIDEOGRAPHER: We are now going off
- 19 camera and the time is 3:38.
  - (Discussion held off the record.)
- 21 THE VIDEOGRAPHER: We are now back on
- 22 camera and the time is 3:40 p.m.
- 23 BY MS. FISHER:
- 24 Q Doctor, you've now had a chance to review
- 25 the medical records that I've attached as Exhibit 3.

Page 21 Page 23 Q 1 And as we discussed, there seems to be two copies of 1 Would you have reviewed any blood work 2 the same documents within this exhibit. One was faxed 2 that had been done? maybe -- perhaps one was faxed. One was not. 3 Α Yes. 3 4 Does reviewing these records refresh your 4 Q Would you have looked at his 5 catheterization results? memory about your treatment of Mr. Schreffler? 6 No. Α Yes. 6 7 Q 7 Q Okay. Would you have looked at the report or 8 the film? 8 Do you remember the circumstances under which you came to treat Mr. Schreffler? 9 Α Definitely the film and sometimes the 9 10 Not specifically, no. 10 report. 11 If you turn to page CSI\_0032 to 34, this 11 Q If you look at the last three pages --12 appears to be a report prepared by Timothy Walsh. 12 I'm sorry -- the next three pages, number 32 to 34, It's not signed, but Timothy Walsh's name, on page 34. 13 which is information dictated by Dr. Walsh, it was Do you see that? 14 dictated on May 8th of 2006 but not transcribed, it 14 15 Α 15 appears, until May 11th. So you would not have I see it, yes. Yes. 16 Q And you were copied on this report? 16 had this particular document to look at prior to examining Mr. Schreffler, correct? 17 Α 17 18 Q Do you know who Dr. Walsh is? 18 Α That's correct. 19 Q So would you have taken your own history 19 Yes. Α 20 Q Who is he? 20 of his complaints; or how would you -- what would you normally do? Α 21 He's a cardiologist. And is he a doctor you work with on cases 22 MR. SPIZER: Objection. 22 O 23 sometimes? 23 MS. FISHER: Let me try that question 24 Α Yes. 24 again. 25 Q You can tell from the top of page 32 that 25 Page 22 Page 24 1 the admission date for this patient, Mr. Schreffler, 1 BY MS. FISHER: was May 8th of 2006. Do you see that? 2 2 Again, recognizing you don't recall Α 3 Yes. 3 meeting with Mr. Schreffler in May of 2006, but Q If you turn to page number 30 at the 4 typically would you take a history from the patient? 4 5 bottom, 30 and 31. 5 Α Yes. 6 Q 6 Yes. So when -- I'm looking on document Α 7 Q Do you recognize that document? 7 number -- page number 30 where it says, "Dear Doctors, 8 Α 8 Thank you for allowing us to help in the care of 9 Q And was that document dictated by you? 9 Mr. Schreffler who is, as you know, a very pleasant 10 Α Yes. 10 59-year-old gentleman with history of diabetes for a Q Do you want to take just a few seconds, a 11 number of years and family history of coronary 11 12 disease. He was admitted yesterday with progressive minute, to read through that to see if it refreshes your memory of treating Mr. Schreffler? 13 13 angina after having chest pain and shortness of breath 14 Α Okay. 14 several weeks ago, and then it returned yesterday. He Q 15 Is this a letter or a document you would 15 was sent directly for catheterization today." 16 typically dictate after examining someone and before Would you have prepared that, dictated 16 doing surgery? 17 that, from information you obtained from 17 18 Mr. Schreffler directly? 18 Α Yes. 19 Q And I realize you have no recollection of 19 Α Yes. Q 20 actually treating Mr. Schreffler because it's been 20 Under past medical history, you stated, 21 several years. But let me ask a couple questions. 21 "significant for longstanding diabetes mellitis." Why 22 Prior to dictating this, what would you 22 would that be significant? 23 23 typically do with a patient? Would you have examined MR. SPIZER: Objection. 24 Mr. Schreffler? 24 You can answer. 25 25 Α Yes. MS. FISHER: You can answer.

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1 MR. SPIZER: There will be times I

2 object. Just pretend you're my wife and ignore me.

3 MS. FISHER: That can only get you into

4 trouble.

BY MS. FISHER: 5

6 Q But, yes, you can go ahead and answer the 7 question.

8 The statement "significant for

longstanding diabetes" indicates that that's a

positive finding in his history that he has diabetes.

11 Does the fact that it was longstanding

12 make a difference for purposes of your treatment of

him? 13

14 Α No, not really.

15 Q If you look at the bottom of page 30, you

16 reference his labs and then you describe the "cath

17 films reviewed and interpreted". Could you just

describe what the cath -- you were writing that the

cath films revealed or showed? 19

20 The catheterization films demonstrated

severe atherosclerotic occlusive coronary disease. 21

22 Since we are videoing this, it may be

23 shown to the jury, and so you need to make it a little

24 more clear for people like me who did not go to the

25 medical school what you just described.

Page 26

1 Α The films show that he has significant 2 severe blockage in his arteries that go to his heart,

3 that supply his heart with oxygen and blood. The

4 blockages are severe enough that they are, indeed,

5 life-threatening at this point.

6 In addition, the catheterization films

7 show that his heart function, although it has not --

8 it is not normal, it is not what we would consider to

9 be a completely normal functioning heart, it still has

10 adequate function to sustain him for his life -- for

11 his future life.

12 Q And that's referencing the ejection

13 fraction?

14 Α Correct, yes.

Q You referenced -- it states that right 15

16 dominant system. And you also reference later on

severe left main disease. Does that mean that the

right side was compensating for the left? 18

19 No. When we refer to right dominant 20 system in a catheterization film, it indicates which

21 coronary artery, the right side or the left side, a

22 particular artery originates from. And in his case,

23 the PDA, which is the posterior descending artery,

24 originates from the right side. And by convention

25 that's defined as a right dominant system, a right

1 dominant coronary circulation.

2 Q All right. And you stated that this was Page 27

3 life-threatening at this point, right?

4 Yes.

Q And according to the document you 5

6 dictated, you discussed this with Mr. Schreffler?

7 Yes.

8 Q And he was prepared to proceed with the

9 surgery, is that correct?

10 Α Yes.

11 Q If you go to page 28 and 29 of Exhibit 3,

12 is this the operating report?

13 Α Yes.

14 Q In layman's terms, could you describe

15 what you did for Mr. Schreffler that day, on May 9th

16 of 2006.

17 Mr. Schreffler had quadruple coronary

18 bypass surgery. He had four bypasses to the specific

19 arteries on his heart which were in jeopardy, which

20 were not receiving adequate blood and adequate oxygen

21 due to his severe coronary blockages. And so he had

22 four bypasses to those particular arteries, which were

23 going to supply his heart with additional oxygen and

24 blood.

25 Q And were there any complications during

Page 28

1 the surgery?

2 Α

3 Q I just want to back up a little bit.

5 history from him, do you know -- let me strike that.

6

as progressive -- is it angino, angina?

Α 8 Angina, yes.

Angina. What does progressive mean?

11 angina?

9

12

13 a low level, tolerable, but increases in severity and

16 Dr. Walsh, it refers to Mr. Schreffler reporting that

18 indigestion or reflux and he treated it with Maalox at

Is that normal for someone to first treat

21 this type of pain as reflux or indigestion?

22 MR. SPIZER: Objection.

23 Α It's not unusual.

24 BY MS. FISHER:

25 O That's a better word. So it's not

4 Before you operated on him and you were taking a

Going back to page 30, you referenced it

Q

10 What do you mean when you refer to it as progressive

Α That the chest pain perhaps starts off at

14 frequency over a course of perhaps days or weeks.

15 Q In the information that was recorded by

17 he had actually treated it -- he thought it was

19 first.

20

Page 29 Page 31 Q 1 unusual for someone to think it's ingestion first or 1 If you turn to page 23 of Osevala Exhibit 2 reflux? 2 3, could you explain to me or describe to me what this 3 Α 3 is. Correct. 4 Q And is there a reason why Maalox might 4 Α This is a -- an office visit summary 5 sheet which is used in the office when patients come help the symptoms at first? 6 in for visits. Α Not to my knowledge, no. 7 7 Q If you turn to page 27 of Exhibit 3, this Q Can you tell who saw him when he came 8 is the discharge diagnosis, is that correct? in for an office visit on May 9th of 2006? 9 It's the discharge summary. 9 Dr. Park. Α 10 Q 10 Q I'm sorry. Discharge summary? If you turn to Exhibit 3, page 22, 11 Α Yes. 11 there's a letter from Dr. Park dated May 16th of 2006. Q 12 In the second sentence -- and this was 12 Do you see that? prepared by you, correct? 13 Α Yes. 13 14 Α 14 Q Yes. And he referenced seeing Mr. Frank 15 Q 15 Schreffler in the office today. So this was -- the In the second sentence, it states, "The patient is a pleasant 59-year-old gentleman with 16 letter was sent the same day that he saw him, is that extensive history of progressive coronary syndrome." 17 correct? 17 18 Again, I'm going to ask you to describe 18 Α Yes. Q what you mean by progressive coronary syndrome. 19 This would be one week after the surgery, 19 20 Chest pain and difficulty with perhaps 20 is that correct? 21 Α Yes. 21 breathing on an ongoing, continual basis that, again, 22 increases in severity and frequency as days and weeks O And why would Dr. Park have seen 23 Mr. Schreffler instead of you? go by. 24 Q When you did the surgery, did you have 24 I believe that I was doing an emergency 25 any way -- was there any way for you to tell how long 25 operation, emergency surgery, and so Dr. Park was kind Page 32 the syndrome or the blockage had been developing? 1 enough to see the patient. 1 2 2 Α Q All right. Q 3 Was it a matter of days, weeks, 3 According to the letter that Dr. Park 4 wrote to Dr. -- is it Maini? 4 months? 5 MR. SPIZER: Objection. 5 Α Dr. Maini, yes. 6 6 Q -- Maini, he ordered Keflex for No way to tell. 7 BY MS. FISHER: 7 Mr. Schreffler? 8 No way to tell at all. 8 Α Keflex, yes. 9 If you turn to page 25 of Exhibit 3, can 9 O Keflex. I'm sorry. 10 you describe -- tell me what this is? 10 And what -- why would that have been This is a report of a phone call that's 11 ordered for Mr. Schreffler? 11 12 received at the office from a patient. 12 Keflex is an antibiotic. And frequently 13 It appears that Mr. Schreffler had called 13 when incisions or wounds are draining, antibiotics are 14 and reported that his wound had started draining --14 ordered as a treatment. 15 Α Yes. 15 Q And Dr. Park was sending this to -- is that correct? 16 Q 16 Dr. Maini because, is Dr. Maini his cardiologist? 17 Is that a common problem after surgery? 17 Dr. Maini and Dr. Walsh are in the same Α 18 18 cardiology practice, yes. 19 Q Okay. Do you know why this happened with 19 Q They're with the Moffitt Group? Α Mr. Schreffler's wound? 20 Yes. 20

21

24

25

Q

Α

Q

Yes.

that, is that correct?

Yes.

It looks as though you were originally

scheduled to see him but then you had to reschedule

Α

Q

21

22

24

25

Control No.: 10012195

If you turn to page 20 and 21 of Exhibit

And the letter dated May 23rd, prepared

22 3, based on what you said, page 21 is the -- sort of

the notes, the office visit notes that are prepared?

Page 33 Page 35 1 Α 1 the same day, is numbered page 20, is that correct? Infrequently. 2 Q 2 Α Yes. What would cause you to discuss it with 3 Q This was your follow-up visit with 3 the patient? 4 Mr. Schreffler after his surgery? 4 Α If they would have a particular question 5 Α Yes. about perhaps the time of day or something along that 6 Q 6 line. And he is about two weeks post-operation, 7 7 Q postsurgery, is that correct? If you look at page 20, which is the May 8 Α Yes. 23rd letter to Dr. Perna, you prepared this letter? 9 Q If you turn to page 21, which is the 9 Α 10 office visit notes, it says "no med list." Does that 10 Q By sending this letter, were you mean he did not bring a med list with him to the 11 discharging Mr. Schreffler from your care back to 12 office visit? 12 Dr. Perna? 13 Α It could. That sometimes does occur. 13 Α Yes. 14 O What else could that mean, the no med 14 Q When you read through this letter, do you 15 list? 15 believe this would be the last time you saw Α That the patient was not aware of which 16 Mr. Schreffler? 16 17 Α Yes. 17 medications that he or she was taking. Q 18 Then there's a list of six medications 18 Looking at the letter, the first 19 underneath that in someone's handwriting, is that 19 paragraph, the last sentence states, "He is doing 20 correct? 20 guite well at this time without any major issues." 21 21 Α Yes. Had the infection or the drainage 22 Would that have been information that he 22 resolved itself at that time, do you believe? 23 gave the person writing these notes? 23 I don't recall. 24 Q 24 Α It could have been. If you look at the notes, the office 25 Q While he was in the hospital for the 25 notes on the next page, someone wrote, "last two days Page 34 1 very minimal discharge." Would that have been what he 1 surgery, would he have been on these medications to 2 the best of your knowledge, or you don't recall? 2 would have reported to you or someone in 3 your office? 3 Α I don't recall. Q 4 Α 4 The list of medications include Yes. Amiodarone? Is that how you pronounce it? 5 Q If the infection had not resolved, you 5 6 Amiodarone. would have -- would you have mentioned it in your Α 6 7 Q Yes, Amiodarone. 7 letter --8 Is that something you typically prescribe 8 Α Q 9 for patients who have gone through surgery? 9 -- to draw Dr. Perna's attention to it? 10 Α Yes. 10 Α Yes. O Q Did you also prescribe the Lopressor 11 And why is that? 11 12 Α It helps prevent irregular heart beats. 12 that's listed on the med list for Mr. Schreffler? I saw somewhere, maybe his discharge 13 Either myself or the cardiologist who was 14 note, that he was on that for only one month. Is that 14 taking care of him prior to discharge would have been

16

13 a typical time period for it? Α Yes. 16 17 Q At this point was he still on the Keflex? Α Which point? 18 19 Q On May 23rd, when you last saw him. Α I wouldn't be able to say for sure. 20 21 Do you recall whether you discussed with

22 him any of the medications he was taking for diabetes? 23 Α No.

24 Is that something you would ever discuss, 25 is the medication a patient was on for diabetes?

Osevala, Mark, D.O.

15 responsible for that. Q I noticed that you copied the Moffitt

17 Heart and Vascular Group in your letter of May 23rd. 18 Α Yes. 19 Q Was that because Mr. Schreffler would be

20 continuing to consult with a member of that group? 21 Α Yes.

22 Q Do you know looking at these records 23 whether or not Mr. Schreffler's heart had sustained 24 any permanent damage as a result of the heart attack? 25 No.

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1	Page 37 MR. SPIZER: Objection.	1	Page 39 patient is diabetic, with a family history of coronary
	BY MS. FISHER:		artery disease?
3	Q No, you don't know or	3	A No.
4	A I do not know.	4	Q The same message to everyone?
5	Q If you turn to the next page, which is	5	A Yes.
6	page number 19, can you tell me what this is?	6	Q Earlier you said about 80 percent, I
7	A This is a note from our office which	7	believe, of your patients are diabetic.
8	essentially allows the patient to return to	8	A Yes.
9	activities, work, that kind of thing.	9	Q Is that because diabetes is a risk factor
10	Q It states, "Restrictions or limitations:		for cardiovascular disease?
11		11	A Yes.
	pounds for 4 months after surgery date."	12	Q If you look at page 19, the I'm going
13	At the end of the four months, would he		to say it's a note to allow Mr I think you
	have any would Mr. Schreffler have any		described it as a note to allow Mr. Schreffler to go
	restrictions?	15	
16	A No.	16	A Yes.
17	Q So he would be able to hunt and fish as	17	Q It states, This is to verify that the
18	he wanted?	18	above patient has been under our care since May 8th of
19	A Yes.		2006. And it's dated June 6th of '06.
20	Q Okay. And even before the four months,	20	But by that time, you had already
21	would he be able to go to the gym as long as he didn't	21	discharged Mr. Schreffler to Mr. Perna's care and the
22	lift more than 10 pounds?	22	cardiologist group, is that correct?
23	A Yes.	23	A Correct.
24	Q Do you recall or looking at this letter,	24	Q If you look at the documents that are
25	does it refresh your memory whether or not you would	25	included in Exhibit 3 and I realize you don't have
	Page 38		Page 40
1		1	Page 40 your original files/records with you in front of you,
1 2	=		-
	have given him any type of prognosis?	2	your original files/records with you in front of you, but can you think of any documents that you would have
2	have given him any type of prognosis?  A No.  Q You just don't have any recollection?  A No, I don't.	2	your original files/records with you in front of you, but can you think of any documents that you would have in your file normally that are not in this group?  A No.
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Page 43 1 Q So Mr. Schreffler testified that you told 1 Α No. 2 him he had three strikes against him with his 2 MS. FISHER: If we could go off the 3 diabetes. Do you have any recollection of that? 3 record for about two minutes, I probably am done. I 4 4 just want to make sure. And then turn it over to you. 5 MR. SPIZER: Objection. 5 MR. SPIZER: Sure. 6 BY MS. FISHER: 6 THE VIDEOGRAPHER: We are now going off 7 Is that something -- do you ever 7 camera and the time is 4:14. 8 opine as to a cause of a heart attack? 8 (Recess.) 9 I'm sorry. Could you repeat the 9 THE VIDEOGRAPHER: We are now back on 10 question? 10 camera and the time is 4:18. 11 Q Strike that. It was a bad question. 11 BY MS. FISHER: 12 Do patients typically ask for a reason or 12 Q I just have a few more questions for you. 13 a cause -- what caused their heart attacks or the 13 I think you mentioned that occasionally 14 blockage? 14 you might question a patient's medication if you think 15 Α Yes. 15 it's the wrong medication for that patient, is that 16 MR. SPIZER: Objection. 16 correct? 17 BY MS. FISHER: 17 Α No. 18 Do you provide answers to the patients 18 MR. SPIZER: Objection. 19 when they ask those questions? 19 BY MS. FISHER: 20 Α Yes. 20 Q When we were looking at Mr. Schreffler's 21 Q Is there a typical response that you have 21 list of medications, I asked if you ever suggested 22 to patients? 22 changes in the medication to the treating physician, 23 MR. SPIZER: Objection. 23 is that correct? 24 Α Yes. 24 Α Yes. 25 25 Q Do you remember that? Page 42 Page 44 1 BY MS. FISHER: And have you ever made any suggestions or 1 2 And what is that typical response? 2 recommendations on changing medication? 3 3 MR. SPIZER: Objection. Α Yes. Q 4 Heart attacks are commonly caused by 4 Under what circumstances would you do 5 blockage in the heart arteries, which is a result of 5 that? 6 buildup of fatty plaque and deposits over a period of 6 Usually it's blood pressure medication, 7 time. The plaque can become so big and so obtrusive 7 adjustments for the patient's blood pressure when it's 8 that clots can form on the fatty deposits, which can 8 either too high or too low, or medications that affect the heart rate. If the heart rate is too high or too 9 suddenly shut off blood flow to that area of the 10 heart. That can result in a heart attack. Or the 10 low, medications there can be adjusted. 11 deposits can build up slowly and eventually totally 11 If a patient is on a diabetic drug, a TZD 12 block off your artery, and that can cause a heart 12 or anything like that, do you ever make any 13 attack. 13 recommendations about the diabetic drug --14 BY MS. FISHER: 14 Α No. Q Do you typically discuss risk factors 15 -- the drug for diabetes? 15 16 with patients who you've performed this bypass surgery Α 16 17 on? 17 Q The medical records that we've -- strike 18 Α 18 that. Yes. 19 Q In Mr. Schreffler's case, since he was 19 The records that are attached included in 20 diabetic and also had a family history with his mother 20 Exhibit 3, are these kept in your normal course of having had bypass surgery at the age of 68, would you 21 business? 22 22 have discussed those risk factors with him? Α Yes. 23 23 Q Α Yes. Were you aware that Mr. Schreffler had 24 Q Have you ever opined whether a medication 24 brought a lawsuit against GlaxoSmithKline regarding

25 the use of Avandia?

25 has caused a heart attack?

	Page 45		Page 47
1	A No.	1	A No.
2	MS. FISHER: I have no further questions	2	Q Okay. In the recent past, in the last
3		3	few years, have you ever spoken on behalf of a
4		4	pharmaceutical company?
5	CROSS-EXAMINATION	5	A No.
6		6	Q Okay. Have you ever done any work for
7	BY MR. SPIZER:	7	the defendant in this case, GlaxoSmithKline, either as
8	Q Doctor, good afternoon. Thank you for	8	a consultant or a speaking engagement, something like
9	your time.	9	that?
10	A Sure.	10	A No.
11	Q My name is Greg Spizer and I represent	11	Q Okay. Have you ever done that for any
12	Frank Schreffler. Mr. Schreffler alleges that his May	12	pharmaceutical company?
13	2006 heart attack was caused by his use of Avandia.	13	A No.
14	And I'm just going to have some additional questions	14	Q Okay. How did you become aware that your
15	for you today, okay?	15	deposition was requested in this case?
16	A Yes.	16	A Through our office manager.
17	Q Great.	17	Q Okay. And I presume she received a
18	And I tried to look over your today	18	letter, some communication that your deposition was
19	was the first time I saw your CV. So I tried to look	19	wanted and she approached you about it?
20	it over quickly.	20	A Yes.
21	In your experience since	21	Q Okay. Were the arrangements of
22	basically medical school, have you ever worked in the	22	scheduling this deposition today all done by your
23	pharmaceutical industry?	23	office manager?
24	A No.	24	A Yes.
25	Q Have you ever been involved in any	25	Q Did you have any communications, meaning
	Page 46		Page 48
1	clinical trials?	1	you personally, with any of the lawyers for
2	A Yes.	2	GlaxoSmithKline?
		_	
3	Q Okay. Are we was that back when you	3	A No.
	Q Okay. Are we was that back when you were practicing in New Jersey?	3	A No. Q Have you spoken about this case with any
	were practicing in New Jersey?  A Yes.	3 4 5	A No. Q Have you spoken about this case with any lawyers from GlaxoSmithKline?
4	were practicing in New Jersey?	3 4 5 6	A No. Q Have you spoken about this case with any lawyers from GlaxoSmithKline? A No.
4	were practicing in New Jersey?  A Yes.  Q Okay. Do you remember the drugs or drug?  A No.	3 4 5 6 7	A No. Q Have you spoken about this case with any lawyers from GlaxoSmithKline? A No. Q Have you spoken about this case with any
4 5 6 7 8	were practicing in New Jersey?  A Yes.  Q Okay. Do you remember the drugs or drug?  A No.  Q Okay. Do you remember the companies	3 4 5 6 7 8	A No. Q Have you spoken about this case with any lawyers from GlaxoSmithKline? A No. Q Have you spoken about this case with any representatives of GlaxoSmithKline?
4 5 6 7 8 9	were practicing in New Jersey?  A Yes.  Q Okay. Do you remember the drugs or drug?  A No.  Q Okay. Do you remember the companies involved?	3 4 5 6 7 8	A No. Q Have you spoken about this case with any lawyers from GlaxoSmithKline? A No. Q Have you spoken about this case with any representatives of GlaxoSmithKline? A No.
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4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	were practicing in New Jersey?  A Yes.  Q Okay. Do you remember the drugs or drug?  A No.  Q Okay. Do you remember the companies involved?  A No.  Q Okay. Do you and currently, within maybe the last few years, do you ever speak on behalf of pharmaceutical  A I do recall.  Q Okay.  A The trial was looking at the preparation the skin preparation prior to surgery, comparing a standard Betadine wash or solution to a single swipe with a with what at that time was a new product.  Q Okay. Do you know who what companies were involved with that product?  A No.	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A No. Q Have you spoken about this case with any lawyers from GlaxoSmithKline? A No. Q Have you spoken about this case with any representatives of GlaxoSmithKline? A No. Q Have you spoken with this case about any well, let me ask you this: Are you ever visited by sales representatives, pharmaceutical sales representatives? A No. Q No. Okay. So you wouldn't have talked about this case with any GlaxoSmithKline pharmaceutical reps? A No. Q Okay. I'm going to try not to tread over the same ground so we can all get out of here. My understanding from your answers to counsel's questions was that you do not have an

Page 49

Q Okay. If he were to walk in this room

2 right now, would you able to recognize him?

3 A No.

1

4 Q Okay. Now, just generally about your

5 practice, I understand that most times when you see a

6 patient for the first time, it's in the hospital?

7 A Yes.

8 Q Okay. And I'm pointing out the window

9 because I think the hospital is across the street.

10 A Yes.

11 Q All right. I went there first by

12 mistake.

The -- how does it work generally? Who

14 -- who calls either you or your practice into a case?

15 How does that work?

16 A One of two ways usually. The

17 cardiologists, after they perform the catheterization,

18 calls a surgeon directly or calls the office directly

19 and let's either the surgeon or the office know that

20 there's a patient they want to have seen for a

21 surgical evaluation. Or nursing personnel or

22 secretarial personnel in the hospital, when they're

23 transcribing orders that the cardiologist will write,

24 will notify either the surgeon or the office of a

25 patient that needs to be seen.

Page 50

1 Q Okay. All right. In this case I presume

2 you don't have a recollection as to how you were

3 called into the case?

4 A No.

5 Q I apologize. Dr. Walsh, I believe, was

6 the cardiologist caring for Mr. Schreffler. And you

7 testified that you know Dr. Walsh?

8 A Yes.

9 Q Does he -- do you have a

10 relationship with him whereby he would call you

11 personally; or would he call the office if there was a

12 case where he felt he needed a CT surgeon?

13 A Usually he calls the office.

14 Q Okay. And let's assuming that followed

15 course. He's treating Mr. Schreffler at Holy Spirit

16 Hospital, across the street, and he realizes he needs

17 a cardiothoracic surgeon. They call your practice

18 here, the Cardio -- I don't want to butcher the name.

19 A CVSI.

20 Q Capital Area Cardiovascular Surgical

21 Institute gets a phone call. How is it decided

22 amongst the five doctors here who's going to be

23 assigned to that particular case?

24 A It's often done on availability, who is

25 not in the operating room, who is in that hospital at

1 that particular time. That's the usual manner in

2 which it's handled.

3 Q Okay. Just based on the rotation and

4 availability?

5 A Yes.

6 THE VIDEOGRAPHER: Excuse me. Can we

7 pause one minute. I just want to check the audio on

8 that mic. It seems like there might be a minor

9 problem with it since it was --

10 MR. SPIZER: Sure.

11 THE VIDEOGRAPHER: We are now going off

12 camera and the time is 4:27.

13 (Recess.)

14 THE VIDEOGRAPHER: We are now going back

15 on camera and the time is 4:39 p.m.

16 BY MR. SPIZER:

17 Q Doctor, we were discussing before we took

18 the break of how you became the surgeon on

19 Mr. Schreffler's case. And it sounds like through the

20 normal practice, you were -- the office likely

21 received a call; and due to availability, you were the

22 one that happened to see Mr. Schreffler and then

23 ultimately performed the surgery. Is that likely what

24 happened?

3

25 A Yes.

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Page 51

1 Q Okay. So I understand the role of a

2 cardiothoracic surgeon, do you do the catheterization?

A No.

4 Q Okay. And just so we're clear, a

5 catheterization is what?

6 A The cardio catheterization is the

7 visualization of the arteries around the heart. And

8 it's done by the cardiologist; and they thread a small

9 thin catheter up through the abdominal aorta and it

10 engages into the coronary arteries -- up through the

11 thoracic artery into the coronary arteries, and it

12 outlines the path of the coronary arteries and details

13 any blockages that may exist.

14 Q And in Mr. Schreffler's case, do you know

15 if during that catheterization did they do an

16 angioplasty or a stent? Do you recall or do the

17 records indicate that to you?

18 A I don't recall.

19 Q If there was a stent required or

20 angioplasty, would that be something done by the

21 interventional cardiologist or would that be something

22 you would do?

23 A The interventional cardiologist.

24 Q Okay. Now, the -- is Dr. Walsh an

25 interventional cardiologist?

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Page 53 Page 55 1 Α No. 1 heart muscle around the blockage in the native 2 Q But in order for you to be called in, the 2 coronary artery. 3 cardiologist on call, whether it be the cardiologist 3 Typically in a vein bypass, one end of 4 or the interventional cardiologist, believes that a 4 the vein is attached to the aorta. The other end of patient needs to be seen as a potential surgical 5 the vein is attached -- and this is done with suturing 6 candidate, is that fair? 6 -- to the coronary artery where the blockage occurs 7 Α Yes. 7 but beyond the level of the blockage so that the blood 8 Q Okay. And then you then come in. 8 will come out of the heart, into the aorta, travel And I believe you testified that you then will see 9 down the vein into the heart artery downstream beyond 10 the patient. You will do a physical exam on the 10 the blockage in the heart artery. patient, is that right? So in Mr. Schreffler's case, is that what 11 11 O 12 Α Yes. 12 you did? 13 O You'll also actually review the cath 13 Α Yes. 14 films --14 Q Now, I think in one of your notes, when 15 Α Yes. 15 you did a letter, I believe, to his doctors, you Q 16 -- is that right? 16 indicated that you discussed the risks and the 17 And you also look at the lab results benefits of the surgery with the patient? 17 18 and other, I guess, diagnostic tests? 18 Α Yes. 19 Α Yes. Q 19 Is that your common practice? 20 Q Okay. And at that point, after you've 20 Α Yes. 21 done that analysis, you're able to make a decision 21 Q And what are some of the risks of bypass 22 whether this patient is a -- whether surgery is a 22 surgery? 23 proper option for this patient? 23 Infection and the incisions bleeding, 24 Α Yes. 24 which could necessitate going back to the operating 25 In Mr. Schreffler's case, you felt that O 25 room; stroke, heart failure, kidneys can fail, Page 54 Page 56 1 the -- well, let me ask you this: Mr. Schreffler had 1 pulmonary complications and death. 2 2 bypass surgery, correct? Okay. And you -- do you advise patients 3 Α Yes. 3 of those risks before doing the surgery? Q 4 4 Α And just so I'm clear, and if this tape Yes. 5 is ever shown, so the jury is clear, when you say 5 Okay. And you as a physician, I take it, 6 bypass surgery -- and I know you explained a little 6 have to -- when you're analyzing the patient and the 7 cath films and diagnostic tests, you're then analyzing 7 bit -- but what does it mean, bypass surgery? Does 8 that mean that the heart is actually stopped and blood 8 whether that patient then -- whether the benefit of 9 is passed away -- it's bypassed through a machine, in 9 the surgery outweighs the risks of the surgery, 10 essence? 10 correct? 11 Yes. The heart lung machine is used to 11 Α 12 redirect the blood away from the heart and the lungs 12 Q And in Mr. Schreffler's case, you 13 during the operation and directs the blood to the 13 indicated it was a life-threatening situation? 14 remainder of the body so that the heart can be --14 Α Q 15 remain still, the field can be bloodless and the 15 So in his case, your recommendation was 16 to go forward with the surgery? 16 operation can be done accurately and precisely. 17 Α And when you talk about bypass, for 17 Yes.

Q 18 And the surgery was performed?

Α

19

Q 20 Okay. And then -- so you come in as the

21 cardiothoracic surgeon. You do the surgery. And then

22 after the surgery is over, you have -- is it fair to

23 say you have a few follow-up visits with the -- or

24 the patient has a few follow-up visits with you

25 because you were the surgeon?

Osevala, Mark, D.O.

22 work?

Α

23

18 example, if there's a blockage in the artery, what are

19 you doing as a cardiothoracic surgeon in order to get

20 around that blockage? Are you actually circumventing

21 around for an artery or are you using -- how does that

25 constructing an alternative route for the blood to the

24 into the heart muscle. And that is done by

We bring new blood -- new blood supply

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	Page 57		Page 59
1	A Yes.	1	Q Okay. Because you haven't prescribed
2	Q And then generally the patient is then		well, strike that.
3	discharged to carry out treatment with their primary	3	
4	care physician and their cardiologist?		to your knowledge ever read the warning or the drug
5	A Correct, yes.		label, the Avandia label?
6	Q So is it fair to say that your	6	A No.
	interaction with patients is usually fairly limited?	7	Q Have you ever read any articles about
8	MS. FISHER: Object to the form.	8	Avandia?
9	MR. SPIZER: Maybe that's a badly phrased	9	A No.
	question.	10	MS. FISHER: Object to the form.
11	BY MR. SPIZER:	11	BY MR. SPIZER:
12	Q It's not fairly limited because your	12	Q Have you ever reviewed any Food and Drug
13	performing a major surgery, and I don't want to	13	Administration documents about Avandia?
	minimize what you do.	14	
15	What I guess I'm saying is, from a	15	A No.
	time-frame perspective, you're I mean, you're	16	BY MR. SPIZER:
	called in basically to perform the surgery. After	17	Q Have you ever looked at any internal
18	surgery, assuming all goes pretty well, you have a few	18	GlaxoSmithKline documents about Avandia?
	follow-up visits. And then the patient is released	19	MS. FISHER: Object to the form.
20	back to their primary care physician, cardiologist.	20	A No.
21	From a time frame perspective, you	21	MR. SPIZER: What's with the question
22	it's you don't have a longstanding relationship	22	have you ever looked at any GlaxoSmithKline documents?
23	with a patient?	23	
24	A That's correct.	24	I can explain it or we can just keep going.
25	Q And is it fair to say that when a and	25	MR. SPIZER: I'm entitled to an
	Page 58		Page 60
1	when a patient is first comes into the hospital	1	opportunity if you're saying there's an objection to
2	with chest pain or symptoms that somebody might think	2	the form, but I'll keep going.
3	is indicative of a myocardial infarction, they would	3	MS. FISHER: The form of the question
4	not call you or someone in your group; they would call	4	implies information in documents that are confidential
5	the cardiology group on call?	5	to GlaxoSmithKline. Just the form of the question.
6	A That's correct.	6	MR. SPIZER: I disagree with you, but
7	Q All right. And it would be the	7	we'll let it stand.
8	cardiology group that would be making the assessment	8	BY MR. SPIZER:
9	as to what steps to then take?	9	Q Have you ever looked at any
10	A Correct.	10	GlaxoSmithKline documents about Avandia?
11	Q And it would be the cardiology group that	11	A No.
12	would maybe make assessments as to what caused or did	12	Q Would you consider yourself an expert on
13	not cause the underlying heart attack?	13	the drug Avandia?
14	MS. FISHER: Object to the form.	14	
15	A Yes.	15	Q Would you consider yourself an expert
16	BY MR. SPIZER:		well, strike that.
17	Q Okay. And you're brought in after those	17	
	steps are taken in order to, in essence, fix the	1	expert on any of the diabetic medications?
19	problem?	19	
20	A Yes.	20	
21	Q Okay. In this case, the drug there's	21	
	an allegation about the drug Avandia.		failure?
22	A Okay.	23	•
23			
24 25	<ul><li>Q Have you ever prescribed Avandia?</li><li>A No.</li></ul>	24 25	

Page 63 Page 61 1 BY MR. SPIZER: 1 BY MR. SPIZER: 2 2 Q Given that, as you've said, you've read Q Now, from reading your chart of 3 no -- you know, you've looked at no documents about 3 Mr. Schreffler, you released him after a few visits to 4 Avandia, you haven't prescribed it, you haven't looked 4 his primary care physician and cardiologist, correct? 5 at its label, you haven't looked at any 5 Α Yes. 6 Q 6 GlaxoSmithKline documents, you haven't looked at any Other than the small drainage issue, you 7 Food and Drug Administration documents about it, are 7 saw no other complications from his bypass surgery? 8 you able to give an opinion one way or the other as to 8 Correct. whether Avandia can or cannot cause heart attacks? 9 Q And there's nothing in this -- in your 10 Α 10 chart to reflect that you've seen Mr. Schreffler since 11 MS. FISHER: Object to the form. 11 June of '06? 12 12 BY MR. SPIZER: Α Correct. Q No, meaning you cannot opine on whether 13 Q Does someone who has undergone bypass 13 Avandia can or cannot cause heart attacks? 14 14 surgery, are there any potential long-term Could you repeat the question, please. 15 complications? 15 16 Q Yes. It was poorly phrased. 16 Α Yes. 17 Q 17 Because you have not -- you've never And what are they? 18 prescribed Avandia, correct? 18 The blockages could progress and block 19 Α Correct. 19 off new areas of the -- of the heart arteries. The Q 20 You've never read any articles about 20 bypasses themselves can develop blockage and cause 21 Avandia. You've never looked at any documents about 21 problems. 22 Avandia. You haven't followed any of the news or any 22 Q So, I've heard the expression -- and this 23 of the studies regarding Avandia and its potential 23 may be an inaccurate term from a layman -- restenosis. 24 link to heart attacks or heart failure. 24 But could the bypass you've created, the -- I guess 25 Is it then fair to say you are not in a 25 the detoured route for the blood to get to the heart, Page 62 Page 64 1 position to opine whether or not Avandia can or cannot 1 could that actually form a blockage? 2 Yes. cause a heart attack? Α 2 3 Q 3 MS. FISHER: Object to the form. And is that something that someone like That's true. 4 Mr. Schreffler is going to have to or his doctors be 4 Α 5 BY MR. SPIZER: 5 mindful of? 6 Α 6 And would that be then true in this case, Yes. MR. SPIZER: I have no further questions 7 that you were unable to give an opinion one way or the 7 at this time, Doctor. Thank you. other as to whether Avandia did or did not cause Mr. Schreffler's myocardial infarction? 9 MS. FISHER: I just have a few follow-up 10 MS. FISHER: Object to the form. 10 questions. 11 11 Α Correct. 12 BY MR. SPIZER: 12 REDIRECT EXAMINATION 13 Q So you're not giving a causation opinion 13 14 14 BY MS. FISHER: in this case? 15 Α Correct. 15 Q You were just describing some of the 16 problems that bypass patients may face in the future 16 MS. FISHER: Object to the form. 17 17 or may have to watch out for; the blockage that could, You have to give me a chance to --MR. SPIZER: Why don't we read that back. 18 you said, increase or also the bypasses themselves, 18 BY MR. SPIZER: 19 the graphs could develop blockage; is that correct? 19

20

21

23

24

Α

Α

Q

Yes.

To the best of your knowledge, 22 Mr. Schreffler hasn't developed any of those, right?

25 have any information that suggests Mr. Schreffler has

To the best of your knowledge, you don't

What's the question?

Osevala, Mark, D.O.

My question was -- and we'll give counsel

an opportunity to object. So given that, am I correct

MS. FISHER: Object to the form.

22 that you are not making a causation opinion on this

20

24

23 case?

Page 65 Page 67 Q 1 had any problems after his surgery, is that correct? 1 Okay. So when you were talking to 2 Α Correct. 2 Mr. Schreffler in May of 2006, you could not have 3 3 taken Avandia into account because that was not You were being asked multiple questions 4 about possible causes of Mr. Schreffler's heart something that you have any knowledge about, correct? attack, and you said you were not able to opine on the 5 Α Correct. cause of the heart attack. 6 MS. FISHER: Object to the form. 7 7 If Mr. Schreffler testified in his MR. SPIZER: No further questions. 8 deposition that you told him that your response to his 8 THE VIDEOGRAPHER: This deposition is now 9 question how could I have been blocked, Mr. Schreffler 9 concluded and the time is 4:57 p.m. 10 testified and his response was, "You got three strikes 10 (The deposition was concluded at against you, two of them are you're diabetic and one 11 4:57 p.m.) 12 you've got a heart history in your family, and that's 12 13 the best explanation that anybody ever gave me other 13 14 than, I mean, as far as coming up with any other kind 14 15 of an explanation", do you have any reason to dispute 15 16 Mr. Schreffler's recollection of what you told him? 16 17 MR. SPIZER: Object to the form. 17 18 No. 18 19 BY MS. FISHER: 19 20 Q In fact, based on your testimony that I 20 think 80 percent of your patients are diabetic and a 21 large percentage of them have heart problems in the 22 family, that would be consistent, is that correct? 23 24 Α Yes. 24 25 MR. SPIZER: Objection. 25 Page 66 Page 68 1 MS. FISHER: I have no further questions. 1 STATE OF PENNSYLVANIA: § Thank you. 2 2 **COUNTY OF DAUPHIN** 3 MR. SPIZER: I just have a quick 3 follow-up. 4 4 I, Donna J. Fox, a Reporter-Notary Public, 5 authorized to administer oaths within and for the 5 6 **RECROSS-EXAMINATION** 6 Commonwealth of Pennsylvania and take depositions in the 7 7 trial of causes, do hereby certify that the foregoing is the 8 BY MR. SPIZER: 8 testimony of Mark A. Osevala, D.O. 9 Doctor, you were just read some testimony 9 I further certify that before the taking of 10 from Mr. Schreffler's -- his deposition. You were 10 said deposition, the witness was duly sworn; that the 11 just read that, correct? 11 questions and answers were taken down stenographically by the 12 Α Yes. said reporter Donna J. Fox, a Reporter Notary-Public, 12 13 Okay. And assuming his memory of the approved and agreed to, and afterwards reduced to typewriting conversation is accurate, when he had the conversation under the direction of the said Reporter. 14 15 with you in May of 2006, would it be fair to say that 15 I further certify that the proceedings and you were not -- you did not have any information about evidence contained fully and accurately in the notes by me on 16 Avandia at that time? 17 17 the within deposition, and that this copy is a correct MS. FISHER: Object to the form. 18 18 transcript of the same. 19 That's correct. 19 In testimony whereof, I have hereunto, 20 BY MR. SPIZER: 20 subscribed my hand this 30th day of October, 2009. 21 All right. And -- because you testified 21 22 earlier to my questions that you were not -- you 22 23 have -- you have no -- really, no knowledge base about 23 Donna J. Fox, Reporter 24 Avandia, correct? 24 My commission expires: 25 Α Correct. 25 April 7, 2012

## **EXHIBIT C**

Case ID: 080202733

## In Re:

Avandia/Self v. GSK

Muhamed Saleh Faour, M.D. November 25, 2009

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Case ID: 080202733

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2	PHILADELPHIA COUNTY, PENNSYLVANIA	2	FAOUR, M.D., was taken on behalf of the Defendant at
3		3	1200 Conference Center Boulevard, Murfreesboro,
4	IN RE: ) February Term,	4	Tennessee, commencing at 9:01 a.m., November 25, 2009.
5	AVANDIA LITIGATION ) 2008	5	It is stipulated that all formalities as to
6	) No. 2733	6	notice, caption, et cetera are waived. All objections,
7		7	except as to the form of the question, are reserved
8	JOE SELF, ) October Term,	8	until the time of hearing.
9	Plaintiff, ) 2007	9	It is agreed that Terri Comstock, being a Notary
10	v. ) Case No. 2457	10	Public and Court Reporter for the State of Tennessee,
11	SMITHKLINE BEECHAM )	11	may swear the witness and that the reading and signing
12	CORPORATION d/b/a ) AVANDIA CASE:	12	of the completed deposition by the witness are waived.
13	GLAXOSMITHKLINE, ) "TV"	13	
14	Defendant. )	14	
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1 2	Page 2	1	MUHAMED SALEH FAOUR, M.D.,
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Page 5

- 1 A. Right.
- 2 Q. So it's important that you give clear and
- 3 honest answers; is that okay?
- 4 A. Right, yes.
- 5 Q. You're a medical doctor, are you?
- 6 A. Yes.
- 7 Q. And do you specialize in internal medicine?
- 8 A. Yes.
- 9 Q. And where do you practice?
- 10 A. Right now?
- 11 Q. Yes.
- 12 A. In Shelbyville.
- 13 Q. Shelbyville?
- 14 A. Yes.
- 15 Q. And that's in Tennessee?
- 16 A. Yes.
- 17 Q. And can you describe your medical practice for
- 18 us, please?
- 19 A. It's a private medical practice, an office
- 20 plus hospital patients.
- 21 Q. Well, today, is it a general practice seeing
- 22 adults?
- 23 A. Yes.
- 24 Q. You don't practice in a hospital?
- 25 A. I do, yes.

- 1 Q. Okay. And did Joe Self become a patient of
- 2 that practice?
- з A. Yes.
- 4 Q. And you saw him on a couple of occasions in
- 5 2005?
- 6 A. Yes.
- 7 Q. And do you have some records relating to
- 8 Mr. Self's visits to the practice in front of you today?
- 9 A. Yes.
- 10 Q. Before we talk some more about Mr. Self, I'd
- 11 like to ask you a bit about your background and about
- 12 diabetes. Where did you get your medical degree?
- 13 A. The diploma from Damascus University in Syria.
- 14 Q. And did you come and do a residency in the
- united States?
- 16 A. Yes.
- 17 Q. And where did you do your residency?
- 18 A. Mercy Hospital in Pittsburgh.
- 19 Q. And what area of medicine did you specialize
- 20 in at Mercy Hospital?
- 21 A. Internal Medicine.
- 22 Q. And during your residency, did you learn about
- 23 the treatment of diabetes?
- 24 A. That's right.
- 25 Q. And after your residency, did you become board

Page 6

- 1 certified in Internal Medicine?
  - 2 A. Yes.
  - 3 Q. And what does board certification mean?
  - 4 A. You have to pass the board exam, the national
  - 5 board exam.
  - 6 Q. So it's an additional qualification after
  - 7 medical school?
  - 8 A. Right, right. Well, you have to have a
  - 9 medical school degree and then a residency training and
  - then you pass the board exam.
  - 11 Q. How many years did you spend in Pittsburgh as
  - 12 a resident?
  - 13 A. Three years.
  - 14 Q. And then did you come to practice -- you went
  - to the private practice?
  - 16 A. Yes.
  - 17 Q. Was that in Tennessee or somewhere else?
  - 18 A. In Tennessee.
  - 19 Q. So you've been practicing in Tennessee since
    - the end of your residency?
  - 21 A. Yes.
  - 22 Q. And when did you actually come to Tennessee?
  - 23 A. July 2003.
  - 24 Q. So as of today -- we're here -- it's November
  - 25 2009, so you've been practicing in Tennessee for about

Ü

1 Q. Oh, you do go?

- 2 A. Yes.
- 3 Q. Okay. Tell me how many patients you see in
- 4 the hospital versus see in an office.
- 5 A. About five a day in the hospital, plus 25 --
- 6 20 to 25 in the office.
- 7 Q. Okay. In the year 2005, were you practicing
- 8 somewhere else in Tennessee?
- 9 A. Yes.
- 10 Q. And where was your practice then?
- 11 A. Tennessee Valley Specialty Clinic -- or
- 12 Center, yeah.
- 13 Q. And what was the name of the town that you
- 14 practiced in?
- 15 A. In Pulaski, Tennessee.
- 16 Q. Pulaski?
- 17 A. Yes.
- 18 Q. And is that in southern Tennessee?
- 19 A. Yes.
- 20 Q. And were you in a practice there with another
- 21 doctor called Dr. Haggag?
- 22 A. Yes.
- 23 Q. And was that called the Giles Family Health
- 24 Center?

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25 A. Used to, yes.

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- six and a half years?
- 2 A. Uh-huh.
- 3 Q. Was Avandia a medicine that you and your
- supervisors prescribed to patients with diabetes during
- your residency?
- 6 A. I believe so, yeah.
- 7 Q. And in your current practice, do you have
- patients with diabetes?
- 9 A. Yes.
- 10 Q. About how many? I mean, do you see one a day
- or ten a day or...
- A. About, I would say, three a day.
- Q. Three a day with type 2 diabetes?
- 15 Q. And are some of your current patients on
- Avandia?
- A. Yes. 17
- Q. So you continue to prescribe it?
- A. Yes.
- 20 Q. I take it you believe it's a safe and useful
- medicine for your patients? 21
- MR. DICKENS: Object to the form. 22
- Q. (By Mr. Vale) Well, let me just -- sometimes
- there'll be an objection, Dr. Faour, and that may cause
- me to restate the question.

- 1 Q. Let's talk for a minute about type 2 diabetes.
- How do you diagnose type 2 diabetes?
- A. By symptoms and a blood test.
- Q. What are the typical symptoms of somebody that
- has type 2 diabetes?
- A. Fatigue, frequent urination, thirst, blurred
- vision, generalized weakness, weight loss.
- Q. And then after describing those symptoms to
- determine whether the patient has diabetes, you'll do
- some blood work?
- A. Yes. 11
- Q. And if the blood sugar levels are above a
- certain level, you will determine that they have type 2
- diabetes?
- 15 A. Yes.
- Q. And generally, what's the level at which you
- determine that they have diabetes to see whether --
  - A. On the blood test, you mean?
- Q. Yes. In other words, if the blood test is
- over what would you say that somebody has diabetes?
- A. Well, it depends on which blood test. If it's
- a hemoglobin A1c, usually -- and it also depends on the
- reference lab. If it's above 7, you know, most
- likely there is type 2 diabetes.
- 25 Q. That's 7 on the A1c test?

Page 10

- 1 A. Okay. 2 Q. About how many patients do you have on Avandia
- today?
- 4 A. How many total patients --
- 5 O. Yes.
- 6 A. -- in my practice?
- 7 Q. Just roughly.
- A. I would say about eight or ten.
- Q. Okay. Do you have any family members of yours
- that take Avandia?
- 12 Q. Without naming them, what, are they close
- family relatives?
- 14 A. Yes.
- Q. And who are they? I mean, just say whether
- they're a mother or a father or an uncle or an aunt.
- A. My uncle. 17
- 18 Q. You have an uncle that takes --
- A. He's not like, you know, a real uncle. He's
- like a distant uncle to me, yeah.
- 21 Q. But he takes Avandia?
- 22 A. Yes.
- 23 Q. And are you the prescriber or have you advised
- him on medicines that he takes?
- 25 A. Not the -- I give him samples, yeah.

1 A. Yes, yes.

- Q. And what about for a fasting test?
- A. It also depends on the referene lab.
- Usually, if it's above like 120, most labs, you know...
- Q. So above 120 milligrams per deciliter for a
- fasting blood sugar test?
- A. Yes, yes.
- Q. Are patients that have type 2 diabetes at risk
- for a heart attack?
- A. Yes, they are. 10
- O. And why is that?
- A. Because having diabetes for -- the longer you
- have diabetes and the less controlled the blood sugar
- is, you're going to have a risk of having, you know,
- atherosclerosis in the heart and the peripheral vessels.
- Q. What is -- just because it may be jurors that
- don't understand all the medical terms here, what does 17
- atherosclerosis mean? 18
- A. Well, you get the plate -- do you want me to
- go through the pathology or just --
- Q. Well, not -- no, not too complicated, but in
- general, does atherosclerosis, it means a hardening of
- 23 the arteries?
- A. Yes, yes, hardening and narrowing of the lumen
- of the blood vessels.

Page 12

Page 16

Page 13

- 1 Q. So it makes it more difficult for the blood to
- get through to the heart?
- 3 A. That's right.
- 4 Q. And the heart needs the oxygen in the blood to
- work properly?
- A. Uh-huh.
- 7 Q. I know that's very simple, but that's the gist
- 9 A. Yes.
- 10 Q. Aside from diabetes, what are other risk
- factors for having a heart attack?
- A. High blood pressure, high cholesterol,
- smoking, obesity, family history.
- Q. Are those all factors that you inquire into
- when you first see a patient?
- A. Yes, we do.
- O. You need to know that information? 17
- A. Yeah.
- Q. Are you familiar with a book called the PDR?
- 20 A. PDR, yes.
- 21 Q. And that's the Physicians' Desk Reference?
- 23 Q. And that's a book that -- do you have one in
- your office?
- 25 A. I do.

- here. We'll look at the section on Avandia. It's
- actually on page 1438. Avandia is down at the bottom
- here. Do you see that?
- A. Yes.
- Q. And the book has several pages. It's in
- fairly small type, but it has several pages giving you a
- lot of information about Avandia; is that correct?
- A. Yes.
- Q. And if you turn over the page, there's a
- heading. It says Clinical Studies?
- A. Yes. 11
- Q. Do you see that? 12
- A. Yes.
- Q. And then it provides some more information
- about -- more information about the data that's been 15
- found from the clinical studies. And then if you turn
- over the page again, it's got -- on the right-hand side, 17
- it says Indications and Usage. Go one more page, I
- think. 19
- 20 A. Yes.
- Q. You see it says -- and then it says: Avandia
- is indicated as an adjunct to diet and exercise to
- improve glycemic control in patients with type 2
- diabetes mellitus.
- 25 A. Uh-huh. Okay.

Page 14

- 1 Q. What does that -- what's that mean in lay
- terms?
- A. I'm sorry. Say that --
- 4 Q. Okay. Do you see the sentence that reads
- Avandia is indicated as an adjunct to --
- 7 Q. -- diet and exercise to improve glycemic
- control in patients with type 2 diabetes mellitus?
- 9 A. Yes.
- Q. It says that, right? 10
- A. Yes.
- Q. And could you just translate that into more
- lay language? What does it mean? 13
- 14 A. Well, it's basically -- it's a prescription
- medication, you know, to lower the blood sugar in
- addition to doing, you know, the diet, you know, the low
- carb diet and, you know, the exercise.
- Q. In order to control your blood sugar, do you
- have to diet and exercise?
- 20 A. Yes. Yes, you do.
- Q. In other words, if you don't diet and
- exercise, is the medicine going to work?
- 23 A. To a certain degree.
- 24 Q. But not very well?
- 25 A. Yes.

1 Q. And it contains information on all of the

- prescription medicines that are available?
- з A. Yes.
- 4 Q. And is that a book that you consult from time
- to time to get information about the medicines that
- you're prescribing or you might consider prescribing?
- 7 A. Yes.
- Q. So it has information on like dose and side
- effects, that sort of thing?
- 10 A. Right.
- Q. And does it also provide the information that
- the manufacturer of the drug has determined from the
- clinical trials of the drug? 13
- 14 A. Yes.
- O. Let's take a look at the PDR from 2005. 15
- MR. VALE: We'll mark this as Exhibit 2 for 16 the deposition. 17
- (Documents marked as Exhibit Number 2.) 18
- Q. (By Mr. Vale) And I'm handing you a copy of 19
- not the entire book because it's a big, thick book, 20
- correct? 21
- 22 A. Yes, yes.
- 23 Q. So we just copied the first page of the 2005
- PDR and we've copied the sections on Avandamet and on
- Avandia. So if you turn to -- it's about in the middle

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Page 17

- 1 Q. So do you tell all of your patients with type
- 2 diabetes that diet and exercise is important?
- з A. Yes.
- 4 Q. Let's turn back, if you would, to where it
- says Clinical Studies. It's going one page back. Do
- you see that heading on the left?
- 7 A. Uh-huh.
- 8 Q. And then if you go down the page a little bit,
- there's a paragraph beginning The addition of Avandia.
- Do you see that?
- A. Uh-huh, yes. 11
- 12 Q. And then further down, it says: In all 26-week
- controlled trials, across the recommended dose range,
- Avandia as monotherapy was associated with increases in
- 15 total cholesterol, LDL and HDL and decreases in free
- fatty acids. 16
- Do you see that? 17
- A. Uh-huh. 18
- Q. And then a little further on in the next 19
- 20 column, it says: The pattern of LDL and HDL changes
- 21 following therapy with Avandia in combination with other
- hypoglycemic agents were generally similar to those seen 22
- with Avandia in monotherapy.
- Did I read that right? 24
- 25 A. Uh-huh.

- the placebo-controlled trials -- and that means where
- they're comparing Avandia to a dummy pill -- for
- example, with Avandia at four milligrams a day, the
- patients that took the placebo had an increase in LDL of
- 4.8 percent and the patients that took Avandia had an
- increase of 14 percent?
- A. Uh-huh.
- Q. So this was the information that was available
- to you and other doctors prescribing Avandia?
- A. Yes. 10
- MR. DICKENS: Object to the form. 11
- Q. (By Mr. Vale) All right. Let's -- let me ask 12
- you a question about sales representatives. You're
- familiar with the fact that drug manufacturers have
- sales representatives that call on doctors? 15
- A. Yes, yes. 16
- Q. Do they come and call on you today? 17
- A. Today?
- Q. Yes. 19
- A. Well, I did not go to work today. I mean --20
- O. I don't mean -- I'm not -- I don't mean
- literally Wednesday today, but at the current time, in
- the year 2009. 23
- A. Yes, yes.
- 25 Q. You just have to speak a little more clearly.

Page 18

- 1 A. Yes.
- Q. So you see drug representatives from several
- different companies?
- A. Uh-huh.
- They bring you samples? O.
- They talk about new information on their 7 Q.
- drugs? 8
- 9 MR. DICKENS: Object to the form.
- Q. (By Mr. Vale) Is that fair? 10
- A. Yes.
- 12 Q. And did you use to see drug representatives
- 13 when you were a resident back in Pittsburgh?
- Q. And I take it you see drug representatives for
- diabetes drugs? 16
- 17 A. Yes.
- Q. So, for example, representatives for Actos and
- Avandia have called on you from time to time?
- 20 A. Yes, yes.
- Q. And in general terms, do the representatives
- tend to point out the advantages of their drugs and
- 23 maybe point to disadvantages of competitor drugs?
- MR. DICKENS: Object to the form. 24
- 25 A. Yes.

1 Q. So is that essentially saying that whether you

- use Avandia by itself or you use Avandia with other
- drugs like Metformin --
- 4 A. Uh-huh.
- 5 O. -- there's some increase --
- A. Yes.
- Q. -- in LDL cholesterol and in HDL cholesterol? 7
- A. Yes. 8
- 9 MR. DICKENS: Object to the form.
- 10 Q. (By Mr. Vale) Is that correct?
- A. Yes.
- 12 Q. And do you see there's a table that says Table
- 2 up here? 13
- 14 A. Uh-huh.
- 15 Q. And it says -- it's headed up Summary of Mean
- Lipid Changes in 26-Week Placebo-Controlled and 52-Week
- Glyburide-Controlled Monotherapy Studies? 17
- 18 A. Uh-huh.
- 19 Q. And, again, in lay terms, does that mean that
- 20 it's providing you as the prescribing doctor with some
- information about the increases in cholesterol for 21
- patients that were in the various trials that the 22

manufacturer had conducted?

- 24 A. Yes.
- 25 Q. And do you see -- just to take one example, in

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- 1 Q. (By Mr. Vale) So, for example, the Avandia
- representative would talk about his or her drug and talk
- up -- talk it up?
- 4 A. Right.
- 5 Q. And similarly, the representative for Actos
- would talk up the Actos medicine and --
- 7 A. Yes.
- Q. -- maybe point out some disadvantages or maybe
- point out why Actos would be better than Avandia, for
- example?
- 11 A. Yes.
- 12 Q. So you get that kind of information?
- A. (Witness nods head up and down.)
- Q. In the year 2007, do you remember some
- allegations being made about Avandia?
- A. Yes. 16
- Q. Trying to link up Avandia to heart attacks? 17
- Q. Did you make any evaluation yourself of the
- merit of these allegations?
- 21 A. Yes.
- Q. And what evaluation did you make?
- A. Just, you know, going online and reading
- about, you know, what they came up with, you know,
- making some research.

- 1 A. No, I'm not.
- 2 Q. When you say you've looked at some of the
- evidence, have you looked at anything since 2007
- relating to Avandia?
- A. Well, reading online, you know, here and
- there, you know, listening to drug reps. You know,
- that's about it.
- Q. Right.
- A. I guess.
- Q. When you've prescribed Avandia, have you been
- aware of the fluid retention issues?
- 12
- O. And that's the same with Actos? 13
- MR. DICKENS: Object to the form.
- 15 A. No.
- Q. (By Mr. Vale) Well, are you aware that both
- Actos and Avandia have a warning about the potential for
- fluid retention and that that could lead to or
- exacerbate congestive heart failure?
- A. Yes, yes.
- Q. So you take that into account?
- Q. And you've done that since you first
- prescribed Avandia?
- 25 A. Yes.

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- 2 A. Yes. Plus, I had a few drug reps, you know,
- that came over and they talked about, you know, what's
- going on.
- 5 Q. About the allegations about Avandia?

1 Q. So you did some reading of your own?

- 6 A. Yes, uh-huh.
- Q. And did you reach any judgment or conclusion
- of your own about the safety of Avandia?
- 9 A. Yes.
- 10 Q. And what conclusion did you reach?
- 11 A. Not to prescribe -- I kept prescribing
- Avandia, but not to give it to someone who has heart
- disease, congestive heart failure or heart attack.
- 14 Q. So have you read -- are you aware that in 2009
- there were the results of a study called RECORD
- published?
- 17 A. I don't know anything about the study.
- 18 Q. Okay.
- 19 A. In 2009?
- 20 Q. In 2009, there was a study published in the
- Lancet and the study was called the RECORD study. It 21
- 22 was a prospective randomized trial of Avandia and
- 23 Metformin and sulfonylurea drugs.
- MR. DICKENS: Object to the form.
- 25 Q. (By Mr. Vale) You're not familiar with that?

1 Q. And I take it nothing that you've read about

- Avandia or these allegations about Avandia has caused
- you to think that Avandia is not a safe medicine for
- patients because you have eight or ten patients on
- Avandia today? 5
- MR. DICKENS: Object to the form.
- Q. (By Mr. Vale) Is that right? 7
- A. Yes.
- Q. I mean, if you didn't think it was safe, you
- wouldn't have the eight or ten patients on Avandia?
- Q. So, I mean, knowing -- well, let's -- let me
- ask you this. For patients with type 2 diabetes, do you
- have a goal for their blood sugar levels and their
- cholesterol levels? 15
- A. Yes. 16
- Q. Is the goal today different from what it was 17
- in 2005 when you saw Mr. Self?
- 19 A. On the blood sugar level?
- Q. Well, let's break it down. On the blood sugar
- level, what is your goal for patients today who have
  - type 2 diabetes?
  - 23 A. 110 or below.
- 24 Q. 110 or below?
- 25 A. Yes.

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Page 25

- 1 Q. That's a fasting test?
- 2 A. Yes.
- 3 Q. And what about for their hemoglobin A1c?
- 4 A. Again, it depends on the reference lab.
- 5 Below 7, in most labs.
- 6 Q. All right. Is that the goal that you had in
- 7 2005?
- 8 A. I guess so, yes.
- 9 Q. What about for cholesterol levels? What is
- your goal today for patients with type 2 diabetes?
- 11 A. Their total cholesterol?
- 12 Q. Well, total or you can break it -- either
- total cholesterol or LDL, HDL or the ratio.
- 14 A. Below 160.
- 15 Q. Below 160 for total cholesterol?
- 16 A. Yes.
- 17 Q. And what -- do you have separate goals for LDL
- 18 and HDL?
- 19 A. I would like for it to be as low as possible,
- 20 but again, it depends on the referene lab and --
- 21 Q. Well, can I ask it this way, Dr. Faour? What
- level would you generally prescribe a statin to bring
- down LDL levels today to a type 2 diabetic patient?
- 24 A. Like if I get someone, you know, with a total
- cholesterol of 200, I initially try diet by itself.

- 1 Q. And that's simply because knowledge has
- 2 increased about the benefits of reducing blood sugar?
- з A. Uh-huh, yes.
- 4 Q. And the benefits of reducing cholesterol
- 5 levels?
- 6 A. Yes.
- 7 Q. I guess -- does the same go for blood
- 8 pressure?
- 9 A. Yes.
- 10 Q. Do you have a goal for blood pressure levels
- 11 for patients with type 2 diabetes?
- 12 A. Systolic, below 130.
- 13 O. And diastolic?
- 14 A. I would say, an average, 120/70.
- 15 Q. So you're looking for them to get to 120/70
- and if it's consistently above that today, you might
- prescribe an antihypertensive medicine?
- L8 A. If it's 130, I -- usually not. I push for
- 19 exercise, for diet. Weight loss usually, you know.
- 20 (Documents marked as Exhibit Number 1.)
- 21 Q. All right. Let's talk about Mr. Self. Do you
- 22 have the records in front of you?
- 23 A. Yes.
- 24 Q. Why don't you -- we are marking them as
- Exhibit 1 for the deposition, so I'll just make sure

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- 1 Q. Right.
- 2 A. You know, if that's not going to work, after
- 3 three, four months, you know, then we try medicine, you
- 4 know. It depends on his risk factors, but usually if
- 5 he's got a total cholesterol of 200 and did not respond
- 6 to diet, I would start him on a low dose of statin
- 7 therapy.
- 8 Q. Have your goals for patients with type 2
- 9 diabetes changed or did they -- I'm sorry. Let me
- 10 re-ask that. Have these goals for blood sugar levels
- and cholesterol levels for your patients with type 2
- diabetes changed since 2005?
- 13 A. Yes, I think so.
- 14 Q. In other words, do you treat the patients more
- 15 aggressively ---
- 16 A. Yes.
- 17 Q. -- today than you did --
- 18 A. Yes.
- 19 Q. -- back even four years ago?
- 20 A. Yes.
- 21 Q. So, for example, in the case of Mr. Self, you
- 22 might have treated him more aggressively today --
- 23 A. More today, exactly, --
- 24 Q. -- than --
- 25 A. -- than five years ago, yes.

- 1 that you have those there in front of you, as well.
- 2 A. Okay.
- 3 Q. Looking at the records, does it appear that
- 4 Mr. Self was a new patient for your practice in
- 5 September 2005?
- 6 A. Yes.
- 7 Q. And did you see him on that day?
- 8 A. Yes.
- 9 Q. And was he seen by a nurse practitioner, as
- 10 well?
- 11 A. No.
- 12 Q. Just by you. And are the notes of the
- physical examination in your handwriting?
- 14 A. Yes.
- 15 Q. All right. Let's go over that. How old was
- 16 Mr. Self?
- 17 A. 39.
- 18 Q. And his blood pressure was 120/82?
- 19 A. Yes.
- 20 Q. So that was acceptable?
- 21 A. Yes.
- 22 Q. And his weight was 188 1/2?
- 23 A. Yes.
- 24 Q. Do you remember what his height was or if that
- was acceptable?

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- 1 A. No. No, I don't remember.
- 2 Q. Did he tell you that he had diabetes?
- з A. Yes.
- 4 Q. And what did he tell you about that?
- 5 A. He was taking medicine for diabetes. They
- were not working for him.
- 7 Q. What were the medicines that he had been
- taking?
- 9 A. He was taking Metformin at that time.
- 10 Q. If you'd go to page 5...
- 11 A. Glyburide. Glyburide, Metformin and Actos is
- the three different medicines.
- 13 Q. So he said he had been taking them, but --
- A. Yes.
- 15 Q. -- had he stopped taking them?
- A. Yes.
- Q. And what were his blood sugar levels running 17
- 18
- A. When I saw him at -- that day, he claimed that
- 20 they were running very high, I mean, about 500s or even
- 21 higher.
- 22 Q. And that's way high, right?
- 23 A. Yes. I wrote here 200 to 500 in my note.
- Yes, that's very high.
- 25 Q. Could you go over what else he told you when

you saw him on September the 8th, 2005?

medications in a few weeks; he's tired of taking the

- 1 A. Yes, yeah.
- 2 Q. So you sent him over to the hospital to get
- some blood drawn and have it analyzed immediately?
- Α.
- Q. And let's take a look at that. What were his
- triglycerides?
- A. 940.
- Q. And what are triglycerides?
- A. It's a part of the lipids circulating in the
- Q. So a type of fat in the blood? 11
- 12 A. Yes.
- O. And is 960 high?
- A. That's very high.
- 15 Q. And what was his total cholesterol?
- A. 318. I can't read it. Either 318 or 328.
- 17 Q. Well, whether it's 318 or 328, is that very
- high? 18
- Yes. 19 A.
- 20 Q. And what was his hemoglobin A1c?
- A. 12.8.
- 22 Q. And is that very high?
- 23 A. Yes.
- 24 Q. What does a hemoglobin A1c of 12.8 tell you
- about the control of diabetes?

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- 1 A. Not controlled at all.
  - 2 Q. Based on these results and your evaluation of
  - Mr. Self, what advice did you give him or what was your
  - plan for him?
  - A. Give him new medication for his diabetes since

  - O. And what medicine --7
  - A. -- he said he's trying three different
  - medications and they're not helping him, so...
  - Q. So what did you put him on?
  - A. On the Avandia.
  - Q. If you take a look, I think you prescribed 12
  - Avandamet? 13
  - 14 A. Avandamet, yes.
  - 15 Q. All right. What is Avandamet?
- A. It's a combination of Avandia and Metformin.
- 17 Q. So essentially, you prescribed two drugs for
- him? 18
- Yes. 19 A.
- 20 Q. It's a combination drug?
- 22 Q. Why did you think that the combination drug
  - might be better than either Avandia or Metformin alone?
- 24 A. What's the benefit of combination --
- 25 Q. Yeah. In other words, you -- presumably, you

medicines because they're not helping his diabetes. 5 Q. And that's a reference to Actos, Glyburide and

Metformin? MR. DICKENS: Object to the form. 7

2 A. Well, I said here he did not take his

- 8 Q. (By Mr. Vale) Is that right?
- 9 A. Yes.
- 10 Q. And what symptoms did he have?
- A. He had the frequent urination, you know,
- thirst, fatigue, dry mouth, blurred vision, dizziness.
- 13 Q. What's that?
- 14 A. Dizziness.
- Q. Dizziness, okay. I mean, how serious did you
- -- if -- how serious was the situation that he was in?
- MR. DICKENS: Object to the form. 17
- 18 A. Well, having a blood sugar of 500, that's very
- serious. 19 20 Q. (By Mr. Vale) Okay. So what was your plan?
- Did he get some blood work done?
- 22 A. Yes. I -- on that day, I think so, yes.
- 23 Q. If you turn to page -- it's down on the
- bottom, page 11. I think you'll see some results from
- blood work. 25

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- 1 could have prescribed only Avandia or you could have
- 2 prescribed only Metformin, but you made a decision to
- 3 use the combination tablet, and I'm wondering why.
- 4 A. Well, Metformin by itself was not controlling
- 5 his diabetes, because he was already taking that.
- 6 Avandia is a new medication to him, okay, so he never
- 7 tried that medicine -- to my knowledge, he never tried
- 8 that medicine before, and taking the two medications
- 9 together might cause a synergistic effect and bring the
- 10 blood sugar more ...
- 11 Q. Okay. And what does synergistic mean?
- 12 A. It means the two drugs -- if you give Avandia
- by itself, it brings the blood sugar to a certain limit.
- 14 Giving Metformin by itself brings it to another certain
- 15 limit. The combination will work together and, you
- 16 know, bring the blood sugar down more than either one of
- 17 them.
- 18 Q. Okay. Did you give Mr. Self any advice about
- 19 diet?
- 20 A. Yes.
- 21 Q. And what did you tell him about that?
- 22 A. About the diabetes diet, you know, a limited
- 23 carb diet.
- 24 Q. Did you bring home to him that just taking the
- 25 medicines alone wouldn't do it?

- 1 retinopathy.
- 2 Q. Okay. Again, could you sort of turn that into
- 3 laymen's language? He said he had blurred vision. Did
- 4 you connect that up to the diabetes?
- 5 A. Yes, yes.
- 6 O. And --
- 7 A. To make sure he did not have, you know -- his
- 8 eye problems from the diabetes, you know.
- 9 Q. Did you ask him to come back and see you again
- in a week or two?
- 11 A. Yes.
- 12 Q. And is that common practice for when you first
- 13 --
- 14 A. Yes.
- 15 Q. -- see a patient with type 2 diabetes?
- 16 A. Yes. We put them on new medication and have
- 17 them monitor their blood sugar and bring the numbers in
- in a week or two weeks.
- 19 Q. All right. So did he come back and see you a
- 20 week later? If you look, I think there's a note there
- 21 from September the 15th, 2005.
- 22 A. Yes.
- 23 Q. And did you see him on that day?
- 24 A. Yes.
- 25 Q. Did you have any new blood work at that point?

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- MR. DICKENS: Object to the form.
- 2 A. I'm sorry. What's that?
- 3 Q. (By Mr. Vale) Did you make it clear to him
- 4 that diet was an important part of --
- 5 A. Yes, and I documented that.
- 6 Q. And how did you document it?
- 7 A. I put here strict ADA diet.
- 8 Q. And what does ADA mean?
- 9 A. You know, you limit the carbohydrates in the
- 10 food. Usually, I give the patients a small booklet we
- 11 get from the drug reps about the ADA diet. I can't tell
- you for sure if I gave him that or not because I've not seen that here in the documentation and I never document
- 14 that. I give, you know, the patient, you know, the
- small book, but usually, this is what I do.
- 16 Q. Did you have any other recommendations for Joe
- 17 Self on September 8, 2005?
- 18 A. I asked him to monitor his blood sugar and,
- 19 you know, to check his blood test, his diet, start the
- 20 new medication and follow up with an eye doctor.
- 21 Q. Why did you suggest that he go to an eye
- 22 doctor?
- 23 A. Because he's got uncontrolled diabetes and he
- 24 was complaining about the blurred vision, so he needed
- to have his eyes evaluated for diabetic neuropathy or

- 1 A. I did not order new blood work, no.
- 2 Q. Did he give you any report on how his blood
- 3 sugar was doing?
- 4 A. Yes.
- 5 Q. And what did he tell you?
- 6 A. He said they are much better, running between
- 7 100 to 140.
- 8 Q. Is that fasting?
- 9 A. Fasting, yes.
- 10 Q. Okay. So that's -- is that okay?
- MR. DICKENS: Object to the form.
- 12 A. Well, for a week after therapy, yes, that's
- 13 very good.
- 14 Q. (By Mr. Vale) So were you happy with how he
- was doing a week later?
- 16 A. Yes.
- 17 Q. And what about the symptoms that he'd
- described the week before? Were they still present?
- 19 A. Most of them, they'd gone.
- 20 Q. And which were the ones that had gone?
- 21 A. The polyuria, polydipsia, the fatigue --
- 22 Q. Wait. Just -- let's -- polyuria, polydipsia
- means too thirsty, too many visits to the bathroom?
- 24 A. Yes, yes.
- 25 Q. That had gone away?

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- 1 A. Yes. The fatigue went away and -- oh, well,
- he continued to have the blurred vision.
- 3 O. That was continuing?
- 4 A. Uh-huh.
- 5 Q. What was your plan for Joe Self on September
- 15th, 2005?
- 7 A. To continue taking the medicine twice a day.
- 8 Q. And the medicine, we're talking about
- Avandamet, right?
- 10 A. Yes, Avandamet, yes, twice a day. To continue
- that diet I recommended before, plus do the low-fat diet 11
- 12 because his cholesterol came back high, and to quit
- smoking, exercise and to follow up with an eye doctor. 13
- 14 Q. Is -- why did you advise him to quit smoking?
- A. Well, just to minimize the risk of the
- coronary artery disease.
- Q. I'm sorry. It's a risk for coronary artery 17
- disease?
- 19 A. Yes.
- 20 Q. And diabetes itself is a risk for coronary
- artery disease?
- A. That's right, yes.
- 23 Q. And what did you tell him about his eyes?
- 24 A. To follow up with the eye doctor.
- 25 Q. So to summarize that, you said continue the

- here and knowing what you know today, do you feel that
- was the right decision? 2
- MR. DICKENS: Same objection. 3
- A. Yes, yes.
- Q. (By Mr. Vale) And why do you say it was the
- right decision to prescribe Avandamet?
- A. Because he was already trying the three
- different medications for diabetes at that time and they
- did not control his blood sugar.
- O. And did the Avandamet seem to work? 10
- 11 A. Yes.
- Q. So you'd do the same again today? 12
  - MR. DICKENS: Object to the form.
- Yes. 14 Α.

13

- MR. VALE: Thank you. No further questions. 15
- I appreciate it. 16
- MR. DICKENS: Okay. Doctor, I will have some 17
- follow-up questions for you. 18
- THE WITNESS: Okay. 19
- CROSS-EXAMINATION 20
- BY MR. DICKENS: 21
- Q. Much like counsel for GSK said, if I ask a 22
- question that's not clear to you, just please ask me to
- rephrase that question.
- 25 A. Okay.

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- 1 Q. Doctor, just for preliminary reasons, have you
- ever been a speaker for GlaxoSmithKline?
- A. Never.
- Q. Have you ever been paid in any way by
- GlaxoSmithKline?
- A. Never.
- Q. Prior to today's deposition --
- A. Paid? I'm sorry. Paid in -- what money? You
- Q. In any format. As a speaker, as a consultant 10
- for GlaxoSmithKline.
- A. No, no. Because when we were in residency, we
- used to do a conference, like teleconferences and -- you
- know, to listen about medication and they will send us
- a check, like a \$100 check, you know, at the end of the 15
- conference. That's it. 16
- Q. Did you ever have any of those conferences,
- whether teleconference or going to an actual conference,
- with respect to Avandia? 19
- A. No. 20
- Q. Okay. Doctor, prior to your deposition today,
- did you speak with anyone at GlaxoSmithKline about this
- 23 deposition?
- A. Only with Mr. Vale and Pete.
- MR. VALE: Pete, just to set up the 25

Avandamet, you've got to have a low-fat American Diabetes Association diet, you need to quit smoking, you

- need to exercise --
- 4 A. Uh-huh.
- 5 Q. -- and you need to see the eye doctor?
- A. Uh-huh.
- Q. Do you have any recollection of seeing
- Mr. Self after September 15, 2005?
- A. After September 15?
- 10 Q. Yes.
- A. No, I don't remember.
- Q. He did -- I mean, based on the records, it
- looks like he came in and saw your partner, Dr. Haggag?
- Q. And when -- based on the records, at any rate,
- when did he see Dr. Haggag? Was that in March of 2006?
- 17 A. Yes.
- 18 Q. Based on your seeing Mr. Self on September the
- 8th and September the 15th, 2005 and knowing what you 19
- 20 know today, are you comfortable with your decision to
- have prescribed Avandamet? 21
- MR. DICKENS: Object to the form. 22
- A. I'm sorry? I was comfortable prescribing to him?
- 25 Q. (By Mr. Vale) Yeah. Based on what you see

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- 1 deposition.
- 2 Q. (By Mr. Dickens) What was the substance of
- 3 that conversation?
- 4 A. Well, you know, setting up the time and date
- 5 and I asked them I need the medical record before the
- 6 date. That's all.
- 7 Q. Did you ever tell anyone at GlaxoSmithKline
- s that you had a family member on Avandia?
- A. Did I tell him? Yes, I did.
- 10 Q. You told who?
- 11 A. I told Mr. Vale.
- 12 Q. When did you tell Mr. Vale that?
- 13 A. When I talked -- I spoke with him only one
- 14 time.
- 15 Q. Okay. So you spoke to Mr. Vale about setting
- up this deposition, about you having a family member on
- 17 Avandia. What else did you speak to Mr. Vale about?
- 18 A. That's it.
- 19 Q. Were you asked any questions about your use of
- 20 Avandia?
- 21 A. No. He did not ask me. I volunteered to say,
- you know, that my uncle, he is still taking Avandia.
- 23 Q. Did you volunteer any other information?
- 24 A. No.
- 25 Q. Okay. Did you speak to Mr. Vale personally

- 1 Mr. Self?
- 2 A. I don't remember. I mean, from my record, it
- 3 sounds like, you know, only Avandamet unless, you know,
- 4 there's something we did not document. You know, a lot
- 5 of time, you know, we do medication over the phone.
- 6 You know, we call it in. So just looking at the
- 7 document here, you know, Avandamet seems to be the only
- 8 medication I gave him.
- 9 Q. Now, Doctor, you indicated that Mr. Self had
- been on previous medications prior to his initial visit
- 11 to you; is that correct?
- 12 A. Yes.
- 13 Q. Did you ever see any of the medical --
- 14 previous medical records for Mr. Self on your initial
- visit or on later visits?
- 16 A. No.
- 17 Q. So you don't know what Mr. Self's blood sugar
- was while he was on these other medications?
- 19 A. Only by what he told me.
- 20 Q. Okay. But you personally have no knowledge of
- 21 what his blood sugars were on these other medications?
- 22 A. Not on paper documents. Just, you know, by
- 23 him saying.
- 24 Q. Okay. When he came to you on September 8th,
- 25 2005, he had not been taking any medication at all; is

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Га

- about setting up the deposition?
- 2 A. I think so, yes.
- 3 Q. And you also said a Peter from their office?
- 4 A. Yes.
- 5 Q. Were you personally in charge of setting up
- 6 this deposition?
- 7 A. No.
- 8 Q. Did you have a staff member handle that?
- 9 A. Oh, you mean from my side?
- 10 Q. Yes.
- 11 A. You know, it was me, yeah.
- 12 Q. Okay. And as far as you sit here today, you
- can't recall any other information that you volunteered
- 14 about your prescribing Avandia or treatment of Joe Self?
- MR. VALE: Objection. There's no evidence we
- 16 even mentioned Mr. Self.
- 17 A. I prescribed Avandia and I had my uncle --
- 18 he's still taking Avandia.
- 19 Q. (By Mr. Dickens) And that's all that you --
- 20 A. That's all I said, yes.
- 21 Q. Okay. Doctor, as far as you know, the only
- 22 medication for Mr. Self's diabetes that you prescribed
- was Avandamet: is that correct?
- 24 A. Yes.
- 25 Q. You didn't try any other medications for

- 1 that correct?
- 2 A. Yes.
- 3 Q. And he had been off of all medications for
- 4 some time?
- 5 A. Yes.
- 6 Q. Doctor, in 2005, there were numerous
- 7 medications to treat diabetes; is that correct?
- 8 A. Yes.
- 9 Q. Do you have any estimate how many medications
- 10 there were?
- 11 A. Well, there was Actos, Metformin, Avandia,
- Glyburide, the Glipizide, the insulin, plus the
- 13 combination medications. Those were the most commonly
- 14 prescribed at that time. There was Starlix too.
- 15 Q. So it's fair to say there were numerous
- medications that you could choose from in order to treat
- 17 diabetes?
- 18 A. Yes.
- 19 Q. And in making a decision on which medication
- 20 to treat, you, as a physician, would weigh the risks and
- benefits of those drugs?
- 22 A. Right.
- 23 Q. And you would try to choose the safest drug
- that would also be effective for a patient?
- 25 A. Yes.

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- 1 Q. So if there were two drugs that were equally
- 2 effective for treating diabetes, you would choose the
- safer drug?
- 4 A. That's right.
- 5 Q. Now, Doctor, where did you derive your
- 6 information about risks of a particular medication?
- 7 A. From reading the inserts, from the PDR, from,
- 8 you know, the drug reps.
- 9 Q. Okay. Now, you say the inserts. Can you
- 10 describe what you mean by that?
- 11 A. Like, you know, you get the samples. You
- know, it's got the inserts here for the patients in
- 13 it and we go over those. We go over many in the PDR
- or on the Hippocrates.
- 15 Q. You just mentioned Hippocrates. Can you
- 16 explain what that is?
- 17 A. It's -- well, I have it on my PDA. It's a
- program just like the PDR. It tells you about the
- dosages, the side effects, you know, the benefits,
- 20 you know, prescribing information.
- 21 Q. Does Hippocrates include all of the
- information that's in the PDR?
- 23 A. No.
- 24 Q. It only includes some information?
- 25 A. Exactly.

- 1 Q. And, Doctor, I presume that you treat various
- 2 diseases --
- з A. Uh-huh.
- 4 Q. -- including diabetes?
- 5 A. (Witness nods head up and down.)
- 6 Q. In your practice back in 2005, what were some
- of the other diseases that you were treating?
- 8 A. You know, internal medicine disease of all
- 9 kinds, you know.
- 10 Q. So there were many?
- 11 A. Yes.
- 12 Q. And there were medications you could prescribe
- 13 for all of these?
- 14 A. Yes.
- 15 Q. And you treated people with high cholesterol?
- 16 A. Yes.
- 17 Q. And there's medications called statins?
- 18 A. Yes.
- 19 Q. And those are used to treat high cholesterol?
- 20 A. Yes.
- 21 Q. And you would treat high blood pressure?
- 22 A. Yes
- 23 Q. And there's medications for high blood
- 24 pressure?
- 25 A. Yes.

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- 1 Q. And what is that information?
- 2 A. Like they tell you, you know, the prescribing
- 3 information, the major side effects --
- 4 Q. Does it provide all --
- 5 A. -- contraindications, black box warning, you
- 7 Q. So is it fair to say it provides you the major
- 8 side effects and major warnings of a drug?
- 9 A. Uh-huh.
- 10 Q. Does it provide all information about all
- adverse reactions you can have on the drug?
- 12 A. No.
- 13 Q. Now, was this Hippocrates available to you in
- 14 2005?
- 15 A. I believe so.
- 16 Q. Were you using it in 2005?
- 17 A. I think so.
- **18** Q. When you needed to receive information about a
- 19 particular medication, would you use Hippocrates or
- would you go to the actual hard copy of your PDR?
- 21 A. Both.
- 22 Q. Would you use one more so than the other?
- 23 A. Well, this is more handy to me, you know.
- 24 While I'm in a patient's room, you know, I can click and
- 25 look for the medication.

- 1 Q. So it's fair to say you were prescribing a lot
- 2 of medications in 2005?
- з A. Right, right.
- 4 Q. Now, for all of those medications, do you read
- 5 everything in the prescribing information, everything in
- 6 the Physicians' Desk Reference?
- 7 A. No.
- 8 Q. You don't read everything about every
- 9 particular drug?
- 10 A. No.
- 11 Q. You wouldn't reasonably have time to do that?
- 12 A. Exactly.
- 13 Q. So, Doctor, there's key information that you
- 14 would use in the PDR to read up about these medications?
- 15 A. Right.
- 16 O. What are those?
- MR. VALE: Objection.
- 18 A. Like, you know, what -- you meant when do I go
- to the PDR to look for...
- 20 Q. (By Mr. Dickens) And it wasn't a good
- question at all. When you are learning about a
- particular medication and you're going to read the
- pertinent information from the Physicians' DeskReference, what particular areas included in the
- 25 Physicians' Desk Reference do you read?

mysicians Desk Reference do you read:

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- MR. VALE: Objection.
- A. Indications for treatment, plus the side
- effects, the dosage for them. That's the main things
- that I look for.
- 5 Q. (By Mr. Dickens) So those are the main
- things, and also, you read up about information of side
- effects?
- A. Yes.
- 9 Q. And those are in the warnings?
- 10 A. Yes.
- Q. But regardless, it's fair to say that you 11
- don't read for each medication from top to bottom 12
- everything in the Physicians' --13
- MR. VALE: Objection. 14
- A. No, I don't. 15
- Q. (By Mr. Dickens) So you wouldn't know every
- piece of information that's included in the Physicians'
- Desk Reference about any particular medication; is that
- correct? 19
- 20 A. No.
- 21 Q. Now, Doctor, you indicated the insert. You
- read that to get information about a particular drug.
- Is that also known as prescribing information?
- 24 A. Yes.
- 25 Q. And would you agree that the information

- were at that time working at the Giles Family
- Practice; is that correct? 2
- A. Yes. 3
- Q. Would you run your own blood tests at that
- time or would you send patients out to have it done
- elsewhere?
- A. In the hospital.
- Q. Okay. So then this blood test which is on
- page 11, it was taken the same day as that initial
- visit?
- A. Yes. 11
- Q. And at that time, we've already indicated
- Mr. Self has a glucose of 182; is that correct?
- On that --
- 15 Q. And I'll refer you to page 11.
- Yes. 16 A.
- 17 Q. And a triglycerides of 960?
- 18
- 19 Q. And cholesterol of 318?
- Yes. 20 A.
- 21 O. And an A1c of 12.8?
- 22 A. Yes.
- 23 Q. And those are all high numbers?
- 24 A. Yes.
- 25 Q. And at this point, Mr. Self was not on

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- medication to control his diabetes?
  - Yes. Α.
  - Q. Now, Doctor, on your second visit --
  - A. Now, I'm not sure if this was fasting or not
  - fasting, the blood tests, you know -- but -- you know,
  - those numbers. I don't know if we documented or the lab
  - documented if that was a fasting sample or not.
  - Q. Doctor, generally when the laboratory takes a
  - fasting draw, do they indicate whether it was fasting or
  - not on the report? 10
  - A. Some of them, they do.
  - Q. Now, a nonfasting -- if it was a nonfasting
  - draw, that would affect the glucose, triglycerides and 13
  - cholesterol levels, correct?
  - A. Right. 15
  - O. They would be higher if it was a nonfasting
  - 17
  - Yes. 18
  - 19 Q. You would expect them to be higher?
  - 20 A. Yes.
  - Q. So, for example, had Mr. Self eaten a couple
  - doughnuts prior to taking his blood, those numbers
  - 23 would be expected to be higher?
  - 24 A.
  - MR. VALE: I'm sorry. Did you include A1c in 25

contained in that prescribing information is provided by

- the manufacturer of the drug?
- з A. Yes.
- 4 Q. So if you're going to be referring to the
- prescribing information for side effects, you're relying
- on the truthfulness and accuracy of that information as
- provided by the manufacturer?
- A. Yes. 8
- Q. So if the manufacturer doesn't provide
- truthful or accurate information, you can't reasonably
- 11 undergo a risk-benefit analysis. Would you agree with
- that? 12
- MR. VALE: Objection. 13
- 14 A. Yes.
- Q. (By Mr. Dickens) Now, Doctor, going back to
- the September 8th, '05 visit, which was your initial
- visit with Mr. Self, he had a blood pressure of 120/82? 17
- A. Yes.
- 19 Q. Is that in the normal range for blood
- pressure?
- 21 A. The 120 is. The 82, I mean, I would not treat
- that with medication. You know, I would prefer to bring
- it down a little bit more.
- 24 Q. Okay. And I'll also turn to the blood tests
- that you ran on that date. In the -- I believe you

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- that?
- THE WITNESS: A1c has nothing to do with 2
- 3 fasting.
- 4 MR. DICKENS: Thanks, Tony.
- MR. VALE: No. I didn't hear the question 5
- guite -- that could have been some --
- MR. DICKENS: No, that's fair. 7
- Q. (By Mr. Dickens) So the A1c, is it fair to 8
- say that that number would tell you, as a physician, a
- glucose range over roughly three months? Is that fair
- to say? 11
- A. Yes. 12
- Q. So his A1c at 12.8 indicates that his diabetes
- was uncontrolled?
- 15 A. Yes.
- 16 Q. Regardless of whether --
- A. It was very, very uncontrolled, yes.
- Q. Regardless of, you know, whether the other
- numbers were high or not?
- 20 A. Right.
- 21 Q. Now, Doctor, you indicated on your second
- visit you didn't have any blood drawn for Mr. Self at
- that time?
- 24 A. Yes.
- 25 Q. But it does appear that Mr. Self had his blood

- 1 Q. Now, his blood tests that you took on
- September 8th, '05 had triglycerides of 900?
- A. Yes.
- 4 Q. So 400, while still high, is still --
- Yes.
- Q. It's a decrease from that previous visit?
- 7 A. Oh, yes.
- Q. Now, his cholesterol, Doctor, is 328? 8
- A. Right.
- Q. You would agree that that is an actual 10
- increase from his visit on September 8th, 2009? 11
- MR. VALE: Objection. 12
- A. Not real -- I mean, it's increased but not a 13
- significant increase to me.
- Q. (By Mr. Dickens) Okay. Now, Doctor, at this
- point in time, Mr. Self had been taking a medication to
- control his diabetes, correct? 17
- MR. VALE: Objection. 18
- A. I'm sorry. What's that, again? 19
- Q. (By Mr. Dickens) March 29th, '06 --20
- A. Yeah. 21
- Q. -- Mr. Self had been prescribed by you
- Avandamet for approximately six months; is that correct?
- A. I can't tell you because I left the practice,
- if I remember, in December that year, yeah. I had to

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- taken by Dr. Haggag on the next visit, which I believe
- is March 29, 2006?
- з A. Yes.
- 4 Q. I'll refer you to page 7.
- 5 A. Yes.
- 6 Q. From this record, do you have any indication
- of whether this was a fasting draw or not?
- 8 A. Well, I can't tell you. I wasn't there at
- that time so...
- 10 Q. Now, Doctor, from your review of this
- collection --
- 12 A. Yeah.
- 13 Q. -- Mr. Self had a glucose of 119; is that
- correct?
- 15 A. Yes.
- Q. Was that within your range of -- your goal
- range for a patient with type 2 diabetes?
- A. It's acceptable, yes.
- 19 Q. And his triglycerides at this point were 463?
- 20 A. Yes.
- 21 Q. And that is --
- 22 A. High.
- 23 Q. It's still high?
- A. Yes. And as I said, I don't know if this was
- fasting or not fasting.

- quit that practice and move to a different practice, so
- I'm not sure what happened in between. I left, I think,
- in December of 2005.
- Q. So you, as far as you can recall, left the
- practice in December '05?
- Q. When you worked at the Giles Family Practice,
- Dr. Haggag, was he also a physician there?
- He was the owner.
- O. He was the owner?
- Yeah.
- 12 Q. So you were his employee?
- A. Yes. 13
- 14 Q. Is there any particular reason you left Giles
- Family Practice?
- A. Several reasons. Do I have to mention...
- Q. Oh, no. I'm not necessarily asking. 17
- 18 A. Yeah, several reasons.
- 19 O. Okav.
- A. Mainly financial stuff, yeah.
- Q. Okay. Now, Doctor, if you have a patient who
- presents to you with uncontrolled diabetes and they
- begin taking medications, undergo diet and exercise, would you expect their glucose levels to fall?

25 A. If they've taken their medications?

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- 1 Q. Yes.
- 2 A. Yes.
- 3 Q. And you would expect their A1c levels to fall?
- 4 A. Yes.
- 5 Q. Would you also expect their cholesterol levels
- to be improved?
- A. If they're doing the diet and taking the
- medicine, then yes.
- Q. So you would expect if they're dieting,
- exercising --
- 11 A. And exercising.
- 12 Q. -- taking their medication, that their
- cholesterol level would indeed fall?
- 14 A. Yes.
- 15 Q. Doctor, in fact, you want your diabetic
- patients to lower their cholesterol; is that correct?
- MR. VALE: Objection. 17
- A. My di' -- tolower their cholesterol? 18
- Q. (By Mr. Dickens) Yes.
- 20 A. Yes, I do.
- Q. And you'd also want them to lower their LDL?
- A. Yes, I do.
- O. Can you describe what LDL is?
- A. It's low-molecular lipid in the blood. It's
- associated with a higher risk of atherosclerosis or

- 1 Q. And it is linked to macrovascular
- complications?
- A. Yes.
- O. What are some of those macrovascular
- complications?
- A. Heart attack, stroke, peripheral vascular
- disease.
- Q. So diabetes is a risk factor for heart attack?
- Yes.
- Q. And heart attack is also known as myocardial
- infarction? 11
- 12 Α. Yes.
- What are some of the other risk factors for a
- heart attack?
- A. High cholesterol, hypertension, smoking. 15
- Q. Is family history?
- A. Yes.
- O. Now, Doctor, when Mr. Self presented to you,
- he had high cholesterol?
- A. (Witness nods head up and down.)
- Q. He had a family history?
- A. Did he -- you mean, did he mention he had high
- cholesterol when he came to me? I'm not sure if he
- checked his family history. His personal history -- he
- did not mention he had high cholesterol. All he

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- mentioned -- as I said, at that time I did not have his
- records. You know, we request the previous medical
- records on every patient we see at the clinic, and from
- what he mentioned in his past medical history or what he
- said about the diabetes and the appendicitis --5
- Q. From the blood tests that you drew on
- Mr. Self --
- A. Yes.
- Q. -- would you admit that those numbers
- indicated that Mr. Self had high cholesterol?
- Q. And I'll refer your attention to page 6 and
- the top of the page indicates some family history of
- illness?
- 15 A. Yes.
- Q. It appears he had a family history of heart
- disease?
- 18 A. Yes.
- 19 O. And Mr. Self was a smoker?
- Yes. 20 A.
- 21 Q. And he had diabetes at the time you saw him?
- 22 A. Yes.
- 23 So these are all risk factors for a potential
- heart attack?
- 25 A. Yes.

blockages in the heart and the vessels.

- Q. And is LDL also referred to as bad
- cholesterol?
- 4 A. Yes.
- 5 Q. Doctor, in 2005 when you were prescribing
- Avandamet, were you aware that Avandia was shown to
- cause an increase in LDL?
- MR. VALE: You mean was he like -- well, 8
- objection.
- 10 A. In 2005, I think so.
- Q. (By Mr. Dickens) But you don't know one way
- or the other, as you sit here? 12
- MR. VALE: Objection. 13
- 14 A. I mean, I can't tell you for sure if I was
- aware at that time or not, but -- and, you know, at some 15
- point, you know, we find out, you know, that it will 16
- increase the LDL, but I'm not sure on that date, you 17
- know, if we were aware that, you know, it will increase 18 the LDL or not.
- 20 Q. (By Mr. Dickens) Do you recall at all when
- you found that out or how you found that out? 21
- 22 A. No.

19

- 23 Q. Doctor, you'd agree that diabetes is a serious
- medical condition?
- 25 A. Yes.

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- 1 Q. And, Doctor, you indicated earlier that you
- 2 learned some information fairly recently with respect to
- 3 a potential association with respect to Avandia and
- 4 heart attacks; is that correct?
- 5 A. Yes.
- 6 Q. And you went and researched that information?
- 7 A. Yes.
- 8 Q. Do you recall any specific studies that you
- 9 looked at with respect to that association?
- 10 A. No.
- 11 Q. Do you --
- 12 A. I'm not good with the study names, you know.
- 13 I get the conclusions, you know.
- 14 Q. Okay. You indicated, though, that now you
- 15 have altered your prescribing practices with respect to
- 16 prescribing Avandia?
- 17 A. Yes.
- 18 Q. You prescribe Avandia less?
- 19 A. Yes.
- 20 Q. And to less patients?
- 21 A. Yes.
- 22 Q. And you don't prescribe, you indicated, to
- patients with congestive heart failure?
- 24 A. Yes. I don't.
- 25 Q. And you don't prescribe to patients who have

- 1 history of heart failure or coronary artery disease.
- 2 Q. Do you recall any change with respect to
- 3 myocardial infarction?
- 4 MR. VALE: Objection. I don't think it's fair
- 5 to ask the doctor to try to recite what's on a label
- 6 that you're not showing him.
- 7 MR. DICKENS: I'm just asking.
- 8 Q. (By Mr. Dickens) Do you recall anything, as
- 9 you sit here today?
- 10 MR. VALE: Objection.
- 11 A. Yeah, about heart disease and -- yes.
- 12 Q. (By Mr. Dickens) Okay. Doctor, do you
- subscribe to any medical publications?
- 14 A. I used to, the American -- the New England
- 15 Journal of Medicine before, but not recently; UpToDate,
- 16 all the time.
- 17 Q. When was the last time that you subscribed to
- the New England Journal of Medicine?
- 19 A. Several years ago. Since the UpToDate
- 20 came, I've been using UpToDate since that time.
- 21 Q. Do you recall or have any recollection of an
- 22 article that was published in the New England Journal of
- 23 Medication -- or New England Journal of Medicine
- 24 indicating that there was an association between Avandia
- and an increased risk of myocardial infarction?

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- 1 had a heart attack?
- 2 A. Yes.
- 3 Q. Do you also not prescribe to patients who have
- 4 high risk factors for these diseases?
- 5 MR. VALE: Objection.
- 6 A. No. That's not true.
- 7 Q. (By Mr. Dickens) Okay. So in doing a
- 8 risk-benefit analysis, do you take into consideration
- 9 the potential association between Avandia and a heart
- 10 attack?
- 11 MR. VALE: Objection.
- 12 A. I mean, for someone that had a history of
- 13 heart problems, yes, but for someone that did not have a
- 14 history of heart failure or heart attack, yes, I will
- not prescribe it, but just looking at his risk factors,
- you know, that's not going to alter my therapy that
- 17 much.
- 18 Q. Okay. Now, Doctor, you indicated there are
- many medications that you can prescribe?
- 20 A. Yes.
- 21 Q. Doctor, are you aware of a label change with
- respect to Avandia that occurred in 2007?
- 23 A. Uh-huh.
- 24 Q. What is your knowledge of that label change?
- 25 A. About prescribing Avandia to someone who has a

- 1 MR. VALE: Objection. It didn't exactly say
- 2 that.
- 3 A. I mean, I remember an article, but I don't
- 4 remember if it was from the New England Journal of
- 5 Medicine or --
- 6 Q. (By Mr. Dickens) Do you remember --
- 7 A. -- the American Heart Association or -- I
- 8 don't remember a source, but I remember that there was a
- 9 study about it.
- 10 Q. Do you recall a study published or authored by
- 11 a Steve Nissen?
- 12 A. I'm not good with names, so...
- 13 Q. Doctor, would you agree that one of your main
- 14 goals in treating diabetic patients is to reduce their
- risk for macrovascular complications?
- 16 A. Yes
- 17 Q. One of the main goals for lowering blood sugar
- is to prevent heart attacks?
- 19 A. Yes.
- MR. VALE: Objection.
- 21 Q. (By Mr. Dickens) And prevent other
- 22 cardiovascular events?
- 23 A. Yes.
- 24 Q. And, Doctor, surely you would agree that you
- 25 would not undergo treatment that would, in fact,

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- 1 increase a risk of a diabetic patient to have cardiac
- 2 complications?
- 3 A. I'm sorry. One more time again.
- 4 Q. Surely you would not advise a patient, one of
- 5 your diabetic patients to undergo a treatment that
- 6 would, in fact, increase their risk to have a cardiac
- 7 complication?
- 8 MR. VALE: Objection.
- 9 A. If I know for sure it's going to increase the
- risk, yes, I will not advise the treatment.
- 11 Q. (By Mr. Dickens) And you would not knowingly
- 12 prescribe a medication that could actually increase a
- diabetic patient's risk of having a heart attack?
- MR. VALE: Objection. Are you trying to characterize the witness's prior testimony or is this
- iust a new question?
- MR. DICKENS: It's a new question.
- MR. VALE: Objection.
- 19 A. Yes. Unless, you know, there's certain
- 20 conditions, like if you know the patient, you know, has
- 21 got no alternative to that medicine and there is a risk
- 22 from dying from diabetes versus another risk from
- 23 having, you know, small damage or a different type of
- 24 damage, you know, from taking the medicine, we just have
- to weigh the risks, you know, and the benefits of it.

- 1 Q. Okay. Do you still currently prescribe Actos
- 2 to your patients?
- з A. Yes.
- 4 Q. Do you prescribe Metformin?
- 5 A. Yes.
- 6 Q. Do you prescribe the whole gamut of diabetic
- 7 medications?
- 8 A. Uh-huh.
- 9 Q. Are there any diabetic medications that you
- 10 don't prescribe?
- 11 A. No.
- 12 Q. Okay. Do you prescribe some more than others?
- 13 A. Yes
- 14 Q. What are the ones that you prescribe more
- 15 often?
- 16 A. Metformin.
- 17 Q. Okay. So Metformin is --
- 18 A. Uh-huh.
- 19 Q. -- your go-to drug --
- 20 A. Yes.
- 21 Q. -- on diabetic patients?
- 22 A. Yes.
- 23 O. For a patient who has not tried any other
- 24 medications before that presents to you with
- uncontrolled diabetes, is it your standard of practice

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- 1 Q. (By Mr. Dickens) So what I'm taking is for
- 2 any choice of a diabetic medication, you're going to
- 3 weigh risks and benefits of drugs?
- 4 A. Right, right.
- 5 Q. And so therefore in that risk-benefit
- 6 analysis, you would take into consideration any
- 7 information you had with respect to one drug's
- 8 association of a potential cardiac event?
- 9 MR. VALE: Objection.
- 10 A. Yes.
- 11 O. (By Mr. Dickens) Doctor, as you sit here
- 12 today, are you aware that Avandia is associated with an
- increased risk of myocardial infarction?
- MR. VALE: Objection. It isn't.
- 15 A. Well, it's -- it increased the risk of mainly
- 16 having congestive heart failure. About having acute MI,
- 17 I'm not sure.
- 18 Q. (By Mr. Dickens) Okay. Doctor, Avandia is in
- a class of medicines known as TZD, correct?
- 20 A. Uh-huh.
- 21 Q. And are there any other medications in that
- 22 class?
- 23 A. No.
- 24 Q. Is Actos a TZD?
- 25 A. No, I don't think so.

- 1 to start them on Metformin first?
- 2 A. Unless there's a contraindication.
- 3 Q. Contraindication with another medication?
- 4 A. A contraindication for the Metformin.
- 5 Q. Doctor, we've talked some about information
- 6 that you've learned about Avandia from when you were
- 7 prescribing it in 2005 until today. Can you give me a
- 8 summary of the information that you've learned about
- 9 Avandia in the past four years?
- 10 MR. VALE: Objection.
- 11 A. I will not prescribe it to someone who has a
- 12 history of congestive heart failure. That's the main
- thing, you know, I learned.
- 14 Q. (By Mr. Dickens) And that also applies to you
- won't prescribe it for someone who has a history of
- 16 myocardial infarction?
- MR. VALE: Objection.
- 18 A. Yes.
- 19 Q. (By Mr. Dickens) And why is that?
- MR. VALE: Objection.
- 21 A. Because it will put them at risk for having
- 22 congestive heart failure.
- 23 Q. (By Mr. Dickens) So Avandia would put that
- patient in risk of having another cardiac complication?
- 25 A. Yes.

3 - -

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- 1 Q. Are there any other medications that you don't
- -- diabetic medications that you don't prescribe because
- it puts a patient at risk for cardiac complications?
- 4 A. Cardiac complications, no.
- Q. So Avandia is the only one?
- A. I think so.
- Q. So then, Doctor, it's true that -- or correct
- me if I'm wrong that Avandia is, in your risk-benefit
- analysis, the only medication that cardiac complications
- weighs into the risk in your analysis?
- MR. VALE: Objection. 11
- 12 A. Yes.
- Q. (By Mr. Dickens) Now, Doctor, you talked some 13
- about being visited by sales representatives. Do you
- recall that?
- A. Uh-huh, yes. 16
- Q. Did you talk to any sales representatives 17
- about your deposition today?
- A. No. 19
- 20 Q. Okay. Now, you said when the information came
- out about a potential association of Avandia and 21
- myocardial infarction, you spoke to some sales 22
- representatives about that?
- MR. VALE: Objection. 24
- 25 A. I think so.

- point that Avandia could raise triglyceride numbers?
- MR. VALE: Objection. 2
- A. Yes. 3
- Q. (By Mr. Dickens) So as far as you know, from
- the information that you've read in your clinical
- practice, does Metformin raise triglycerides or LDL?
- 7
- Q. Does Actos raise triglycerides or LDL? 8
- Q. Are there any other diabetic medications
- besides Avandia that you know of that raise LDL and
- triglycerides? 12
- MR. VALE: Objection. 13
- A. Not to my knowledge.
- Q. (By Mr. Dickens) And, Doctor, part of your 15
- goal in prescribing a medication to a physician -- or
- strike that. Part of your goal in prescribing a 17
- medication to control diabetes in your diabetic 18
- population is to reduce their risk of macrovascular 19
- complication, correct? 20
- MR. VALE: Objection. 21
- 22
- 23 Q. (By Mr. Dickens) High LDL is a risk for
- macrovascular complication, is it not?
- 25 A. Yes.

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- 1 Q. And triglycerides is a risk?
- A. Yes.
- Q. So in your risk-benefit analysis on your
- diabetic medications, Avandia is the only diabetic
- medication that you take into consideration in 5
- 6 increase in LDL, correct?
- 7 MR. VALE: Objection.
- A. I'm sorry. What was that?
- Q. (By Mr. Dickens) In comparing the medications
- in a risk-benefit analysis of the diabetic medications 10
- you have, the only medication that you take into
- consideration for risk of increased LDL is Avandia?
- A. Yes. 13
- Q. And the only medication in your risk-benefit
- analysis of diabetic medications for an increase of
- triglycerides is Avandia? 16
- 17 MR. VALE: Objection.
- A. Yes. 18

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- 19 Q. (By Mr. Dickens) And for those patients that
- you said have cardiac history or a negative cardiac
- history, whether that be myocardial infarction or 21
- congestive heart failure, the only medication that you 22
- 23 wouldn't prescribe to them, being a diabetic patient, is
- Avandia? 24 25
  - MR. VALE: Objection.

1 Q. (By Mr. Dickens) Do you recall names of any

- particular sales representatives?
- з A. No.
- 4 Q. Do you currently have Avandia sales
- representatives who visit you?
- A. Not in a few months.
- Q. Okay. Do you recall their names at all?
- A. No.
- Q. What did the drug sales representatives you
- spoke to about a potential association of Avandia and
- myocardial infarction tell you with respect to that 11
- information? 12
- MR. VALE: Objection. 13
- A. Not to prescribe it for someone who has a 14
- history of congestive heart failure or a heart attack or 15
- coronary artery disease. 16
- Q. (By Mr. Dickens) Did they tell you about any 17 head-to-head studies run by GlaxoSmithKline?
- A. They probably did, but I don't remember what.
- Q. Okay. Doctor, you indicated that at some
- point you learned that, in fact, Avandia can raise LDL; is that true? 22
- 23 Α. Yes.

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- MR. VALE: Objection.
- 25 Q. (By Mr. Dickens) Did you also learn at that

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- 1 A. Yes.
- 2 Q. (By Mr. Dickens) So, Doctor, if you had a
- patient where Avandia and another diabetic medication is
- equally effective, is it fair to say with all of these
- factors of LDL, raising triglycerides, cardiac
- complications, that you would choose the other drug
- that's just as effective? 7
- MR. VALE: Objection. Argumentative. 8
- Yes. 9 Α.
- Q. (By Mr. Dickens) So if the other medications 10
- -- just to be clear -- were just as effective, you would 11
- choose those other medications over Avandia? 12
- MR. VALE: Objection. Argumentative. 13
- Unless Avandia is the only alternative he's 15
- Q. (By Mr. Dickens) So being the only 16
- alternative, the other -- if that patient has tried all 17
- of the other medications? 18
- MR. VALE: Objection. Argumentative. 19
- A. Right, or he could not -- you know, he could 20
- not take, you know, any other medicine for, you know, 21
- whatever reason, allergy or side effects. 22
- O. (By Mr. Dickens) Okay. So, Doctor, when you
- saw Mr. Self on your two visits and you ran his blood
- tests, you've already indicated that he had high

- 1 A. And they did not put that on the second blood
- work here, I'm looking at.
- Q. So the second blood work of March 29th, 2006,
- you don't know whether that's fasting or not?
- A. I don't know. We did not document that.
- Q. Doctor, knowing what you know now today about
- Avandia and its association with an increase in
- triglycerides, LDL and a potential association with 8
- myocardial infarction, it's fair to say that knowing
- what you know now today about all of those that you 10 11 would have prescribed another medication for Mr. Self.
- MR. VALE: Objection. 12
- A. No. I would still prescribe it to him at that 13
- time and even at this time.
- Q. (By Mr. Dickens) Okay. Has your risk-benefit 15
- analysis you've taken with respect to Avandia changed
- since 2005? 17
- MR. VALE: Objection. David, how many times
- are we going over this? I mean, we -- this is about the 19
- third or the fourth time. It's --20
- A. What was the question again? 21
- Q. (By Mr. Dickens) Has your risk-benefit
- analysis with Avandia changed at all since 2005? 23
- MR. VALE: Objection. 24
- 25 A. Yes.

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- cholesterol numbers?
- A. Yes.
- 3 Q. And he had high triglyceride numbers?
- 4 A. Not on the first visit. I did not find this
- until the next visit, you know, a week later because the
- first visit, he had the blood tests. The blood test,
- you know, results, you know, were a couple of days 7
- you know, I learned about the high cholesterol.

later. So when he came a week later, that's when I --

- 10 Q. So you learned on the second visit of his high
- cholesterol, his high triglycerides?
- A. As I said, that was nonfasting, the blood 12
- tests, so I can't tell you if it's true high cholesterol 13
- or not. Because I'm looking here. She labeled 14
- wherever, you know, we checked his blood. They labeled, 15
- Is patient fasting? They put no. 16
- Q. And that was which record, just so I'm clear? 17
- A. Number 11.
- Q. Okay. So on Number 11, you indicated they
- said no for fasting?
- A. Yes. 21
- 22 Q. And can you just point me to where it says
- that?
- 24 A. (Witness complies.)
- 25 Q. Okay.

- 1 Q. (By Mr. Dickens) Doctor, do you recall any
- specific conversations you had with GlaxoSmithKline
- sales representatives about myocardial infarction?
- A. I don't remember.
- O. You don't remember any?
- Specifics, no, I don't.
- Q. Doctor, you indicated you have an uncle
- currently on Avandia?
- 9 A. Yes.
- Q. Does he have high cholesterol? 10
- Yes. 11 A.
- 12 Q. Does he have high blood pressure?
- 13 A. Yes.
- 14 Q. Does he have high triglycerides?
- A. I don't remember, but he's taking medicine for
- high cholesterol. I mean, I can't remember his LDL or
- triglyceride levels, but... 17
- Q. Doctor, you also indicated that the samples
- your uncle has for his Avandia come from you?
- A. Uh-huh. And from another doctor friend of 20 mine, too.
- Q. Doctor, would you, as a prescribing -- as a 22
- prescribing physician of Avandia to patients including 23
- an own family member, be concerned if GlaxoSmithKline
- did not want to publish studies because it put their 25

21

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- drug in a negative light?
- MR. VALE: Objection. 2
- A. I'm sorry. Say --3
- 4 Q. (By Mr. Dickens) Well, Doctor, I've handed
- you earlier a protective order. Did you happen to have
- a chance to read that and endorse --
- A. Not the whole thing, no, but... 7
- MR. DICKENS: I'll just ask if we can go off 8
- the record and we'll discuss the signing of the
- protective order, or we can do it on record. 10
- MR. VALE: I mean, are you really going to 11 show him some documents from --12
- MR. DICKENS: I am, yes, Tony. If the doctor 13 is willing to --14
- 15 MR. VALE: I object to doing that. He's never
- seen them before. How could he possibly evaluate 16
- 17 documents that you're going to handpick a few pages and
- a few sentences out of a few pages -- out of ten million 18
- pages and you're going to ask him like, well, what if 19
- this or what if that? I mean, it's totally improper. 20
- MR. DICKENS: I appreciate your objection and 21
- I know that you've placed it on the record; however, if 22
- the doctor is willing to sign a protective order, I'll
- be willing to show him some internal documents. 24
- 25 MR. VALE: I can't stop you doing it. I think

- 1 Q. Did they ever indicate to you that they had an
  - advisory board prior to the study being released? 2
  - MR. VALE: Objection. 3
  - 4 A. Well, I learned, I mean, before that study
  - about, you know, increased, you know, edema, you know,
  - fluid retention with Avandia, but, I mean, to stop 6
  - 7 taking Avandia because of the congestive heart failure,
  - you know, not until that study was published. 8
  - Q. Doctor, did anyone at GSK ever tell you that a
  - member of their own advisory board indicated that their
  - own clinical trials raised a red flag for Avandamet 11
  - 12 because Avandia and Metformin showed a higher myocardial
  - ischemic event than they had originally predicted? 13
  - A. No. 14

15

- MR. VALE: Objection. No foundation.
- Q. (By Mr. Dickens) Nobody ever told you that? MR. VALE: Objection. 17
- 18 A. No.
- Q. (By Mr. Dickens) Would that be something you 19
- would be concerned with? 20
- MR. VALE: Objection. 21
- A. About the red flag, you mean?
- O. (By Mr. Dickens) Would you be concerned if 23
- GSK's own clinical studies showed that Avandia and
- Metformin, being Avandamet, showed higher myocardial

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- events than other medications? 1
- MR. VALE: Objection. Foundation. 2
- A. Well, there is a lot of medicines, you know, 3
- that carries the risk of, you know, heart events. You 4
- 5 just have to weigh the benefit and the risk and
- 6 decide, you know, which one concerns you more.
- Q. (By Mr. Dickens) Doctor, you indicated 7
- earlier -- and correct me if I'm wrong -- that none of 8
- 9 the other medications that you're aware of for treating
- 10 diabetic patients have a -- that you have a concern
- with respect to increasing cardiovascular complications? 11
- MR. VALE: Objection. 12
- Q. (By Mr. Dickens) Isn't that correct? 13
- A. I'm sorry. What's that, again?
- O. You indicated earlier that out of the diabetic
- medications that you prescribe, the only one that
- you're -- weigh in the risk-benefit analysis --17
- A. Concerned, yes. Concerned more than the other 18
- medications, yes.

25

- Q. -- is Avandia? So, Doctor, assuming that it 20
- is true that Avandia, in fact -- or what has been said 21 in these articles that there is an increased association
- 23 with Avandia in myocardial infarction, would that have
- changed your risk-benefit analysis for Mr. Self? 24
  - MR. VALE: Objection. This is about the

it's absurd. I think it's inappropriate. 1

THE WITNESS: In a few minutes, I can't do 2 that. It's going to take time. 3

4

5 6

7

- MR. DICKENS: Well, we can go off the record, have you have a chance to read the protective order and
- if you're willing to agree to the terms of those, that you won't share these documents or this information with
- anybody else, then we can move forward. 8
- 9 MR. VALE: I don't think that's the point. He can look at that. It's -- what you're going to do is 10 ask him to look at some snippets and somehow or other
- 11 make an evaluation of that. 12
- MR. DICKENS: Well, Tony, you have every 13 opportunity to cross-examine the witness. 14
- MR. VALE: Well, I do, but I think what I'm 15 hearing Dr. Faour saying is that he doesn't sound like 16
- he likes the idea of that. 17
- THE WITNESS: If you, you know, sent me those 18 documents yesterday or a few days ago, I mean, I'd go 19
- over them. Now, I --20 Q. (By Mr. Dickens) All right. That's fine. If 21
- 22 -- okay. I understand. Doctor, did anyone at
- GlaxoSmithKline ever indicate to you that they had an advisory board for cardiovascular complications?
- 25 A. I mean, after -- yes. After that study, yes.

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- fourth or fifth time we've had this, and it's
- speculative. I mean, how is this question different --
- Q. (By Mr. Dickens) And the difference is
- I'm saying assuming that this information is
- true --
- A. Yes.
- Q. -- that, in fact, Avandia increases myocardial
- infarction over the other diabetic medications, would
- that fact change your decision --
- A. No. No, it would not.
- Q. So it wouldn't change -- your risk-benefit 11
- 12 analysis wouldn't change even knowing that Mr. Self had
- risk factors for myocardial infarction and prescribing a 13
- diabetic medication would, in fact, increase his risk 14
- 15 for myocardial infarction? That wouldn't change at all?
- MR. VALE: Objection. Objection, David. 16
- You're just arguing with the doctor now. 17
- A. No, it would not because his blood sugar was 18
- way, way out of control to weigh the risk of -- a small 19
- risk of, you know, having, you know, heart failure from 20
- the medicine versus, you know, the risk from dying, you 21
- know, a week later from having blood sugar of 600 or, 22
- you know, getting into DKA or a coma from, you know...
- Q. So you needed to prescribe him a diabetic
- medication?

- medications, you know, including Metformin and they were
- not doing any good for him. That's why he quit taking 2
- 3 them, so...
- 4 MR. DICKENS: Okay. If I can just take maybe
- 5 a five-minute break and then I'll wrap up with maybe one
- or two more questions, if that's all right. 6
- 7 MR. VALE: Sure.
  - THE VIDEOGRAPHER: We're off the record at
- 10:32 a.m. 9

8

10

- (Whereupon, a short break was had.)
- 11 THE VIDEOGRAPHER: We're back on the record at 12 10:36 a.m.
- Q. (By Mr. Dickens) Doctor, just a couple more 13
- questions for you. Just for some clarification, when
- you indicated that you wouldn't prescribe Avandia to a 15
- patient who had prior congestive heart failure and
- myocardial infarction, does that also include other 17 cardiovascular complications?
- MR. VALE: Objection. We've gone over this 19 20 several times.
- Q. (By Mr. Dickens) And all I'm asking here is
- there -- if a --
- A. No. There's CHF and the coronary artery
- disease.
- 25 Q. So are you aware of something called a bundle

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- Q. And the reason you didn't prescribe him
- Metformin alone is because he indicated that it wasn't
- working in the past?
- A. Right. 5
- Q. So had he not been on any other diabetic
- medications, would you have prescribed Metformin?
- MR. VALE: Object. 8
- A. Yes. 9
- Q. (By Mr. Dickens) And had Metformin actually 10
- worked at treating his diabetes, would you have
- prescribed Metformin again? 12
- A. If it helped his diabetes, yes, I would.
- Q. So if Mr. Self had documented evidence that,
- in fact, Metformin was effective at lowering his blood 15
- sugar, you would have continued or renewed his 16
- prescription for Metformin? 17
- MR. VALE: Objection. His blood sugar was 18 over 500. 19
- A. Yes. If he documented that, yes. 20
- Q. (By Mr. Dickens) Okay. And when his blood 21
- sugar when he presented to you was at 500, he wasn't 22
- on any medications at that time?
- A. Yes, but he said -- that's what he told me and
- documented that. He was taking three different

branch block?

- Yes. Α.
- Q. Would that be something you would consider in
- your risk-benefit analysis of patients who had a
- previous bundle branch block? 5
- MR. VALE: Objection. 6
- A. No. I mean, a bundle branch block, there is 7
- several reasons. You know, a lot of times, it's just
- 9 normal. You know, you are just born with it or it just
- happens, you know, a conduction defect in the heart, but 10
- sometimes it happens from having, you know, a heart
- attack that affects, you know, that bundle, you know, 12
- and, you know, causes the block. But if it's just a 13
- bundle branch block without heart failure or heart
- attack, no, it would not affect my prescription.
- Q. (By Mr. Dickens) Now, Doctor, after your
- second visit in 2005 with Mr. Self, did you ever treat 17
- Mr. Self after that? 18
- A. Just from looking at the records, no.
- 20 Q. You don't recall ever --
- A. No, I don't recall. 21
- Q. Ever recall prescribing any more medications
- 23 for Mr. Self?
- 24 A. I don't. Me just personally, I don't remember
- unless, you know, you've got some other records or

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Page 85 1 pharmacy records. 2 2 Q. I'm just asking for your recollection. з A. Yeah. I don't. MR. DICKENS: Okay. I have no further questions. REDIRECT EXAMINATION 6 BY MR. VALE: Q. One question, Dr. Faour. Do you have a copy of the -- what we marked as Exhibit 2, the PDR? 10 10 A. I should. 11 11 Q. If you'd just turn to the page for Avandia, it's actually under the heading Precautions on page 1441 12 in the top right-hand corner. Do you have that? 13 14 14 A. Yeah. 15 Q. And so we're looking at the PDR for 2005 for 15 the section on Avandia and -- under the heading 16 Precautions, and then on the left-hand side, it's got a 17 17 heading Edema? 18 19 A. Yes. 19 20 Q. Do you see that? What is edema? 20 A. Edema is fluid retention. 21 O. And does GlaxoSmithKline write in this 22 information under Precautions "Since thiazolidinediones, 23 including rosiglitazone, can cause fluid retention --25 A. Uh-huh, yes. 25 Page 86 1 Q. -- which can exacerbate or lead to congestive heart failure, Avandia should be used with caution in

patients at risk for heart failure"? 4 A. Yes. 5 Q. And then it goes on to say "Patients should be monitored for signs and symptoms of heart failure"? A. Yes. Q. And it refers you to the warning section of the label? A. Yes. 10 O. So that's what doctors were informed in 2005? A. Uh-huh, yes. 12 MR. VALE: Thank you very much, Dr. Faour. I 13 appreciate you coming in today. 14 MR. DICKENS: Thank you very much. We're all 15 16 set. THE VIDEOGRAPHER: We're off the record at 17 10:40 a.m. 18 19 (End of proceedings.) 20 21

CERTIFICATE I, TERRI COMSTOCK, Court Reporter and Notary Public in and for the State of Tennessee, do hereby certify that I reported by means of stenotype the foregoing deposition at the time and place stated in the caption thereof; that later the deposition was reduced to computerized transcription under my supervision and the foregoing pages contain a full, true and accurate transcript of the testimony of said witness on said I further certify that I am neither of counsel nor related to any of the parties of said cause nor in any manner interested in the result hereof. Given under my hand and seal of office on the 4th day of December, 2009. Terri Comstock, Court Reporter and Notary Public State of Tennessee

My Commission Expires: September 13, 2010

Plaintiffs' Motion re: Defendant's Ex Parte Contacts with Plaintiffs' Treating Physicians

## IN THE COURT OF COMMON PLEAS PHILADELPHIA COUNTY, PENNSYLVANIA

: February Term 2008

IN RE: AVANDIA LITIGATION

: No. 2733

\_\_\_\_\_\_

## **CERTIFICATE OF SERVICE**

I, Tracy A. Finken, Esquire, hereby certify that on this 19th day of January, 2010, I served the foregoing Plaintiffs' Letter Motion re: Defendant's *Ex Parte* Contacts with Plaintiffs' Treating Physicians via the Court's Electronic Filing System upon the following:

Christopher W. Wasson, Esquire Joseph C. Crawford, Esquire Pepper Hamilton LLP 3000 Two Logan Square Eighteenth and Arch Streets Philadelphia, PA 19103-2799

Track A. Finken

Case ID: 080202733