IN THE STATE COURT OF FULTON COUNTY
STATE OF GEORGIA

TALMADGE KING, as the natural mother of Samuel J. Moody, deceased, and EUNICE WHITE and CYNTHIA MOORE, as the natural sisters of Samuel J. Moody, deceased,
Plaintiffs,
v. CIVIL ACTION FILE NO. 09EV007396-J
NOVARTIS PHARMACEUTICALS CORPORATION, ABBOTT LABORATORIES, INC., TIMOTHY A. YOUNG, M.D. and PACES FERRY MEDICAL GROUP, P.C.,
Defendants.

Deposition of NEAL L. JULIE, M.D.
Rockville, Maryland
Wednesday, July 27, 2011
8:05 a.m.
Reported by: Stephany L. Jerome, RPR



A P P E A R A N C E S

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Deposition of NEIL L. JULIE, M.D., held at the offices of:

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Pursuant to agreement, before Stephany L. Jerome, Registered Professional Reporter and Notary Public in and for the State of Maryland.



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1 PROCEEDINGS
2 MR. BAZINETT: This is going to be the
3 deposition of Neal L. Julie, M.D. taken in the case
4 of White versus Young, et al., which is Civil Action
5 File Number 09EV007396 dash J in the State Court of
6 Fulton County, Georgia. It is being taken for the
7 purposes of discovery and all other purposes allowed
8 by the Georgia Civil Practice Act.
9 Do you want to stipulate that all
10 objections, except to the form of question,
11 responsiveness of the answer or privilege, however,
12 are reserved? John?
13 MR. STEEL: Yes.
14 EXAMINATION BY COUNSEL FOR THE DEFENDANTS
15 BY MR. BAZINETT:
16 Q Will you state your full name for the
17 record, please?
18 **A Neal Louis Julie.**
19 Q You've given deposition before, correct?
20 **A Yes.**
21 Q Just a couple things. If I ask a question
22 that you don't understand, rather than trying to
23 answer it in any way, will you agree just to tell me
24 you don't understand it?
25 **A Sure.**

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1 Q Second thing is, we can take a break at
2 any time you want to. The only thing that I ask is
3 that if there's a question pending, in other words,
4 if I've already asked a question, that you answer
5 the question before we break. Will you agree to
6 that?
7 **A Okay.**
8 Q What I want to do right off the bat is to
9 get an understanding of the nature and scope of the
10 opinions that you're going to be offering in this
11 case. One of the first questions I want to ask is,
12 do you intend to offer any opinions to the effect
13 that Dr. Timothy Young breached the standard of care
14 in any way with respect to his treatment of Samuel
15 Moody?
16 **A I do.**
17 Q What are your opinions with respect
18 Dr. Young's compliance with the standard of care as
19 it relates to Samuel Moody?
20 **A Well, the first opinion is that he failed**
21 **to determine to a degree of more likely than not**
22 **that the patient actually had a case of**
23 **onychomycosis, O-N-Y-C-H-O-M-Y-C-O-S-I-S, due to a**
24 **fungus treatable with Lamisil.**
25 Q What other opinions do you have with

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1 respect to Dr. Young's compliance with the standard
2 of care?
3 **A Secondly, Dr. Young had deficiencies in**
4 **his documentation that are reflective in his record**
5 **that make it really unclear as to what the diagnosis**
6 **he was entertaining at the time truly was and what**
7 **the results of treatment were, what the physical**
8 **findings were on examination.**
9 Q What other opinions, if any, do you have
10 regarding Dr. Young's compliance with the standard
11 of care?
12 **A The third would be that while Dr. Young**
13 **expressed an intent to check liver enzymes at six**
14 **weeks due to his familiarity with the fact that**
15 **Lamisil had potential hepatotoxicity and he failed**
16 **to do so, and also failed to document a follow-up**
17 **appointment in six weeks for the purposes of doing**
18 **such a test and doing other types of steps in his**
19 **evaluation and treatment.**
20 Q What other steps?
21 **A Just physical examination.**
22 Q Other than what you've already told me, do
23 you have any other opinions concerning Dr. Young's
24 compliance with the standard of care?
25 **A The next would be that he deviated from**

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1 **the standard of care in the 12-week follow-up which**
2 **was on April 12th in failing to establish the**
3 **diagnosis of cholestatic liver injury and to,**
4 **therefore, avoid the administration of other**
5 **hepatotoxic medications to a patient who already had**
6 **a clinical pattern consistent with liver injury.**
7 Q What other opinions do you have with
8 regard to Dr. Young's compliance with the standard
9 of care?
10 **A Well, those are the basic opinions, and**
11 **whether there are other particular aspects of his**
12 **care that you may discuss in terms of other visits**
13 **and I may have comments on those, I think I've hit**
14 **on the major deviations as I see them.**
15 Q Do you also intend to offer opinion
16 testimony that one or more of the drugs that
17 Dr. Young prescribed to Samuel Moody caused liver
18 injury?
19 **A Yes.**
20 Q What are your opinions in that regard?
21 **A Well, my opinion is that Lamisil initiated**
22 **a cholestatic liver injury with injury to the**
23 **patient's bile ducts and that the subsequent**
24 **administration of Biaxin acted as a second hit, sort**
25 **of a one-two punch, and carried the patient over the**

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1 **edge to irreversible liver failure and ultimately**
2 **transplant and death.**
3 Q What is your business address?
4 **A 15225 Shady Grove Road.**
5 Q How long have you been operating at that
6 address?
7 **A Actually, I was in that building, then**
8 **left that building, then came back to the building.**
9 **So, you know, there's an interruption there for a**
10 **while, but essentially 25 years.**
11 Q Do you have any relatives that live in
12 Fulton County, Georgia?
13 **A No.**
14 Q I do not mean anything by this question.
15 It's standard. Have you ever been convicted of a
16 crime?
17 **A No.**
18 Q Have you ever been a defendant in a
19 medical malpractice lawsuit?
20 **A Yes.**
21 Q More than one?
22 **A Yes. I mean, it depended on how far it**
23 **goes to become considered a lawsuit, but I think**
24 **actually of the three none of them ever made it to**
25 **Court and trial; but I have been named.**

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1 Q With respect to the first medical
2 malpractice lawsuit in which you were named as a
3 defendant, what were the allegations against you?
4 **A Well, that was when I was finished with my**
5 **residency and I was working for a year in emergency**
6 **medicine, and I was working at a small hospital,**
7 **didn't have a CT scan, maybe only had about 50 or 60**
8 **beds. And there was a guy who was in a single car**
9 **crash. He was very drunk and drove his car into a**
10 **telephone pole or a pylon, and dislocated his**
11 **shoulder and had a closed-head injury.**
12 **So because of the closed-head injury I**
13 **stabilized him and sent him to the local medical**
14 **center so he could get a head CT scan because that**
15 **was his biggest risk, and he subsequently recovered**
16 **and had his shoulder relocated and put back into the**
17 **socket by an orthopedist at this other institution,**
18 **but then suffered some loss of function in that**
19 **shoulder. And he was suing, and part of his**
20 **allegation was that as a result of chronic shoulder**
21 **pain he had to drink 15 beers a day to control his**
22 **pain.**
23 Q What did the plaintiff allege that you
24 particularly did wrong?
25 **A I guess his allegation was that I did not**

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1 **put his shoulder back in place at the time, but**
2 **instead immobilized it and sent him on.**
3 Q What was the resolution of that lawsuit?
4 **A It was in California. It went to an**
5 **arbitration hearing with either a judge or a senior**
6 **lawyer, and was dismissed and tossed out.**
7 Q In what year was that lawsuit filed?
8 **A Probably around 1985-86.**
9 Q In what county in California?
10 **A I'm sorry, let me correct that. It would**
11 **have been 1983-84.**
12 Q In what county in California?
13 **A I'm not sure.**
14 Q Where were you living at the time?
15 **A Well, the city -- and you can look up what**
16 **the county is because I'm not very good on the**
17 **counties in California, but the city was called**
18 **Tracy, T-R-A-C-Y, California, and that's in northern**
19 **California.**
20 Q Were you the only defendant in the
21 lawsuit?
22 **A I don't think so, but I don't remember the**
23 **full details of who else was named.**
24 Q What was the subject matter of the second
25 medical malpractice lawsuit in which you were a

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1 defendant?
2 **A The second lawsuit was a case where a**
3 **patient was admitted with either diverticulitis or**
4 **some type of intraabdominal infection to a surgical**
5 **service -- might have also been gallbladder, acute**
6 **cholecystitis, I'm not sure. So the surgeon wrote**
7 **an order for cefoxitin. The patient was penicillin**
8 **allergic, and over the course of several days in the**
9 **hospital developed some respiratory symptoms, some**
10 **mild respiratory distress, that resolved, and I was**
11 **a consultant in the case as a gastroenterologist so**
12 **she sued with a claim that the cefoxitin had induced**
13 **a pulmonary allergic reaction due to**
14 **cross-sensitivity for a penicillin allergy, and she**
15 **just named both of us, the surgeon and myself.**
16 **And that also went to -- I'm not sure if**
17 **it went to mediation or not, but it basically was**
18 **dismissed with prejudice. Is that what they call**
19 **it?**
20 Q In what state was that lawsuit filed?
21 **A Montgomery County.**
22 Q That's in Maryland?
23 **A Right.**
24 Q What year was the lawsuit filed?
25 **A Let's see. Probably the late '80s.**

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1 Q What was the resolution -- I'm sorry, the
2 entire lawsuit, including the claims against you,
3 were dismissed with prejudice?
4 **A Yes. I mean, I don't think -- I think the**
5 **whole thing was dismissed with prejudice, but I**
6 **don't know what happened in terms of the surgeon. I**
7 **mean, I know there was no settlement paid, but to my**
8 **understanding it was dismissed.**
9 Q What was the subject matter of the third
10 medical malpractice lawsuit in which you were the
11 defendant?
12 **A The third case was a patient who had had a**
13 **cholecystectomy at Montgomery General Hospital, and**
14 **the surgeon had, unbeknownst to him, transected the**
15 **common bile duct, and, you know, the patient was**
16 **having some trouble with pain and fluid accumulation**
17 **in the abdomen. And I was called as a**
18 **gastroenterologist to do an ERCP on the patient. I**
19 **did the first ERCP, during which the patient became**
20 **quite combative so we had to terminate the procedure**
21 **early, and then we repeated the ERCP a few days**
22 **later and identified the duct transection. And the**
23 **patient went to a tertiary institution where they**
24 **tried to repair the duct, and there was a lawsuit**
25 **primarily against the surgeon, but I was also**

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1 **included in the defendants.**
2 Q In what year was the lawsuit you've just
3 described to me filed?
4 **A It was early to mid-1990s.**
5 Q Where was it filed?
6 **A Montgomery County.**
7 Q What was the resolution of the lawsuit as
8 to you?
9 **A It was settled. I paid, I think, 15**
10 **percent of the settlement or maybe 10 percent. My**
11 **settlement portion was around 60 to $90,000.**
12 **(Brief interruption.)**
13 BY MR. BAZINETT:
14 Q Other than the three lawsuits you just
15 described to me, have you ever been a party to any
16 other lawsuit?
17 **A Not an active party, no.**
18 Q I'll show you what I've marked as Exhibit
19 1. It is a copy of your c.v. Is the copy that I
20 have marked up-to-date?
21 **A Actually, it's not. There's a 2010**
22 **updated version that is more up-to-date than this.**
23 Q What is on the 2010 updated version that
24 is not on Exhibit 1?
25 **A There is a -- I'm on the editorial board**

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1 **of a journal called The World Journal of Hepatology.**
2 **That's new. I also have two additional**
3 **publications. One is in a peer-reviewed**
4 **international journal. The other is an internal**
5 **publication within my hospital's system where we**
6 **have sort of like "MediScene." It's sort of**
7 **distributed to all the doctors who are on staff in**
8 **the Adventist hospitals in this area. So it's**
9 **published there.**
10 **And what else? Maybe one new committee**
11 **assignment. I think I'm on the Pharmacy and**
12 **Therapeutics Committee. But if you want, I might be**
13 **able to -- we can check, I think I may have my c.v.**
14 **on a memory stick, and we can try and see if we can**
15 **pull it up on your computer, if you'd like me to.**
16 MR. BAZINETT: Let's go off the record a
17 second and try to do that.
18 (A brief recess was taken from 8:25 to
19 8:27 a.m.)
20 BY THE WITNESS:
21 Q While we were off the record we tried to
22 pull up or access your c.v. -- updated c.v. and
23 weren't able to do that. What is the publication
24 you described to me as being a peer-reviewed journal
25 that is on the updated c.v. that's not on the c.v.

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1 we've marked as Exhibit 1?
2 **A Complicated title, but I'll do it as best**
3 **I can from memory. Troglitazone,**
4 **T-R-O-G-L-I-T-A-Z-U-O-N-E, but not rosiglitazone --**
5 **which is R-O-S-I with the same ending -- alters**
6 **mitochondrial DNA in hepatocytes.**
7 Q Is the article you just described to me
8 the article I marked as Exhibit 2?
9 **A Yes, it is.**
10 Q What journal is that in?
11 **A Let's see, it is in Toxicology and Applied**
12 **Pharmacology, 2010.**
13 Q What was your role in the preparation of
14 that article?
15 **A Well, my role was in the clinical side of**
16 **the discussion of mitochondrial liver disease, and**
17 **in the review, and the editing and the writing of**
18 **the introduction and the discussion.**
19 Q When you say the clinical side of
20 mitochondrial liver disease, describe to me with
21 specificity what you did particularly to contribute
22 to the article.
23 **A My role was mainly in review of the**
24 **photographs and the data and in decisions in terms**
25 **of how the experiments were going to be planned and**

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1 **the, you know, various doses of the drug that were**
2 **used. And, like I said, it was involved in the**
3 **writing and the editing of a lot of the introduction**
4 **and the discussion, and, actually, additionally**
5 **there was a presentation that I made of a poster of**
6 **this article in a meeting of the AASLD, which is the**
7 **American Association for The Study of Liver Disease,**
8 **in San Francisco, I think, in 2009 or 10 -- probably**
9 **2010, might have been 2009 -- at which I, you know,**
10 **presented the poster and discussed the findings of**
11 **the poster with various people who came to look**
12 **things over.**
13 Q Does this case we're here about today
14 involve mitochondrial liver disease in any way?
15 **A Well, that's a difficult question in terms**
16 **of, you know, the pathophysiology of Lamisil and**
17 **erythromycin liver toxicity. To my knowledge,**
18 **mitochondrial dysfunction hasn't been invoked as a**
19 **central component of their toxicity. So in that**
20 **sense, no. But whether or not those drugs may act**
21 **on mitochrondria in some way to induce part of their**
22 **damage, it's possible.**
23 Q Is there anything in the article we've
24 marked as Exhibit 2 that you think bears on any of
25 your opinions in this case?

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1 **A I don't think that there's anything in the**
2 **article that pertains to this particular case, but,**
3 **you know, the field of drug-induced hepatotoxicity**
4 **covers a lot of different causes. So, you know, the**
5 **expertise that I have and have utilized in the**
6 **preparation of that paper carries over to having**
7 **expertise in hepatotoxicity due to non-mitochondrial**
8 **causes as well.**
9 Q What is the subject matter of the hospital
10 publication that is not listed on the copy of the
11 c.v. that we have.
12 **A Let's see. That was on looking -- because**
13 **of a committee that I was on at the time -- looking**
14 **at patients who presented to the emergency room with**
15 **elevated immature white cells called bands,**
16 **B-A-N-D-S, and what those numbers were, and, if the**
17 **person's numbers exceeded a certain threshhold, even**
18 **if they didn't have a fever, was that an indicator**
19 **of serious infection? So that again is not going to**
20 **really relate to this case, but that was the topic.**
21 Q You also mentioned that -- something about
22 the Pharmacy and Therapeutics Committee is not on
23 the c.v. that we've marked as Exhibit 1. When did
24 you became a member of the Pharmacy and Therapeutics
25 Committee?

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1 **A About two years ago.**
2 Q What is your role on that committee?
3 **A I'm one of the member doctors, and so, you**
4 **know, I get to be part of the decision-making in**
5 **terms of new guidelines, protocols, what drugs come**
6 **into the hospital, what drugs do not, what**
7 **monitoring requirements or recommendations we want**
8 **to make, what drugs should be restricted, things**
9 **like that.**
10 Q With which hospital is this Pharmacy and
11 Therapeutics Committee associated?
12 **A Shady Grove Adventist Hospital.**
13 Q In your role as a member of the Pharmacy
14 and Therapeutics Committee at Shady Grove Adventist
15 Hospital, have you done anything at all with respect
16 to either terbinafine or chlarithromycin?
17 **A Not that I recall --**
18 Q The other thing that you mentioned as not
19 being cited on the c.v. we've marked as Exhibit 1 is
20 your membership on the editorial board of The World
21 Journal of Hepatology. Who publishes that?
22 **A I think the spelling I may get wrong, but**
23 **I think it's Baisheng, B-A-I-S-H-E-N-G, Publishing,**
24 **and it's based in China.**
25 Q Is it a peer-reviewed journal?

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1 **A Yes, it is.**
2 Q How long has it been in publication?
3 **A The journal?**
4 Q Yes.
5 **A Well, it's kind of a brother-sister**
6 **journal. There was a sister journal which was The**
7 **World Journal of Gastroenterology, and, you know,**
8 **hepatology is a subcomponent, in essence, to**
9 **gastroenterology since it does not have, you know,**
10 **or it has not generally had its own unique Boards**
11 **that are mutually exclusive. So there's a Journal**
12 **of Gastroenterology which predated the World Journal**
13 **of Hepatology, which probably came into being**
14 **somewhere around 2008-2009. And so it kind of**
15 **budded off of The World Journal of Gastroenterology**
16 **and became a World Journal of Hepatology, and I**
17 **joined at that time.**
18 Q In what year did you join?
19 **A I think it was about 2009.**
20 Q In your role as a member of the editorial
21 board of The World Journal of Hepatology, have you
22 ever reviewed any articles that touched on
23 drug-induced liver injury involving either
24 terbinafine or chlarithromycin?
25 **A No.**

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1 Q Looking at your c.v., what was your
2 undergraduate major?
3 **A My undergraduate major was biological**
4 **oceanography.**
5 Q What made you want to go to medical
6 school?
7 **A You know, I think I was very good at**
8 **science and also liked people and liked helping**
9 **people. And so I liked the humanities, but at the**
10 **same time my skill sets were mostly science and math**
11 **so I decided medicine would be a good marriage of**
12 **those things.**
13 Q On your c.v. on the third page there is a
14 section that is entitled Research, and the first
15 line in that section or the first bullet point in
16 that section is listed as Environmental Science Lab
17 at Mount Sinai Hospital by Irving Selikoff,
18 Director. During what period of time did you do
19 research at the Environmental Science Lab?
20 **A I did that for a year between college and**
21 **medical school.**
22 Q What particularly were your duties at the
23 Environmental Science Lab?
24 **A You know, those were pretty broad-ranging,**
25 **but I'll give you have a couple examples. I worked,**

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1 **you know, with a lot of investigators so on the one**
2 **hand there were epidemiological studies that were**
3 **being done by one of the woman physicians who was**
4 **studying the exposure of painters, I think, probably**
5 **to lead-based paints so we did a lot of epidemiology**
6 **and numbers crunching.**
7 **Then I also worked on actual millipore**
8 **filter analyses using electron microscopy to look**
9 **for particulates where we pulled samples from air in**
10 **different parts of New York City, where I lived at**
11 **the time, to see what the ambient concentrations of**
12 **particulates and the size range of particulates were**
13 **in those various neighborhoods. I went on a trip to**
14 **Groton, Connecticut, where we did actual field**
15 **surveys of workers who were exposed primarily to**
16 **asbestos in the shipyards. We took a trip up to**
17 **Hudson Falls, New York, where GE had a big PCB**
18 **plant. It was for capacitors where they used a lot**
19 **of PCBs. And at that I did interviews of**
20 **patients -- of workers and also took photographs of**
21 **their skin lesions, which are called chloracne.**
22 **So there were a lot of different aspects**
23 **of the entreprise in which I participated.**
24 Q For what period of time were you at the
25 Environmental Science Lab in terms of how many

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1 months or how many years?
2 **A For about a year.**
3 Q While you were at the Environmental
4 Science Lab, did you do any work that related
5 specifically to exposures of railroad workers to any
6 type of toxic substances?
7 **A No.**
8 Q Was most of your work at the Environmental
9 Science Lab focused on asbestos or was there an
10 equal distribution among various potential
11 toxicants?
12 **A Well, you know, asbestos is actually how**
13 **Selikoff actually got started, but actually it was**
14 **probably a little less than half of what we did.**
15 Q On that same page, page three, at the top
16 of the page there is a bullet point that says,
17 "Clinical and scientific research: Extensive study
18 in field of drug-induced hepatotoxicity and
19 mechanisms of liver injury." That is a bullet point
20 that is under the title, Clinical Practice:
21 Interest and Accomplishments.
22 What research have you done in the area of
23 drug-induced hepatotoxicity and mechanisms of liver
24 injury?
25 **A Well, you know, I think that, you know,**

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1 **for the clinical -- the physician is sort of the**
2 **clinical first responder in the early identification**
3 **of drug-induced hepatotoxicity or in any kind of**
4 **hepatotoxicity due to things in the environment to**
5 **which we may be exposed so, you know, I have**
6 **written case reports. So there was a case report on**
7 **a drug. I wrote the first paper on that drug and**
8 **subsequently, due to the toxicity of the drug, it**
9 **was taken off of the market three or four years**
10 **later because of the drug toxicity, some of which I**
11 **had helped to identify.**
12 **As far as other research that I've done,**
13 **subsequent to my explorations of the toxicity of**
14 **Rezulin, R-E-Z-U-L-I-N, I then did a look back and**
15 **reviewed a lot of clinical records and identified a**
16 **mechanism of the drug-induced liver toxicity which**
17 **had not really been identified before. So that was**
18 **more on the epidemiological side of the tracks.**
19 **In the paper that you just described, you**
20 **know, or that we were just talking about, I had an**
21 **opportunity to work with some people who were more**
22 **bench researchers looking on a cellular level to try**
23 **and explain what are the disruptions that take place**
24 **within the cell that manifest clinically as drug**
25 **toxicity. And then also I've done some -- attended**

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1 **meetings that are held primarily by the FDA in**
2 **conjunction with the AASLD and also even with the**
3 **input of PhRMA, P-H-R-M-A, part of that capitalized,**
4 **which is a multidisciplinary event at which doctors**
5 **from all over the country and even all over the**
6 **world come and discuss the latest findings in**
7 **hepatotoxicity. So, you know, that's the gist of**
8 **it.**
9 **And I've read hundreds of papers on**
10 **hepatotoxicity and know a lot of the luminaries in**
11 **the field, and I've had some good conversations and**
12 **debates with them about our understanding of modern**
13 **day drug-induced hepatotoxicity.**
14 Q I show you what I've marked as Exhibit 3.
15 Is that the case report that you just described to
16 me?
17 **A Yes. That's the case from 1998, correct.**
18 Q I'll show you what I'll mark as Exhibit 4.
19 Is this one of the articles that you just described
20 to me?
21 **A Right, that is.**
22 Q Is that the one on Rezulin?
23 **A Well, actually all of those three are on**
24 **Rezulin in one way or another, but this is the one**
25 **that was a look-back on a set of 11 different**

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1 **patients where I looked at the underlying mechanism**
2 **that explained the pathophysicology of what went on.**
3 Q And what is the relevance or importance of
4 the article being a look-back as opposed to
5 something else?
6 **A Well, I think that, you know, in a lot of**
7 **things in life one has the opportunity to learn from**
8 **their mistakes, and I think in terms of the case of**
9 **Rezulin, you know, it was a drug that in retrospect**
10 **was a mistake and caused a lot more harm than good.**
11 **And so I think that if you really want to understand**
12 **more about drug-induced hepatotoxicity, if you look**
13 **and do sort of a postmortem analysis of, you know,**
14 **what is this drug, what does it do, how did it work,**
15 **how did it cause damage, then you can learn a lot of**
16 **things that will help you the next time a drug comes**
17 **along to ask the right questions in advance so that**
18 **you can avoid another therapeutic misadventure.**
19 **So, you know, because of the fact that a**
20 **lot of times once these drugs are off the market**
21 **people sort of forget about and don't discuss it any**
22 **further, I had a unique opportunity to go back and**
23 **go through these patients' charts, really break it**
24 **down, sort of do like a documentary autopsy to see**
25 **if I could figure out what the situation was, and**

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1 **I've learned some valuable lessons which I put into**
2 **the paper.**
3 Q With reference to one of the articles that
4 you have authored or coauthored you mentioned
5 working with bench researchers. What was your role
6 as opposed to the bench researchers' role in the
7 preparation of that article?
8 **A In that article that we were discussing**
9 **earlier on?**
10 Q Yes. In reference to which you discussed
11 bench researchers?
12 **A Right. Well, you know, when we first**
13 **wrote this paper -- here, let me actually, you know,**
14 **kind of read the title in because there's a few**
15 **papers around. And it's called, "Mitochondrial**
16 **dysfunction and delayed hepatotoxicity: Another**
17 **lesson from troglitazone."**
18 **So when we first put together this**
19 **article -- the bench researcher of whom I'm speaking**
20 **is a guy named Dr. Glenn Wilson, who's a**
21 **mitochondrial expert at the University of Southern**
22 **Alabama. We actually had taken this paper and this**
23 **paper and had tried to present it to the editorial**
24 **board as a hybrid, as a single paper where we**
25 **integrated the two aspects, the clinical and the**

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1 **scientific cellular. There's this field now -- are**
2 **you familiar with the term translational medicine?**
3 Q What does translational medicine mean?
4 **A It means taking things that you see at the**
5 **bedside and bringing them to the bench and vice**
6 **versa. Being able to actually kind of make that**
7 **kind of communication and connection between the two**
8 **aspects of scientific knowledge so that you can take**
9 **the latest bench breakthroughs and figure out how to**
10 **integrate it clinically, or you can take the most,**
11 **you know, compelling clinical problems and break**
12 **them down and help people who are working in the**
13 **labs direct their attentions at that.**
14 **So what we tried to do is to do that,**
15 **which was to synthesize those two into one paper.**
16 **We sent it to the editor, and the editor said, wait,**
17 **you know, this is way too unusual a concept and too**
18 **confusing; you should really break it down into two**
19 **papers and then submit them to their separate, you**
20 **know, kind of disciplines and do it that way. So**
21 **that's how it happened.**
22 **So initially it was actually Dr. Wilson**
23 **looking at mitochondria and looking at troglitazone**
24 **and looking at rosiglitazone in isolettes, in cells,**
25 **in laboratories. Me looking at the clinical records**

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1 **and the clinical manifestations, the liver biopsies,**
2 **the outcomes, the lab results, and we wove that all**
3 **together, but then to get it published we had to**
4 **break it apart. And so that is how, you know, the**
5 **relationship began. That's how one paper became two**
6 **papers.**
7 Q You mentioned in describing to me your
8 work in the area of drug-induced hepatotoxicity and
9 liver injury attendance at certain FDA meetings.
10 What FDA meetings have you attended with specific
11 reference to drug-induced hepatotoxicity and/or
12 mechanisms of liver injury?
13 **A There are -- and, again, I'm sorry, but**
14 **it's on my c.v., the updated c.v., so I'll get you a**
15 **copy of that. But generally there's an annual**
16 **meeting, usually in the month of March or April, and**
17 **it usually occurs at the National Labor College here**
18 **in Washington, D.C., and I've attended -- I guess in**
19 **the last four years I've attended either two or**
20 **three of those. One of them was not at the National**
21 **Labor College. I think that might have been**
22 **somewhere else. But, anyway, so it's an interesting**
23 **meeting and, you know, I think there's a lot of**
24 **interesting information that goes back and forth so**
25 **that's the extent of it.**

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1 Q The meetings, whether at the National
2 Labor College or not, are they limited to the topic
3 of hepatotoxicity and mechanisms of liver injury or
4 are they broader than that?
5 **A They are limited to hepatotoxicity, and**
6 **usually they break it down even further than that**
7 **so, you know, one meeting may just be looking at**
8 **causation scoring systems, you know, and how**
9 **reliable are they and how can we make them better.**
10 **And so, you know, they even go a little bit further**
11 **and more granular in terms of like not looking at --**
12 **they look at hepatotoxicity, but they look at a**
13 **particular subject within that topic.**
14 Q Does your updated c.v. describe on it the
15 particular years that you attended those FDA
16 meetings?
17 **A It will give the years, and it might give**
18 **the title of that particular year's meeting, but it**
19 **doesn't get any more detailed than that. Although,**
20 **I mean, I have notebooks that have some of the**
21 **information there, I didn't put that on the c.v.**
22 Q Another thing you mentioned in connection
23 with your experience in the field of drug-induced
24 hepatoxicity and mechanisms of liver injury is
25 attendance at events involving PhRMA. Does your

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1 updated c.v. have it on the particular PhRMA events
2 you've attended?
3 **A No. Let me clarify that. The events that**
4 **I'm talking about that usually occur at the National**
5 **Labor College are jointly cosponsored by the FDA,**
6 **AASLD and PhRMA. So it's a tripartite kind of a**
7 **hosting.**
8 Q The AASLD is what?
9 **A The American Association for The Study of**
10 **Liver Disease.**
11 Q Are you a member of that organization?
12 **A Yes.**
13 Q How long have you been a member?
14 **A About a year or two.**
15 Q What are the qualifications that are
16 required for membership in the AASLD?
17 **A I think you've got to be Board certified**
18 **in gastroenterology. You have to, you know, have**
19 **sufficient academic training. You need to have, I**
20 **think, two AASLD members who write letters**
21 **sponsoring you.**
22 Q Who sponsored you?
23 **A A doctor named Scott Friedman. I can**
24 **never remember if it's F-R-I-E or F-R-E-I.**
25 Q In what state does he practice?

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1 **A In New York City. He's the Chief of**
2 **Gastroenterology, I believe, at Mount Sinai**
3 **Hospital.**
4 Q And who is your other sponsor?
5 **A John Senior.**
6 Q Where does he practice?
7 **A He was previously the head of the Liver**
8 **Section of -- I think there's something called**
9 **CEDER, C-E-D-E-R, at the FDA. So he was one of the**
10 **heads in some subdivision regarding liver disease at**
11 **the FDA.**
12 Q Does the AASLD publish a journal?
13 **A Yes.**
14 Q What's the title?
15 **A Hepatology. And they may have a second**
16 **journal called Liver Transplantation.**
17 Q Do you regularly review either of those
18 two journals?
19 **A Not as a reviewer, but for my own benefit,**
20 **yes.**
21 Q Are those two journals that
22 gastroenterologists would regularly consult for
23 information about drug-induced liver injury?
24 **A Hopefully. Although, I don't rely on the**
25 **journal.**

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1 Q On page three of your c.v. two bullet
2 points down from the bullet point we've been
3 discussing about hepatotoxicity and mechanisms of
4 liver injury, the entry is, "Interests include TQM,
5 outcomes research and guidelines implementation in a
6 community setting, medicine and the environment."
7 To what does that relate?
8 **A That is -- those are areas that I had**
9 **worked in in -- you know, dating back six, seven,**
10 **eight years ago. So outcomes research, you know,**
11 **the point of doing a lot of medical care you want**
12 **take make sure it's actually going to benefit your**
13 **patient. That's what outcomes research is about.**
14 **And guidelines are meant to reflect what's good**
15 **practice and beneficial practice.**
16 **TQM I think is total quality management,**
17 **and, you know, I think those are -- there's**
18 **different names that come along every couple of**
19 **years as they redesign the concept. So TQM, I**
20 **think, has gotten into things like critical pathways**
21 **and things like that that work within health care**
22 **systems to try and make sure, you know, when**
23 **somebody comes in with a broken hip, they get**
24 **managed and they have an optimal outcome, and, you**
25 **know, stay the appropriate number of days, and get**

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1 **the antibiotics at the right time, et cetera.**
2 **What else is there? And, you know,**
3 **medicine and the environment, you know, I think**
4 **drugs are just an extreme example of how things that**
5 **are exogenous or sometimes called xenobiotics,**
6 **X-E-N-O biotics, can come into our systems and do us**
7 **harm. So that's true for the environment. It's**
8 **true for the BP oil spill. It's true for drugs.**
9 Q Have you been involved in promulgating any
10 type of guidelines that are intended to be applied
11 to medical practice?
12 **A Well, I was involved in sort of quality**
13 **monitoring, which I guess relates tangentially. So,**
14 **you know, we wanted to make sure that the doctors**
15 **were doing a good job when it came to doing**
16 **colonoscopies, and I was an active participant in**
17 **setting up the parameters to benchmark competence by**
18 **gastroenterologists in terms of endoscopy skills.**
19 Q And are those guidelines that you just
20 described to me about endoscopy published in any
21 journal or any type of publication at all?
22 **A Only internally within our hospital**
23 **system.**
24 Q It's hospital related?
25 **A Right.**

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1 Q Is it correct to say that you have not
2 been involved in the publication of any guidelines
3 that are intended for use by physicians across the
4 country generally to guide their practice?
5 **A Well, I mean, if you go into the**
6 **discussion portion of my paper on mitochondrial**
7 **dysfunction, you'll see some very clear guidelines**
8 **of how doctors should approach abnormal liver**
9 **enzymes in patients who are on those particulars**
10 **drugs. So in a way that's a guideline, but it's not**
11 **written out as such; it's in the body of an article.**
12 Q The next bullet point on page three
13 references in its first clause a special clinical
14 interest in hepatology. You touched on it earlier,
15 but I would like to ask you directly what is the
16 difference between gastroenterology and hepatology?
17 **A I'll try to make that short. So**
18 **historically, you know, the liver buds off of your**
19 **intestines when you're a fetus and, you know, is**
20 **intimately attached to your G.I. tract, and when**
21 **people broke medicine down into specialties, many**
22 **decades ago, they included the liver in**
23 **gastroenterology, and they have right to this date.**
24 **So if you do a fellowship in gastroenterology, you**
25 **learn about all the lumenal G.I. tract, colon,**

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1 **intestines, but also learn about the liver, the**
2 **pancreas, the gallbladder. That's all part and**
3 **parcel of gastroenterology.**
4 **Now, in the advent of transplant**
5 **hepatology because they have such a special set of**
6 **problems that they deal with, end stage liver**
7 **disease, hepatitis A, B, C, Delta hepatitis and**
8 **liver transplantation and liver failure, they have**
9 **gotten a set of training that's useful for people**
10 **who deal with patients pre- and post-transplant so**
11 **that's a field called transplant hepatology, and I**
12 **think actually they're starting to create a Board to**
13 **look at that. But right now gastroenterology is a**
14 **single Board that covers both gastroenterology and**
15 **hepatology, but the liver is a complex and**
16 **mysterious and fascinating organ that, you know, I'm**
17 **especially interested in.**
18 Q Is particular fellowship training
19 available in the area of hepatology?
20 **A Like I said, it is done in the context of**
21 **transplant programs so there's transplant**
22 **hematology. Now, as an entity of training that's**
23 **not related to transplant hepatology and not related**
24 **to gastroenterology, I'm not aware of any additional**
25 **training program that is uniquely hepatology that's**

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1 **not related to transplant and that's not related to**
2 **lumenal gastroenterology.**
3 Q On page two of your c.v. at the bottom
4 under the clinical practice interests and
5 accomplishments section is listed quality
6 improvements: "Initiated a major CQI program in the
7 G.I. subsection at SGAH." What was that program?
8 **A That program was the one I had mentioned**
9 **about, you know, completion of colonoscopy and**
10 **threshholds. The other things that I did maybe that**
11 **might reflect is there was a question whether**
12 **gastroenterologists, colorectal surgeons and general**
13 **surgeons should have to go through the same type of**
14 **credentialing requirements and preconditions to be**
15 **given privileges to do colonoscopy and polypectomy.**
16 **So in each of those three specialties should there**
17 **be a set of standard requirements that you needed to**
18 **meet to be considered to be qualified? And so the**
19 **answer to that was yes, there needed to be. So we**
20 **put together a multidisciplinary committee, which I**
21 **headed, to establish those parameters.**
22 Q And when you're talking about
23 qualifications and credentialing, you're talking
24 about credentialing at Shady Grove Adventist
25 Hospital?

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1 **A Right.**
2 Q There are three hospital affiliations
3 listed in the middle of page two of your c.v. Do
4 you still have full privileges at all three of those
5 hospitals?
6 **A I think that -- I still have full**
7 **privileges, yeah.**
8 Q Are you still admitting patients to all`
9 three of those hospitals?
10 **A I don't really admit to Montgomery General**
11 **Hospital much at all. I mean, I go there more for**
12 **cross-coverage, but I just had to simplify my life**
13 **so that one was a little far away so I stopped going**
14 **there. I still can. I still have privileges there.**
15 Q At what hospitals, other than those
16 listed, have you had privileges in the past?
17 **A Just my fellowship, you know, I had**
18 **privileges at the hospital at the University of**
19 **Pennsylvania, at the Philadelphia VA Hospital, but**
20 **these were special kind of privileges that are**
21 **stipulated as being for people in training, you**
22 **know.**
23 Q Have you ever had your privileges at any
24 hospital denied, suspended, restricted or revoked?
25 **A No.**

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1 Q Have you ever had any type of dispute over
2 your hospital privileges?
3 **A No.**
4 Q In the professional membership section you
5 have listed ASGE and AGA. What are those two
6 groups?
7 **A The American Society for Gastrointestinal**
8 **Endoscopy, and the AGA is the American**
9 **Gastroenterological Association.**
10 Q What are the qualifications for AGA
11 membership?
12 **A Again, you've got to be Board certified in**
13 **gastroenterology. I don't remember because I've**
14 **been a member for so many years that I kind of**
15 **forgot what else I needed. You know, you do an**
16 **application and all that.**
17 Q Also in that section of your c.v. is
18 listed participant at the first national meeting of
19 NAPE, National Association of Physicians for the
20 Environment. When was that meeting?
21 **A Wow. That was way back. Probably in the**
22 **late '80s, early '90s.**
23 Q Is NAPE a group that still exists today?
24 **A I don't think so.**
25 Q For how long did the group exist?

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1 **A Don't know.**
2 Q What was the purpose of NAPE?
3 **A Well, you know, there's an organization**
4 **that has existed for many years called Physicians**
5 **for Social Responsibility, and, you know, the gist**
6 **of what they represent is doctors who unite using**
7 **the perspective of doctors and healers to take a**
8 **stand against, you know, nuclear war and perhaps**
9 **unjustified war. And so this was an organization**
10 **that was intended to be, because of our position as**
11 **physicians and healers, a group of doctors to step**
12 **into the debate and discuss the environmental issues**
13 **of lead exposure, noise polution, workplace hazards,**
14 **water polution, to try and do that using what we**
15 **knew about science and health and to play a role in**
16 **that debate.**
17 Q Are you currently a member of any groups
18 that have a similar mission to NAPE?
19 **A Not really.**
20 Q Have you been in the past?
21 **A I don't know that there's any doctor based**
22 **groups that, you know, fit that description so not**
23 **that I recall.**
24 Q Earlier on in your deposition you
25 mentioned that one of the lawsuits that was filed

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1 against you involved your working as an emergency
2 room physician. During what period of time did you
3 work as an emergency room physician?
4 **A From '83 to '84.**
5 Q At what particular hospital or hospitals
6 was that?
7 **A Let's see. I worked at a hospital called**
8 **Tracy Memorial Hospital. I worked at a hospital**
9 **that I think was called Dos Palos, P-A-L-O-S,**
10 **Hospital. I did a little moonlighting at the Kaiser**
11 **Hospital in Redwood City. And that was it.**
12 Q What were the circumstances under which
13 you were working as an ER physician as opposed to
14 either straight internal medicine or as a
15 gastroenterologist?
16 **A Well, with internal medicine, you know,**
17 **when you're doing your residency, it's a three-year**
18 **residency, and you're so busy the first year you**
19 **don't have time to think about anything. And then**
20 **by the time you're just beginning your second year,**
21 **the idea is you're supposed to decide what you want**
22 **to do for a fellowship, and I wasn't really ready to**
23 **decide whether I wanted to do gastroenterology or**
24 **pulmonary or cardiology or endocrinology. I just**
25 **didn't know that early on.**

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1 **So I gave myself an extra year to think**
2 **about it. And, because of that, that meant there**
3 **was a one-year gap between completing my residency**
4 **and starting my fellowship so I used that time to**
5 **work as an ER doctor.**
6 Q Why was it that you decided to pursue a
7 fellowship in gastroenterology?
8 **A I just found it a very interesting field**
9 **with a lot of different diseases, a patient**
10 **population that, you know, both were young and old.**
11 **I like the interventional aspects of being able to**
12 **work with my hands and do endoscopic therapies. So**
13 **it was a medical discipline with some surgical**
14 **skills thrown in there and, you know, that was --**
15 **found the liver interesting too.**
16 Q Are you familiar with the term
17 occupational medicine?
18 **A Yes.**
19 Q Do you have any particular training in the
20 area of occupational medicine?
21 **A No.**
22 Q Is a recognized Board certification
23 available in the area of occupational medicine?
24 **A Well, I think there's two different**
25 **meanings for occupational medicine in my mind. So**

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1 **occupational medicine frequently has to do, I think,**
2 **with workplace injuries, a lot of people who are,**
3 **say, doctors at factories, at, you know, Staples or**
4 **at, you know, Target, you know, will take the**
5 **employees and they'll be -- because of the fact that**
6 **they're employed by the business, they're considered**
7 **to be doing occupational medicine because they're**
8 **working for people in an occupation.**
9 **There's also, you know, occupational**
10 **injuries, back injuries at work, what kind of rehab**
11 **should this person get? What kind of work**
12 **restrictions should they get? I don't get involved**
13 **in any of that. When I was doing the environmental**
14 **work, there's the whole issue of occupational safety**
15 **and health, which then kind of moves into a**
16 **different area. So, for instance, the area of**
17 **overlap is there may be workers who are exposed at a**
18 **plant to a certain set of chemicals. A good example**
19 **is workers in the plastic industry used to work with**
20 **something called polyvinyl chloride, and they would**
21 **get a rare kind of liver cancer called angiosarcoma**
22 **of the liver, and that -- the doctors who research**
23 **that and investigate that are involved with**
24 **occupational health, which I am involved through my**
25 **liver interests, but I'm not actually doing kind of**

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1 **like that in the trenches working at the factory**
2 **occupational medicine that the doctor who works at,**
3 **you know, Costco is doing.**
4 Q What is your involvement in occupational
5 health?
6 **A What is my what?**
7 Q Involvement in occupational health.
8 **A My involvement is in the sense that with**
9 **certain types of exposures there are the greatest**
10 **levels of exposure experienced by workers, and they**
11 **play a canary in a coal mine kind of role. So like**
12 **if you look, for instance, at what what's happening**
13 **down in the Gulf, you know, you've got a low level**
14 **exposure to certain types of chemicals, dispersants,**
15 **et cetera that are spread throughout Louisiana and**
16 **Florida. On the other hand, if you look at the guy**
17 **whose occupation it is to be out there dumping all**
18 **of the dispersants into the Gulf of Mexico, and, you**
19 **know, some of the symptoms that they're having, they**
20 **are experiencing an occupational risk, but they're**
21 **the canary in the coal mine because they're just**
22 **experiencing the risk at a much higher level of**
23 **exposure. So, you know, that's where I get involved**
24 **in occupational health.**
25 Q And what is it that you actually do in the

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1 area of occupational health and occupational
2 exposures to various chemicals or possible
3 toxicants?
4 **A Well, you know, I will assess, just like**
5 **you would do with a lot of things, infectious**
6 **organisms as well. You assess whether the thing to**
7 **which a person is exposed is causing them clinical**
8 **harm, and then the nature of the clinical injury and**
9 **whether the clinical injury is caused by that or**
10 **some other alternative explanation that's even**
11 **better, and then make recommendations in terms of**
12 **guidelines for helping treat that patient and to**
13 **prevent excessive exposure by others if you**
14 **recognize it as a risk.**
15 Q How much of your current medical practice
16 is involved in the assessment of patients who have
17 had some type of occupational exposure to some type
18 of chemical?
19 **A Very little.**
20 Q When you say very little, by percentage
21 what would it be approximately?
22 **A Less than one percent. So I mean, you**
23 **know, it's kind of a skill set that I have, which is**
24 **not to say that I'm doing this on a regular basis in**
25 **my clinical practice.**

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1 Q Has your practice involved greater than
2 one percent occupational health oriented assessment
3 in the past?
4 **A Well, you know, when I was working at the**
5 **Environmental Science Lab before I was a doctor,**
6 **there was a lot of that. Since I've actually gone**
7 **out into practice, it's always been less than**
8 **one percent.**
9 Q Do you have any specialized training in
10 the area of toxicology?
11 **A I think my articles speak to my knowledge,**
12 **but I haven't gone through any kind of formal**
13 **training. But on the basis of my experience, my**
14 **investigations, my research, my training, I am**
15 **well-versed on, you know, hepatotoxicology.**
16 Q And what particularly have you done to
17 become knowledgeable about hepatotoxicity and
18 particularly the toxicological aspects of
19 hepatotoxicity?
20 **A I've read multiple high quality textbooks.**
21 **I've read hundreds and hundreds of manuscripts. I**
22 **have spoken to more than a dozen of the world's best**
23 **experts in the field of hepatotoxicity, and I have**
24 **attended meetings and discussions and conducted some**
25 **research on my own, as we've already discussed.**

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1 Q Other than what you've already told me
2 about meetings that you've attended, what other
3 meetings have you attended that deal specifically
4 with hepatotoxicity?
5 **A Let's see. There was a meeting down in**
6 **Atlanta that was on drug-induced liver injury that I**
7 **attended. I don't remember the year that that was.**
8 **There was a meeting at the Howard Hughes Institute**
9 **in Washington that I attended, which was -- it**
10 **touched heavily on the liver, but it was really on**
11 **mitochrondria as their main focus. You know, when I**
12 **go to the various meetings at AASLD, AGA, you know,**
13 **you get a copy of the syllabus, you get to pick and**
14 **choose which lectures and seminars you want to go**
15 **to. I gravitate towards the ones that have to do**
16 **with the hepatotoxicity.**
17 Q Do you regularly attend the AGA's annual
18 meetings?
19 **A Usually once every two for three years.**
20 Q Do you have particular records as to which
21 particular AGA meetings you've attended over the
22 last 10 or 15 years?
23 **A No. You know, I might be able to find**
24 **some of that, but it would be -- it would be time**
25 **consuming, but I could probably get you some**

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1 **information on that.**
2 Q Does the AASLD have an annual meeting?
3 **A Yes.**
4 Q Do you regularly attend the AASLD annual
5 meetings?
6 **A When it's in San Francisco and I can go, I**
7 **usually go. When it's in Boston in the wintertime,**
8 **I generally don't.**
9 Q Like you did with AGA, do you have some
10 records of which AASLD meetings you've attended?
11 **A Sketchy records but some records. The**
12 **last time I was at an AASLD, I'll tell you, was the**
13 **time that I presented that poster that I had just**
14 **told you about, which would have been the last time**
15 **or the time before the last time that I was in San**
16 **Francisco in October.**
17 Q The conference you attended at the Howard
18 Hughes Institute, in what year was that?
19 **A My best guess would be about between 2005**
20 **and 2007.**
21 Q And the conference that you attended in
22 Atlanta that you mentioned, what was the subject
23 matter of that conference?
24 **A It was all about what they call DILI,**
25 **capital D-I-L-I, which is just short for**

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1 **drug-induced liver injury.**
2 Q And like the AASLD and the AGA, do you
3 think you might have some information, documents
4 about the Atlanta drug-induced liver injury meeting?
5 **A Maybe.**
6 Q One of the things you mentioned with
7 respect to toxicology is that you had read multiple
8 high quality texts. What texts have you read about
9 toxicology?
10 **A There's Hyman, with a Y, Zimmerman's**
11 **"Hepatotoxicity." There is a book with the editor**
12 **being, I think, Neil Kaplowitz and L. DeLeve, I**
13 **think D-E-L-E-V-E maybe, which is called**
14 **"Drug-Induced Liver Injury," I think. I've read**
15 **"Mitochrondria and Pathogenesis," which was a real**
16 **page-turner. I've read books -- there's something**
17 **called "Seminars in Liver Disease," which comes out**
18 **usually once every month or every quarter, and it's**
19 **usually about 250 pages and it's topically based.**
20 **So they had one that was all about drug-induced**
21 **liver injury. I've read books on liver biopsy and**
22 **liver histology.**
23 Q Which books were those?
24 **A I think one is called Schreuers or**
25 **Scheuers, S-C-H-R-E-U-E-R, something like that.**

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1 Q Is that all the textbooks that you can
2 recall reading regarding toxicology?
3 **A You know, I'd have to actually look at my**
4 **bookshelf to give you a really complete list, but**
5 **those are the top ones.**
6 Q You also mentioned reading hundreds of
7 manuscripts. So I can get an idea in my mind, what
8 is different about the manuscripts from the texts
9 that you just described to me? Are they papers?
10 Are they something else?
11 **A They're articles from peer-reviewed**
12 **journals -- articles.**
13 Q Do you maintain any type of list of those
14 articles?
15 **A There is no list, no.**
16 Q You mentioned that you've spoken with
17 experts concerning the area of toxicology as it
18 relates to liver injury. Who are those experts?
19 **A Okay. Ready? Leonard Seeff, S-E-E-F-F.**
20 **Robert Fontana, F-O-N-T-A-N-A. Let's see. John**
21 **Senior, S-E-N-I-O-R. Bill Lee, L-E-E.**
22 Q Where is Bill Lee from?
23 **A I think he's down in Texas. He's the big**
24 **guy behind the Tylenol, acetaminophen, liver**
25 **transplant, liver failure group. There's a guy, his**

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1 **first name I'm blocking on, named Kleiner,**
2 **K-L-E-I-N-E-R. There's a Dr. -- Swedish. I can't**
3 **remember his name. It's very tough. Bjornsson,**
4 **B-J-O-R-N-S-S-O-N, I think. Don't remember his**
5 **first name. Scott Friedman. But I haven't really**
6 **talked that much about drug-induced liver injury**
7 **with him, really. And there's a guy that he works**
8 **with whose name I'm drawing a blank on. And a guy**
9 **named -- what's his name? Jim Lewis, L-E-W-I-S.**
10 **And a guy named Herbert Bonkovsky,**
11 **B-O-N-K-O-V-S-K-Y, and Dr. Chalasani,**
12 **C-H-A-L-A-S-A-N-I, and Dr. Feldstein,**
13 **F-E-L-D-S-T-E-I-N.**
14 Q What is Dr. Feldstein's first name?
15 **A I think it's Ariel, something with an A.**
16 Q I just want to get go through this list
17 and get state or country that these people are from.
18 Leonard Skiff?
19 **A No. SEEFF, S-E-E-F-F. Washington, D.C.**
20 Q What does he do?
21 **A He is -- I think he's got dual chairs with**
22 **the NIH and the FDA. He's one of the preeminent**
23 **guys on hepatitis C and also, you know, is**
24 **interested in drug-induced liver disease.**
25 Q Where is Robert Fontana from and what does

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1 he do?
2 **A University of Michigan. Again,**
3 **drug-induced liver injury.**
4 Q John Senior, is that the same John Senior
5 you described to me earlier?
6 **A Right.**
7 Q First name you couldn't remember, last
8 name Kleiner, where is he from and what does he do?
9 **A He is more of a hepatopathologist, and I**
10 **think he used to be with the Armed Forces Institute**
11 **of Pathology, which now is no longer so I'm not sure**
12 **where he is now.**
13 Q I know that Bjornsson is from Sweden.
14 What does he do?
15 **A He is, again, an expert in DILI.**
16 Q Scott Friedman?
17 **A He's an expert on liver inflammation and**
18 **fibrosis at Mount Sinai, New York.**
19 Q The person who works with Friedman whose
20 name you couldn't remember, also from Mount Sinai,
21 New York?
22 **A Yes.**
23 Q Jim Lewis?
24 **A He works in Washington, D.C. I'm not sure**
25 **whether he's Georgetown or G.W. He's also involved**

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1 **with DILI.**
2 Q Herbert Bonkovsky?
3 **A Down in North Carolina. Also DILI.**
4 Q Ariel Feldstein?
5 **A He is somewhere out in the Midwest, and**
6 **I'm not sure which university, and he is looking at**
7 **pathophysiology and mechanisms of liver injury**
8 **related to steatosis, S-T-E-A-T-O-S-I-S, and he's**
9 **looking for early markers of liver cell death,**
10 **primarily the CK-18, very good test.**
11 Q The last person I have to ask you about
12 you didn't give me the first name, but the last name
13 is C-H --
14 **A Chalasani?**
15 Q Yes.
16 **A He is at the University of Indiana doing**
17 **very nice work with animal models of steatotic liver**
18 **injury. Recent work on the combination of high**
19 **fructose corn syrup, high fat diets, fast food. If**
20 **you feed it to pigs, it's bad for them.**
21 Q Over the past few minutes have we
22 essentially covered your base of knowledge, training
23 and experience as it relates particularly to the
24 toxicology of liver injury?
25 **A Well, I mean, I think those are some of**

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1 **the foundational elements of it, yeah. So, you**
2 **know, I think my skills are well honed in terms of**
3 **being able to assess and evaluate and comprehend**
4 **mechanisms and pathways and categories of liver**
5 **injury.**
6 Q Do you have any specific training in the
7 area of pharmacology?
8 **A Well, I'm on the Pharmacy and Therapeutic**
9 **Committee at my hospital, and, you know, all doctors**
10 **take mandatory courses that involve pharmacology**
11 **because we write for more drugs than any other**
12 **category of human being on the face of the earth.**
13 **So we do pharmacology in medical school in depth,**
14 **but I don't have any particular additional degree in**
15 **pharmacology.**
16 Q You're Board certified in internal
17 medicine, correct?
18 **A Yes.**
19 Q And you also have a subspecialty
20 certification in gastroenterology?
21 **A That's right.**
22 Q In what year did you first become Board
23 certified in internal medicine?
24 **A Eighty-three.**
25 Q At the time that you took it, did the

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1 internal medicine Boards have both a verbal
2 component and a written component?
3 **A For the Boards in internal medicine I**
4 **think it was a written only.**
5 Q Did you pass the internal medicine Board
6 on the first try?
7 **A Yes.**
8 Q Is an exam required for Board
9 certification in gastroenterology?
10 **A Yes.**
11 Q Does that have a written and verbal
12 component or just a written component?
13 **A Written.**
14 Q Did you pass the written component on the
15 first try?
16 **A Yes.**
17 Q In what year?
18 **A Eighty-seven.**
19 Q Are you required to maintain your Board
20 certification in either internal medicine or
21 gastroenterology to recertify?
22 **A No. I got grandfathered in.**
23 Q I know you have told me already earlier on
24 in the deposition, and we do not need to cover it
25 again, about a couple of publications that do not

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1 appear on your c.v., but taking what you've already
2 told me into account and what is on the printed c.v.
3 we've marked as Exhibit 1, is that the sum total of
4 your publications -- medically related publications?
5 **A Yes.**
6 Q In any of your publications has there been
7 any discussion of terbinafine at all?
8 **A No.**
9 Q In any of your publications has there been
10 any discussion of chlarithromycin?
11 **A Let's see. I don't believe there have.**
12 Q In any of your publications has there been
13 any discussion of erythromycin?
14 **A I don't think so.**
15 Q Do any of your publications touch on
16 fulminant hepatic failure?
17 **A Yes.**
18 Q Just by the quickest way to identify them,
19 which ones?
20 **A Well, I think when I wrote this paper**
21 **marked Exhibit Number 4, you know, there was**
22 **probably mention of the fact that troglitazone had**
23 **caused cases of hepatic failure. I've focused on**
24 **more of the chronic disease so that these cases that**
25 **I reviewed here wouldn't have fallen into the**

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1 **category of fulminant, but in the introduction or**
2 **the discussion I might have commented on that.**
3 Q Do any of your published articles touch in
4 any way on work-related exposures to various
5 chemicals or toxicants?
6 **A No.**
7 Q Have you ever done any teaching to medical
8 students?
9 **A Just as a resident, but not since then.**
10 Q What about teaching to medical
11 professionals who are not medical students?
12 **A When I was doing my practice, you know,**
13 **I'd occasionally give lectures to nurses on the**
14 **floor or nurses in the operating room. That was the**
15 **extent of it.**
16 Q When you say lectures, what is the nature
17 and extent of the lecture that you're describing to
18 me?
19 **A Well, for instance, let's say we were**
20 **using some new devices to do a special kind of**
21 **procedure called an ORCP, I would familiarize them**
22 **with it and how it worked, how the pieces fit**
23 **together, how they were supposed to utilize them,**
24 **how to do it correctly. So it was a show-and-tell**
25 **kind of a thing for 15 or 20 nurses. And I did a**

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1 **couple of grand rounds over the course of the years,**
2 **but I didn't bother to put those in my c.v.**
3 Q Did the grand rounds that you've done
4 touch in any way on liver injury?
5 **A One of the lectures I gave touched on**
6 **liver injury, but not either Lamisil or**
7 **chlarithromycin.**
8 Q What is it the drug-induced liver injury
9 that your grand rounds discussed?
10 **A Well, this was at, actually, a conference**
11 **we have of the G.I. doctors so it was not either of**
12 **those two drugs.**
13 Q The articles that we've marked as Exhibits
14 2, 3 and 4, are all of those published in
15 peer-reviewed publications?
16 **A Yes.**
17 Q The case report, would that have been peer
18 reviewed?
19 **A Well, I mean, I think -- I'm sure the**
20 **Annals of Internal Medicine is a peer-reviewed**
21 **journal. It's pretty famous prominent journal so**
22 **yes. You're asking Number 3 or Number 2?**
23 Q Any of the articles, 2, 3 or 4. What I
24 wanted to know is whether those are published in
25 peer-reviewed journals.

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1 **A To the best of my knowledge they all are,**
2 **yeah. They are. Yes, they're all peer-reviewed.**
3 Q Are all of the hospital staff positions
4 that you have held over time reflected on your c.v.
5 somewhere?
6 **A Since I finished my fellowship, yes.**
7 Q Are all of your committee memberships and
8 appointments reflected in your c.v. somewhere?
9 **A Yes. Except for the ones that I told you**
10 **are new.**
11 MR. BAZINETT: We've been going about an
12 hour and a half. Why don't we take about a
13 five-minute break.
14 THE WITNESS: All right. Sure.
15 (A brief recess was taken from 9:36 to
16 9:46 a.m.)
17 BY MR. BAZINET:
18 Q We're are back on the record after a
19 little break. I want to pick back up and finish
20 off. We were talking about your c.v. Are all of
21 the medical societies and organizations of which you
22 are a member reflected in the professional
23 membership section of your c.v.?
24 **A Yes, I think they are. Oh, pardon me. I**
25 **did just recently rejoin the American College of**

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1 **Physicians, the ACP.**
2 Q Why did you rejoin?
3 **A They're a good organization, and they**
4 **publish the Annals of Internal Medicine, and I like**
5 **that journal.**
6 Q Had you been a member at some time in the
7 past?
8 **A Yes.**
9 Q Why was it you stopped being a member at
10 some time in the past?
11 **A Well, the big problem with these**
12 **organizations is they charge annual dues, and they**
13 **tend to run a little bit high. So I just was trying**
14 **to cut costs and so I gave that up.**
15 Q Do you regularly review the Annals of
16 Internal Medicine?
17 **A Most -- about 50-50, half the time. It**
18 **depends on what my schedule is like.**
19 Q Is the Annals of Internal Medicine a
20 journal to which internal medicine physicians could
21 regularly refer for information about the practice
22 of internal medicine?
23 **A You know, I mean, I think that you take**
24 **information from a lot of different sources.**
25 **Especially now in the days of the Internet, you**

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1 **know, there's access to lots of different**
2 **information and you kind of -- I think there's an**
3 **interesting concept called the impact factor of**
4 **journals, and, you know, I think depending on how**
5 **much you regard that particular journal, you give it**
6 **an impact in your own mind as to how much you will**
7 **count on what they're telling you about a given**
8 **topic.**
9 Q Which journal do you give the most credit
10 or the most impact?
11 **A Well, I don't get to read it very much,**
12 **but I've always been impressed with the Journal of**
13 **Hepatology, which is actually a European journal**
14 **regarding liver disease.**
15 Q What body publishes the Journal of
16 Hepatology?
17 **A I think it might be called the EASL.**
18 Q And what is it about the Journal of
19 Hepatology that particularly impresses you?
20 **A I think they've got extremely good**
21 **scientific rigor. They write on cutting edge topics**
22 **and knowledge, but they're scrupulous in making sure**
23 **that the authors know what they're talking about,**
24 **and they're totally untouched by any kind of**
25 **attempts by industry to perhaps spin or steer the**

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1 **story line when it comes to pharmacotoxicology.**
2 Q Are there any journals published in the
3 United States that you believe have any type of
4 impact as you've described it?
5 **A Any type of impact? Oh, yeah.**
6 Q Well, the type of impact that you find
7 personally to be impactful.
8 **A Well, you know, I think you have to look**
9 **at the -- you know, and that's the issue with these**
10 **things like journals is, you have to look at the**
11 **nature of what the particular article is, who the**
12 **authors are, what they're writing about, how**
13 **knowledgeable they are in their particular field.**
14 **And then if you look at the scientific actual, you**
15 **know, primary research articles, I think some of the**
16 **journals are quite good. The problem is when you**
17 **get into things like opinion pieces, like I've seen**
18 **opinion pieces in hepatology that I think were poor,**
19 **and so those, you know, you really can't give**
20 **them -- they probably have more impact than they**
21 **deserve in that circumstance. But I think in terms**
22 **of the actual scientific articles, depending on the**
23 **authors, some of them are very impactful.**
24 Q When you are looking at a journal article
25 and you're attempting to determine its validity or

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1 the type of impact it's going to have on you, do I
2 understand you to say you look at the nature of the
3 article, and the authors and the authors' knowledge
4 as part of what you consider in evaluating the
5 article?
6 **A Yes.**
7 Q What other things do you look at other
8 than the nature of the article, the authors and the
9 authors' knowledge?
10 **A Well, you know, there's a lot. You know,**
11 **you look at the scientific methodology. You would**
12 **look in a clinical study at the population size. In**
13 **an animal study you'd look at how good a model is**
14 **this particular species in terms of representing a**
15 **disease in human beings. So when I was talking**
16 **about the doctor in Indiana, you know, he used a**
17 **particular kind of pig. Is that a good model? Is**
18 **it a bad model? So you look at the statistics and**
19 **what kind of statistical results they get and how**
20 **compelling they are. If they're using particular**
21 **types of stains or slides or visuals or graphs, you**
22 **look at those and you see how strong they are. So**
23 **it is a -- it's an analytic process.**
24 Q What journals, either European or American
25 or somewhere else, do you review on a regular basis?

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1 **A We have a group of gastroenterologists who**
2 **meet once a month, and we have a journal club. So**
3 **that improves our range, you know, so because we get**
4 **each doctor reviewing three or four different**
5 **journals each time, there's a rotating list, we get**
6 **to hear articles in our field from maybe 10 or 15**
7 **journals every month. So it's not a direct review,**
8 **but -- and it's in a journal club context -- we get**
9 **to hear about them and discuss them.**
10 Q Are there any journals that you regularly
11 review personally outside the context of the journal
12 club?
13 **A You know, I'll scan through journals, and**
14 **it depends if an article catches my eye, I'll read**
15 **it. And that would probably be, you know,**
16 **Gastroenterology, Hepatology, Annals of Internal**
17 **Medicine, Clinical Gastroenterology and Hepatology.**
18 **That's it?**
19 Q The journal club that you described to me,
20 does it review a certain set of journals or are the
21 journals chosen at random?
22 **A A certain set.**
23 Q What is that set of journals?
24 **A It's a long list.**
25 Q Is there a published list?

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1 **A Well, the library keeps a list, but I**
2 **could run through them quicker if you really want to**
3 **know.**
4 Q I do.
5 **A New England Journal, Annals of Internal**
6 **Medicine, Gastroenterology, Hepatology, Clinical**
7 **Gastroenterology and Hepatology -- I'm sorry if I go**
8 **too fast -- Digestive Disease and Science, Gut,**
9 **Lancet, American Journal of Medicine,**
10 **Gastrointestinal Endoscopy, Endoscopy, which is a**
11 **different journal, and a few others I'm missing.**
12 Q The journal club, is it gastroenterology
13 related or does it encompass the entirety of
14 internal medicine?
15 **A G.I.**
16 Q And the journal club, is it specific to a
17 particular hospital or is it broader than that?
18 **A We get people from three different**
19 **hospitals.**
20 Q Have you ever participated in any clinical
21 trials?
22 **A Yes.**
23 Q Are you currently involved in any clinical
24 trials?
25 **A No.**

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1 Q When was the last time you participated in
2 a clinical trial?
3 **A About seven years ago.**
4 Q For what drug was it?
5 **A It was for AcipHex.**
6 Q What was your particular involvement in
7 the clinical trial?
8 **A We were starting people with bad reflux**
9 **and erosive esophagitis on AcipHex and assessing how**
10 **quickly they had an endoscopic and clinical**
11 **response.**
12 Q Have you ever been involved in any
13 clinical trial for drugs that have an association
14 with liver injury?
15 **A Probably not.**
16 Q Other than AcipHex, what other drugs have
17 you been involved in clinical trials?
18 **A Interferon ribavirin. Some triple therapy**
19 **for H. pylori. That's all I can remember.**
20 Q In the clinical trial that you were
21 involved with H. pylori, what was the three drug
22 cocktail?
23 **A It's been a long time. I don't remember.**
24 Q Do you remember -- well, let me ask you
25 this. Were all three of the drugs in the triple

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1 therapy antibiotics?
2 **A I think they were, but I don't think**
3 **chlarithromycin was one of them.**
4 Q Any macrolides in the triple therapy?
5 **A I don't remember.**
6 Q The clinical trial that you did involving
7 AcipHex, did it in any way look at concomitant
8 administration of any type of antibiotic?
9 **A No.**
10 Q And your involvement in clinical trials
11 generally, is it patient monitoring or is it
12 something else?
13 **A Patient monitoring.**
14 Q Are you involved in any way in either the
15 toxicological or pharmacological aspects of the
16 clinical trials that you've participated?
17 **A Not in terms of, you know, any kind of**
18 **extra role. I mean, you know, clearly any patient**
19 **that I would see I would be monitoring them for**
20 **signs of toxicity, but not in anything in terms of**
21 **pharmacovigilance or anything like that.**
22 Q Describe to me what your current medical
23 practice is like?
24 **A It's 90 to 95 percent, you know, G.I. and**
25 **liver, and I spend about two days a week strictly**

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1 **doing procedures. The rest of the time I'm**
2 **basically in the office, except for occasionally**
3 **seeing patients in the hospital. And, you know, I**
4 **work out of one office on a regular basis. There's**
5 **a satellite office I go to once a week.**
6 Q Do you have set procedure days during the
7 week?
8 **A Yes.**
9 Q What are those days?
10 **A Thursdays and Fridays.**
11 Q What procedures do you do?
12 **A EGD, colonoscopy, and, up until recently,**
13 **ERCP, which I stopped.**
14 Q Why did you stop ERCP?
15 **A You know, I'd been doing them for about 30**
16 **yes, and I just decided that I could spend my time**
17 **better elsewhere, and there's a new young generation**
18 **of gastroenterologists who are perfectly good at**
19 **doing the procedures now.**
20 Q When did you stop ERCP?
21 **A About six months ago.**
22 Q Do you have during the week set days on
23 which you see patients in an office setting?
24 **A Yes.**
25 Q Is that Monday, Tuesday and Wednesday?

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1 **A Monday and Wednesday.**
2 Q I know you told me that you see most of
3 your patients at the 15225 Shady Grove Road address.
4 Where else do you see patients in the office
5 setting?
6 **A It's called the Camalier Building, and I**
7 **think it's on Fernwood Road, but I don't have the**
8 **exact address.**
9 Q On an average day how many patients do you
10 see in the office?
11 **A Average day, about 15 to 20.**
12 Q Of those 15 to 20 patients that you see on
13 an average day, how many of them are you seeing just
14 as their primary care physician and not with
15 specific reference to any gastrointestinal issue?
16 **A Maybe one. One a day. Sometimes two.**
17 Q Do you have certain set days out of the
18 week that you see patients in the hospital?
19 **A No.**
20 Q Do you do rounds on a daily basis at the
21 hospital?
22 **A When I have patients in the hospital,**
23 **yeah.**
24 Q When you have patients in the hospital,
25 are they admitted to your service or are they

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1 admitted to someone else's service with you as a
2 consultant?
3 **A Usually the latter, they're admitted to**
4 **somebody else's service with me as a consultant.**
5 Q We talked about Monday, Wednesday,
6 Thursday and Friday. What is your generally
7 scheduled Tuesday look like?
8 **A Usually it's administrative or, you know,**
9 **things like that.**
10 Q Do you have any regular medical practice
11 on the weekends at all?
12 **A Every fifth weekend I'm on call.**
13 Q We've talked about your medical practice
14 in the modern day. Was the nature and scope of your
15 medical practice as you just described it to me what
16 your practice looked like back in 2005 with the
17 exception of back then you did ERCP?
18 **A Right. And then back then I probably had**
19 **Tuesday hours also, but other than that, it's**
20 **fundamentally the same.**
21 Q Is the change to Tuesday as an
22 administrative day a fairly recent development?
23 **A It's been a year.**
24 Q And I asked you particularly if and how
25 your current practice related to 2005. With the

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1 qualifications you've already given me, would your
2 practice have been essentially the same back in 2000
3 as well?
4 **A Pretty much, yeah. Different office**
5 **address, but pretty much.**
6 Q In an average week, how many hours do you
7 spend involved in medical practice? And I would
8 intend that to include both administrative time and
9 other time.
10 **A I would say about 40 hours.**
11 Q Was that different in any way back in 2000
12 or 2005?
13 **A It was more back then.**
14 Q Was your time about the same in 2000 and
15 in 2005?
16 **A Yes.**
17 Q About how much was that?
18 **A Fifty.**
19 Q In your practice of medicine, do you
20 regularly treat onychomycosis?
21 **A No, I don't.**
22 Q Since 2000 how many cases of onychomycosis
23 have you treated?
24 **A None.**
25 Q Have you ever prescribed oral terbinafine

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1 to a patient?
2 **A I don't think I have.**
3 Q Have you ever prescribed chlarithromycin
4 to a patient?
5 **A Yes.**
6 Q I think that the trends, if you will, in
7 prescribing chlarithromycin is that prescribing
8 peaked somewhere in the 2004 to 2005 range. Is that
9 consistent with your practice?
10 **A Well, it's probably true in general, but**
11 **in terms of the way that we use it in**
12 **gastroenterology, a lot of times we use it from**
13 **something called the Prevpac, and so that's still a**
14 **frequently utilized protocol and regimen, and that,**
15 **you know, has chlarithromycin in it. So that's**
16 **continued unabated.**
17 Q The term that you used, Prevpac; is that
18 correct?
19 **A Right.**
20 Q What does that mean?
21 **A Well, it's a combination of three**
22 **different drugs so it's got Prevacid, it's got**
23 **amoxicillin, and it's got chlarithromycin all in a**
24 **nifty package.**
25 Q Are those three medications that you

Page 75

1 described packaged together as individual pills or
2 are they combined in some way in one tablet?
3 **A Individual pills.**
4 Q For what indications is the Prevpac
5 prescribed?
6 **A For the treatment of H. pylori.**
7 Q When did the Prevpac first come into use
8 in the United States?
9 **A Well, I wouldn't want to guess wrong, but**
10 **it was probably right around 2000, give or take a**
11 **year or two.**
12 Q And the 2000 date, is that when the three
13 medications were being packaged together for
14 prescription?
15 **A You know, I'd have to really actually**
16 **defer to like a PDR to see when it actually came**
17 **into play, but, I mean, Prevpac as a term always**
18 **really talks about that little combination packet.**
19 Q So was the combination of Prevacid,
20 amoxicillin and chlarithromycin being prescribed by
21 physicians even before it was marketed as one
22 particular package?
23 **A Yeah, definitely.**
24 Q How far back in time does just the
25 prescription of Prevacid, amoxicillin and

Page 76

1 chlarithromycin together to treat H. pylori go?
2 **A I couldn't say. I mean, I would say it**
3 **was sometime late '90s, is my best guess.**
4 Q The chlarithromycin that is part of the
5 Prevpac, in what dose is that?
6 **A I believe it's 500 BID.**
7 Q And is it an extended release?
8 **A I don't really know.**
9 Q Outside of the context of the Prevpac, for
10 what indications do you prescribe chlarithromycin in
11 the modern day?
12 **A In the modern day I really don't.**
13 Q Aside from treatment of H. pylori, have
14 you historically prescribed chlarithromycin to
15 patients?
16 **A Yes.**
17 Q For what indications?
18 **A Respiratory type issues, infections,**
19 **bronchitis.**
20 Q Aside from the Prevpac, when approximately
21 did you stop prescribing chlarithromycin to patients
22 for respiratory issues?
23 **A Probably four years ago. You know Z-Pak**
24 **came along, and it was an easier regimen and less**
25 **pills, and so I made the switch.**

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1 Q And did you start prescribing
2 chlarithromycin to patients fairly soon after it was
3 introduced to the U.S. market?
4 **A Probably, depending on how you define**
5 **fairly.**
6 Q Well, within a year or so of its
7 introduction in the U.S.
8 **A Probably.**
9 Q Other than the availability of the Z-Pak,
10 are there any other factors that bore on your
11 decision to decrease chlarithromycin prescriptions?
12 **A There were some concerns that I had about**
13 **hepatotoxicity.**
14 Q What were those concerns?
15 **A Well, the erythromycin family of drugs has**
16 **known particular individual drugs that have been**
17 **identified as hepatotoxic. And in the course of my**
18 **reading and studying by, for example, looking at**
19 **Zimmerman's "Hepatotoxicity," which he stopped**
20 **publishing because he died, you know, they mentioned**
21 **the older drugs, erythromycin estolate, things like**
22 **that, but the question always comes up is this a**
23 **unique effect or a class effect? And in terms of**
24 **what I read there are concerns that there was a**
25 **class effect element, and I saw a couple of cases of**

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1 **liver enzyme elevations with Biaxin so I decided to**
2 **steer clear of it.**
3 Q And when you were discussing a class
4 effect in connection with erythromycin, are we
5 talking about the class of antibiotics known as
6 macrolides in general or are we talking about just
7 this erythromycin derivative chain?
8 **A Well, you know, in terms of the**
9 **macrolides, you know, I'd need to kind of see a**
10 **mapped out list of how those two groups compare, you**
11 **know, so as to which ones belong in just the**
12 **erythromycin clan and which ones belong in the big**
13 **family of macrolides. You know what I'm saying? So**
14 **I didn't break it down that fine as to whether it**
15 **was in the erythromycin clan or the macrolide**
16 **family, but I did know that there were multiple**
17 **drugs within the mycin category that have**
18 **hepatotoxic effects, and I have some papers here**
19 **that illustrate that.**
20 Q In part of your previous answer you
21 mentioned that you had seen a couple of increased
22 liver enzymes. Was that with erythromycin?
23 **A Biaxin.**
24 Q The elevated liver enzymes that you saw
25 with Biaxin, how many patients?

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1 **A Two. I mean, there are probably more than**
2 **that, but sometimes when you see a case, you know,**
3 **you look at the whole picture. What are the other**
4 **medications they're on? If they're on five or ten,**
5 **you can't really say it's Biaxin so you do an**
6 **analysis in terms of do I think it's the most likely**
7 **it's that drug? So in two cases I thought it was**
8 **the most likely that Biaxin was the cause.**
9 Q The particular Biaxin that these patients
10 had taken, was that the 500 milligram XL Biaxin or
11 one of the other formulations?
12 **A I don't remember.**
13 Q The patients that you had that had
14 elevated liver enzymes concurrently with taking
15 Biaxin, without giving me any information that would
16 personally identify the patient, did they have any
17 lasting effects on the liver?
18 **A They recovered.**
19 Q And when you say they recovered, did they
20 have a complete recovery or did they have any
21 continued decrease in liver function?
22 **A They had a complete recovery.**
23 Q Did you make any type of case report
24 concerning these two patients with the elevated
25 liver enzymes and the Biaxin?

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1 **A No.**
2 Q In approximately what year or years did
3 you see these two patients with the elevated liver
4 enzymes from Biaxin?
5 **A It was in the early 2000s, late 1990s,**
6 **that range.**
7 Q In your practice of medicine, do you from
8 time to time come into contact with representatives
9 from various drug companies?
10 **A I do.**
11 Q Do you have any recollection at any time
12 of coming into contact and speaking with a
13 representative of any company concerning the drug
14 chlarithromycin?
15 **A I'm sure that they're more contacts having**
16 **to do with the Prevpac when it first became**
17 **available and they drop off samples and, you know,**
18 **talk to me about how useful it was, and there was**
19 **that kind of discussion.**
20 Q Who produces the Prevpac?
21 **A I think it's probably Abbott.**
22 Q Do you have any specific recollection of
23 any representative of any drug company, Abbott or
24 anyone else, discussing with you hepatotoxicity in
25 connection with chlarithromycin?

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1 **A No recollection.**
2 Q Amongst physicians, when you get visits
3 from these drug company representatives, do you
4 refer to it as detailing?
5 **A Yes.**
6 Q So if I mention detailing to you, you'll
7 know what I'm talking about?
8 **A Sure. Absolutely.**
9 Q Do you think that you have ever been
10 detailed by any representatives of Novartis or any
11 other company concerning terbinafine, particularly
12 the oral formulation of terbinafine?
13 **A I don't think so.**
14 Q Are there certain textbooks to which you
15 refer from time to time for information of use in
16 treating your patients?
17 **A Yes, there are textbooks I use. Yes.**
18 Q What are those textbooks?
19 **A Generally I'll use Sleisenger and Fordtran**
20 **for general G.I. issues. That's the main one that**
21 **I'll go to.**
22 Q Do you ever use Yamada's textbook, "The
23 Handbook of Gastroenterology"?
24 **A Yes. I mean, Yamada, you know, it's kind**
25 **of interesting because I think they were related at**

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1 **one point, but I do use Yamada also. That's true.**
2 Q Do you use any type of online resources at
3 all in your medical practice?
4 **A Yes, I do. So, you know, MD Consult**
5 **actually gives you a, you know, searchable database**
6 **of some of those textbooks, including the ones you**
7 **just mentioned. So if you put in a topic, they have**
8 **their online library of, you know, multiple G.I.**
9 **references, you know, at least 10 or so, and they'll**
10 **actually find you the chapter and highlight the**
11 **phrases that, you know, have the search item in it.**
12 **So I use that a lot.**
13 Q Other than MD Consult, are there other
14 online resources that you use?
15 **A There's another called Ovid, O-V-I-D. I**
16 **use that.**
17 Q And you have Ovid available to you?
18 **A Yes. UpToDate.**
19 Q Do you use any type of software like
20 Epocrates or anything like that for information
21 about medications?
22 **A I use Epocrates. You know, my nurse**
23 **practitioner has it on her iPhone. My particular**
24 **smart phone doesn't have it so I don't use it, but I**
25 **use hers. Same thing.**

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1 Q Do you have an Epocrates-like service
2 available on your smart phone?
3 **A No.**
4 Q Just a couple things I'm not going to
5 spend a lot of time on. I'll show you what I'll
6 mark as Exhibit 5. I'll represent to you that I
7 printed this off the Internet in the last day or
8 two. Is that your kind of Web page for your medical
9 practice?
10 **A It is for our Endoscopy Center.**
11 Q Explain to me what the Endoscopy Center
12 is.
13 **A The Endoscopy Center is a place where**
14 **about 12 of us gastroenterologists go to do all our**
15 **colonoscopies and EGDs.**
16 Q And that's located at a different physical
17 address than the practice location you described to
18 me earlier?
19 **A Yes.**
20 Q Do you also maintain a Web site for your
21 medical practice?
22 **A No.**
23 Q And the Endoscopy Center, does that just
24 involve procedures; is there any clinical care that
25 goes on there at all?

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1 **A Well, I mean, you know, it depends on how**
2 **you define clinical care, yeah. So it's all part of**
3 **clinical care, but we don't actually do anything**
4 **beyond the procedures and talking to the patients**
5 **before and after the procedures.**
6 Q Are you responsible for the content of
7 this particular description of you or does someone
8 else do that?
9 **A Yes. I am responsible for it.**
10 Q It mentions at the bottom that
11 Washingtonian Magazine has recognized you four times
12 as one of the top doctors in gastroenterology. In
13 what years were you so recognized?
14 **A Wow. I couldn't tell you. You know, it's**
15 **all since 2003, I would think.**
16 Q I want to move on to talk about your
17 review of this case. When were you first contacted?
18 You can look at any of your notes.
19 **A In April 2007.**
20 Q Who contacted you first?
21 **A Mr. Steel, sitting to my left.**
22 Q Was it by telephone?
23 **A Yes. I have a little list here that is**
24 **just a list of documents I reviewed so you're**
25 **probably going to want to see that at some point,**

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1 **but that just lists, you know, what I've reviewed,**
2 **medical records and the initial date.**
3 Q In the upper right corner it says start
4 4/12/07. That's the contact date?
5 **A That I was first contacted, yeah.**
6 Q What, during the initial phone call, were
7 you told about the background of the case?
8 **A I was told that there was a gentleman who**
9 **had developed liver failure and subsequently needed**
10 **a liver transplant, and that in the course of his**
11 **illness leading up to the liver transplantation, he**
12 **became ill, you know, somewhere temporally around**
13 **the time where he had been taking certain**
14 **medications, and would I look at it in terms of, you**
15 **know, what the cause of his liver injury was.**
16 Q Do you have any idea how it was that the
17 plaintiffs got your name as a person to contact?
18 **A I think there was a lawyer down in Atlanta**
19 **who I had worked with briefly in the past named**
20 **Mathis, Curtis Mathis -- is that his first name?**
21 MR. STEEL: Charles.
22 THE WITNESS: Charles Mathis. And so I
23 had reviewed a case or two for him and met him
24 previously, and I think my name was gotten through
25 him.

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1 BY MR. BAZINET:
2 Q Let's talk, since the subject was
3 introduced about your previous medical legal reviews
4 and involvement. For how long have you been doing
5 medical legal reviews?
6 **A Since around 1994, 1993.**
7 Q How was it that you first became involved
8 in doing medical legal reviews?
9 **A A colleague of mine, who is a pulmonary**
10 **specialist, asked me if I had any interest in**
11 **reviewing a case because, I guess, somebody he knew**
12 **was looking for a gastroenterologist.**
13 Q Was the first case that you reviewed for a
14 plaintiff or for a defendant?
15 **A Plaintiff.**
16 Q Since you first began doing medical legal
17 reviews, how many depositions have you given as an
18 expert in a medical malpractice case?
19 **A You know, it's tough to get the numbers**
20 **exactly, but I would say between 15 and 30.**
21 Q And the 15 to 30 depositions, is that just
22 medical malpractice cases?
23 **A Right.**
24 Q Have you given depositions also in cases
25 that involved products liability?

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1 **A Yes.**
2 Q How many products liability related
3 depositions have you given?
4 **A Probably between 10 and 20.**
5 Q Of the approximately 15 to 30 depositions
6 that you have given in medical malpractice cases,
7 how many of those have been on behalf of a defendant
8 physician?
9 **A Probably about 30 percent.**
10 Q And have the balance, approximately 70
11 percent, been on behalf of plaintiffs?
12 **A Yes. Although, at this point, in the last**
13 **year or two it's shifted so it's now about 50-50.**
14 Q Of the approximately 10 to 20 depositions
15 that you have given in products liability related
16 cases, how many of those have been on behalf of the
17 plaintiff?
18 **A They have all been on behalf of the**
19 **families or the plaintiff themselves.**
20 Q Have you ever given a deposition in any
21 type of case, either a medical malpractice or a
22 products liability case, that involved the drug
23 terbinafine, oral terbinafine?
24 **A No.**
25 Q Have you ever given a deposition in any

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1 case involving the drug chlarithromycin?
2 **A I mean, again, you know, just to kind of**
3 **make sure that we get the question really clear, I'm**
4 **sure that in some of those cases in which I've**
5 **testified there have been patients who have been on**
6 **chlarithromycin, but it hasn't come up as an issue**
7 **within that case. So within that context, no.**
8 Q You mentioned Rezulin to me earlier as one
9 of the medications involved in cases that you have
10 given expert testimony. What other medications,
11 drugs have been involved in the cases in which
12 you've given expert testimony?
13 **A Baycol, B-A-Y-C-O-L, and Vioxx.**
14 Q In the cases involving Baycol and Vioxx,
15 were they products liability cases or medical
16 malpractice cases?
17 **A Products liability.**
18 Q And so the Baycol, Vioxx and Rezulin
19 cases, the testimony that you gave was all on behalf
20 of the plaintiffs?
21 **A That's correct.**
22 Q The Rezulin, Baycol and Vioxx, the cases
23 in which you were involved, was it alleged that any
24 of the drugs had caused any type of liver injury?
25 **A In the Rezulin cases, yes. In the Baycol**

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1 **cases, yes. And not in the Vioxx.**
2 Q Have you ever testified at the trial of
3 any type of case?
4 **A I didn't understand the question.**
5 Q What we're doing here today is a
6 deposition.
7 **A Right.**
8 Q What I want to know is if you have given
9 testimony as an expert witness in a court of law at
10 the trial of any type of case.
11 **A Oh, yes.**
12 Q How many times?
13 **A You know, again, these are approximations**
14 **so in terms of medical malpractice cases I would say**
15 **six to 15 times at trial.**
16 Q What about products liability cases at
17 trial?
18 **A Probably about three to five.**
19 Q Other than this case, have you ever given
20 a deposition in any type of case that was filed in
21 the State of Georgia?
22 **A Not that I recall.**
23 Q Do you maintain any type of list of cases
24 in which you have given depositions?
25 **A I have a pretty decent list. It's**

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1 **probably not 100 percent complete, but it's pretty**
2 **close.**
3 Q How up-to-date is that list?
4 **A Up to about now. I mean, I think there's**
5 **one other deposition that needs to be added, but**
6 **other than that it's current.**
7 Q What information is recorded in the list?
8 **A It would say if it was a deposition only**
9 **or if it was a trial. It would list the name of the**
10 **plaintiff, and it would list the approximate date.**
11 Q Can you produce a copy of that list to me?
12 **A Sure.**
13 Q And just so I'll have an understanding,
14 the list is just of cases in which you have given
15 some type of testimony and not all the cases you've
16 reviewed?
17 **A Only deposition and trial.**
18 Q Do you keep copies of depositions that
19 you've given over time?
20 **A Mostly no.**
21 Q Are there some depositions that you have
22 maintained?
23 **A A couple.**
24 Q What are the topics of those depositions?
25 **A You know, I might have kept one on a colon**

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1 **cancer case that I had. I think I kept one from my**
2 **product liability deposition. I think those are the**
3 **ones that I remember that I still think I have.**
4 Q Do you advertise your services as an
5 expert in any type of directory, online resource,
6 anything like that?
7 **A No.**
8 Q To the best of your knowledge, are you
9 listed in any online expert witness directories?
10 **A To the best of my knowledge, I am not.**
11 Q Do you ever from time to time receive
12 referrals of cases in which people want you to be an
13 expert through any type of referral service?
14 **A There's only one referral service that I**
15 **will receive cases from, but that's it. The rest is**
16 **from individual law firms.**
17 Q What is the name of the referral service
18 from which you receive referrals?
19 **A It's called FMAS.**
20 Q What does FMAS stand for?
21 **A Forensic Medical Advisory Services.**
22 Q Where is that located?
23 **A It is in Rockville.**
24 Q For how long have you been receiving
25 referrals from FMAS?

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1 **A Probably, you know, they've sent cases to**
2 **me starting from the mid '90s onwards.**
3 Q What is your standard rate for reviewing a
4 medical legal case?
5 **A $400 an hour.**
6 Q And is that for records review?
7 **A That is for records review.**
8 Q Do you charge a different rate for
9 depositions?
10 **A Yes. 450.**
11 Q Do you charge any different rate for
12 trial?
13 **A Yeah. That would be a full day's time so**
14 **that would be $4,000.**
15 Q And does the $4,000 include travel related
16 expenses or are those paid in addition to the
17 $4,000?
18 **A In addition.**
19 Q I asked you specifically about the medical
20 legal work, but do you charge the same rates for the
21 products liability cases on which you work?
22 **A Yes, I do.**
23 Q What percent of your yearly income is
24 related to some type of work as an expert witness?
25 **A About 10 percent.**

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1 Q For approximately what length of time has
2 your income attributable to expert witness work been
3 ten percent?
4 **A For most of the time. During the, you**
5 **know, times -- you know, as far as the medical**
6 **malpractice, that's been fairly steady throughout.**
7 **When things were really busy with the Rezulin**
8 **litigation, then that took up more time.**
9 Q How many cases involving Rezulin have you
10 been involved in?
11 **A It's complicated because there are a lot**
12 **of consolidated cases so I would review, you know**
13 **records on eight patients for one case. So is that**
14 **one case or is that eight cases? It's, you know,**
15 **hard to know how to count that up. But, I mean, I**
16 **guess in that context how many cases have I been**
17 **involved with? Probably about five or ten.**
18 Q Up until we started this deposition today,
19 how much time in terms of hours have you spent
20 working on this case?
21 **A Let's see. Over the course of basically**
22 **four years since it began in April of 2007, I think**
23 **I've spent between 25 and 40 hours.**
24 Q Of the approximately 25 to 40 hours that
25 you've spent, how much of it has been specifically

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1 for the purpose of preparing for this deposition?
2 **A Well, I think it's been about two months**
3 **that we kind of knew that this deposition was coming**
4 **up so at a certain point I went back and pulled out**
5 **the records and started to re-review the case. So I**
6 **would say probably about 10 or 15 hours.**
7 Q Over the course of your work on this case,
8 have you billed the plaintiff for your time?
9 **A Yes.**
10 Q Have you been paid for those bills?
11 **A Yes.**
12 Q To date how much have you been paid for
13 your work on this case?
14 **A Yeah, you know, I couldn't really tell you**
15 **because, like we had discussed, this extended over a**
16 **four-year period of time so I couldn't really tell**
17 **you with great accuracy, but it was over $10,000.**
18 Q Do you keep any type of records of receipt
19 of payment or copies of the invoices you send,
20 anything like that?
21 **A Once the bills are sent, I just don't**
22 **bother to keep them.**
23 Q You mentioned to me already that the
24 Rezulin and Baycol cases in which you've testified
25 involved some type of drug-induced liver injury?

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1 **A Right.**
2 Q Other than those cases, have you testified
3 in any other cases that involved drug-induced liver
4 injury?
5 **A Liver injury, no.**
6 Q What about any type of drug-induced injury
7 beyond the liver?
8 **A Vioxx.**
9 Q I know about Vioxx. So other than
10 Rezulin, Baycol and Vioxx, you haven't testified in
11 any cases that involved a drug-induced injury?
12 **A There was one case I reviewed on a drug**
13 **called Serzone, S-E-R-Z-O-N-E, but I don't think**
14 **that even went to deposition.**
15 Q Somewhere in the medical records of Samuel
16 Moody I saw the term -- I think I saw the term
17 fulminant liver failure. Does that have a medical
18 definition?
19 **A Generally it does, yes.**
20 Q What does it mean in medicine?
21 **A Well, in medicine it is the onset of**
22 **jaundice with progression to altered mental status**
23 **and even coma, encephalopathy basically, within a**
24 **certain number of weeks' time.**
25 Q And is the certain number of weeks part of

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1 the definition of fulminant liver failure or is it
2 variable?
3 **A Well, you know, there's acute liver**
4 **failure, there's fulminant liver failure and**
5 **subacute liver failure. So I think that those are**
6 **largely time-driven definitions.**
7 Q So within medicine, not law but medicine,
8 different definitions are assigned to fulminant
9 liver failure, acute liver failure and chronic liver
10 failure?
11 **A Subacute.**
12 Q How would subacute liver failure be
13 defined?
14 **A Well, you know, there are certain gray**
15 **areas there so, for instance, fulminant liver**
16 **failure is included in the greater, you know, set of**
17 **acute liver failure. So fulminant is a subset**
18 **within acute liver failure, and as far as subacute,**
19 **I forget whether it's three months or six months'**
20 **progression in time. I would have to look that up**
21 **to verify.**
22 Q Now that we have those terms, have you
23 ever testified in a case that involved fulminant
24 liver failure?
25 **A Yes, in the Rezulin litigation.**

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1 Q Other than the Rezulin litigation, any
2 other cases that involved fulminant liver failure?
3 **A One other case.**
4 Q Was it a medical malpractice or products
5 liability case?
6 **A It was a medical malpractice case.**
7 Q And what was the cause of the fulminant
8 liver failure in that case?
9 **A Well, in that case it was a woman who went**
10 **in for some kind of surgery like a bunionectomy, and**
11 **she developed fulminant liver failure the night**
12 **after she left the surgery center. And the question**
13 **was whether she had developed fulminant liver**
14 **failure from something to which she was exposed or**
15 **whether she developed shocked liver because her**
16 **blood pressure just crashed when she was at home all**
17 **night in a semiobtunded state; and, you know, she**
18 **had massive ischemia of her liver, but she did**
19 **develop acute liver failure. And that was the one**
20 **case, and that was a med mal case in Florida.**
21 Q Have you ever testified in any cases that
22 involved subacute liver failure?
23 **A Again Rezulin is the main thing.**
24 Q Have you ever testified in any cases,
25 either medical malpractice cases or products

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1 liability cases, that involved railroad workers?
2 **A No.**
3 Q You mentioned earlier that you had
4 reviewed a couple cases for Charles Mathis, who is
5 one of the attorneys involved in this case. Did any
6 of those cases proceed to deposition?
7 **A No.**
8 Q Has any Court in any type of case ever
9 excluded any of your expert testimony or prevented
10 you in any way from giving expert testimony?
11 **A There was testimony excluded in a Federal**
12 **Court hearing regarding a certain pattern of injury.**
13 Q What was the pattern of injury?
14 **A Well, that was the Rezulin cases again,**
15 **and the plaintiffs' claim was that patients who had**
16 **been exposed to Rezulin for a certain period of time**
17 **could sustain significant liver injury without**
18 **having a substantial bump in their liver enzymes.**
19 **And this went to the Federal Court in New York.**
20 **Judge Kaplan was presiding, and he tossed out the**
21 **category of that type of injury claiming that**
22 **patients who didn't have the enzyme spikes, could**
23 **not have an injury due to the drug.**
24 Q And is that the only time that your expert
25 testimony has ever been limited in any way by any

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1 Court?
2 **A Yes.**
3 Q If you don't know the answer to this
4 question, just tell me. In the State of Maryland,
5 when one files a medical malpractice lawsuit, does
6 one also have to file an affidavit by a doctor
7 saying that the defendant committed medical
8 malpractice in some way?
9 **A Yes. They have a Certificate of Merit.**
10 Q Have you ever executed or signed any
11 Certificates of Merit in the State of Maryland to
12 the effect that a particular doctor had committed
13 malpractice?
14 **A I may have done that with one Rezulin**
15 **case, but I'm not sure if I was actually the one who**
16 **did that. I mean, I know there was a case of a**
17 **patient of mine that went to trial. It was a**
18 **Rezulin case in Maryland. So somebody had to do a**
19 **Certificate of Merit. I just don't remember if it**
20 **was me or not because it was back all the way in**
21 **1999 probably.**
22 Q And this case, the Rezulin case that
23 you're telling me about now, is different from the
24 Rezulin related products liability litigation you
25 told me about before?

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1 **A Well, it kind of predated it. What**
2 **happened was the case that I was involved with as a**
3 **treater was in the State of Maryland, and I got**
4 **called on to testify as a fact witness but also as**
5 **an expert witness, as it turned out, and that was**
6 **before any of the other cases at all. And that was**
7 **in the State of Maryland. And all the things that**
8 **came after were then in patients who I had never met**
9 **before or treated, but in this particular case that**
10 **was actually my patient.**
11 Q Looking at the small notebook that you've
12 brought with you -- let me see that list, please,
13 quickly. Now, is this list that's reflected here
14 the initial materials that you received?
15 **A Right. That's a list of materials I**
16 **reviewed.**
17 Q List of materials that you reviewed
18 throughout the entirety of the case?
19 **A Right.**
20 Q And not a reflection just of the initial
21 set of materials that you received for the purpose
22 of reviewing the case?
23 **A Correct.**
24 Q When we take a break, we'll make a copy of
25 this and I'll mark it as Exhibit 6.

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1 (A brief recess was taken from 10:51 to
2 10:56 a.m.)
3 BY MR. BAZINET:
4 Q I'll just show you what I've marked as
5 Exhibit 6. Is that a copy of the page of the small
6 spiral notebook you brought with you?
7 **A Good.**
8 Q I'm just going to introduce a couple
9 documents to get this out of the way early. I'm
10 going to mark as Exhibit 7 a copy of the original
11 complaint as filed in this case that's dated
12 May 16th of 2007. Have you looked at that in
13 connection with your review of this case?
14 **A Initially, yes. And I glanced at it**
15 **again.**
16 Q I'll mark as Exhibit 8 a copy of a
17 document called the affidavit of Glen Carter. File
18 date is May 16th, 2007. Have you looked at that?
19 **A Okay.**
20 Q Have you seen that before?
21 **A I don't remember. I'm not sure.**
22 Q I'll show you what I've marked as Exhibit
23 9, which is a copy of your affidavit that was filed
24 along with the complaint. You've seen that before,
25 correct?

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1 **A Yes, I have.**
2 Q And then I'll just show you what I'll mark
3 as Exhibit 10, which is a -- it's a copy of a second
4 complaint that was filed on May 19th, 2009. Have
5 you seen a copy of that?
6 **A Is that the same thing as an amended**
7 **complaint?**
8 Q Well, it's different in some respects, I
9 think.
10 **A I'm not sure whether I saw this, but I'm**
11 **through looking through it now.**
12 Q Just so I'll have a clear record later on,
13 do you think you've seen Exhibit 10 before?
14 **A I couldn't say. I mean, I did bring a**
15 **copy of the complaint that I have, but I think that**
16 **was the earlier one.**
17 Q We can get to that in a minute because the
18 next thing I want to do is go through your records
19 here and ask you about them with some particularity.
20 **A All right.**
21 Q What I'm intending to do now is to go
22 through the records you brought with you, mark them
23 as exhibits and ask you a few questions about them.
24 I'll show you what I've marked as Exhibit 11, which
25 is a letter dated April 12, 2007, from the law firm

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1 of Matthews and Steel. Is this the cover letter
2 that accompanied the first set of medical records
3 that you received in this case?
4 **A Yes.**
5 Q Are you able to tell me, by reference to
6 your records or otherwise, what particular records
7 came with that cover letter?
8 **A I think the records that came with the**
9 **cover letter are the Piedmont Hospital records.**
10 **Where did they go? There was bunch of -- let me**
11 **just go through the stack. I got copies of the**
12 **Paces Ferry Medical Group records.**
13 Q Okay.
14 **A Piedmont Health Care records, Emory**
15 **Crawford Long Hospital records, a copy of the**
16 **initial complaint, I think. Let me just check the**
17 **detail on that.**
18 **Where did those other exhibits go? Do I**
19 **have them or do you have them, 6 through 10?**
20 Q I'm keeping them all over here.
21 **A Let me just take that back. So I hadn't**
22 **gotten the initial complaint because I guess it**
23 **hadn't been filed yet so knock that off the list.**
24 **And that was the extent of what I received.**
25 Q Let me see this pile of medical records,

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1 please.
2 **A And did you mark that letter? Yes, here**
3 **it is.**
4 Q We're going to mark as Exhibit 12 a
5 composite exhibit that consists of the medical
6 records from Paces Ferry Medical Group that
7 Dr. Julie brought with him. I'm going keep it in
8 the hospital group plastic folder that he brought it
9 in so it won't get separated.
10 Dr. Julie, there is some highlighting and
11 some tabs on the records from Paces Ferry Medical
12 Group. Are you responsible for that highlighting
13 and those tabs?
14 **A Yes, I am.**
15 Q I'll mark as Exhibit 13 the records that
16 Dr. Julie received from Emory Crawford Long
17 Hospital. They're stapled together.
18 Dr. Julie, there are some sticky notes
19 that are on the Emory Crawford Long Hospital. Are
20 you responsible for the placement of those sticky
21 notes?
22 **A Yes.**
23 Q I'll mark as Exhibit 14 the records from
24 Piedmont. On the first page it says Piedmont Health
25 Care.

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1 And again are you responsible for the tabs
2 and the highlighting in the Piedmont Health Care
3 records?
4 **A Yes.**
5 Q Anything else over there that you think
6 you received under the initial April 12, 2007, cover
7 letter?
8 **A There is a possibility -- and this I can't**
9 **really tell you because I don't really mark stuff**
10 **when it comes in as to when I got it, but there's a**
11 **good likelihood that this pharmacy printout from CVS**
12 **Pharmacy came with the other records, but let me**
13 **just see if I can verify that because it may have**
14 **been that these got printed out at a later date.**
15 **Let's see. Sometimes they'll put a run date down.**
16 **And so along with the pharmacy records**
17 **there's a certificate of authentication from the**
18 **pharmacy dated 2006 so it's more likely than not**
19 **that I got this at the same time as I got the other**
20 **records.**
21 Q And are you responsible for the
22 highlighting on the pharmacy records?
23 **A That and the paper clip.**
24 Q I'll mark the pharmacy records as Exhibit
25 15, and I'll leave it in the blue plastic folder.

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1 There are some records in front of you
2 from Crawford Long Hospital. Do you think you got
3 those under the initial April 12th, 2007, cover?
4 **A You know, it's a little difficult for me**
5 **to get a grasp on the iterations of the name**
6 **Crawford Long Emory Hospital, Crawford Long Hospital**
7 **and which is the same and which is different --**
8 **Emory Hospital. So I do have some sheets here.**
9 **Now, whether those came to me as records that had**
10 **been pulled or whether I myself had copied excerpts,**
11 **which I do do from time to time in preparation for**
12 **deposition so I'll have the stuff that I need**
13 **quickly on hand. That I can't tell you. So I just**
14 **do have a bunch of loose sheets from various, you**
15 **know, facilities that I have together here as a set,**
16 **but I don't know if I made this stack or it came to**
17 **me already made.**
18 Q I'll just mark that as a composite
19 exhibit, and it will be Exhibit Number 16. Are you
20 responsible for all the highlighting, writing and
21 tabbings in exhibit?
22 **A Yes.**
23 Q I'm just going to look at this red -- I
24 guess it's a blue folder inside the red folder you
25 brought with you. There's a copy of your c.v. in

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1 there. Is that the updated c.v.?
2 **A How about that. Sorry about that. Yes,**
3 **it is.**
4 Q I'll mark the updated c.v. as Exhibit 17.
5 Is there anything else you see on the updated c.v.
6 that you didn't describe to me earlier?
7 **A If you want, I can take a marking pen and**
8 **I can highlight some of the stuff that I think is**
9 **new. That might make it easier for you.**
10 Q That will be fine.
11 **A And if you'd like to take a quick look**
12 **through here, you know, this does cover some of the**
13 **joint conferences on DILI that I mentioned that were**
14 **in FDA, PhRMA and AASLD so if you want to take a**
15 **look and go back to that to ask questions on that, I**
16 **totally understand.**
17 Q Okay.
18 **A All right. There you go.**
19 Q I'll mark this updated c.v. as Exhibit 17.
20 At the top of page two of your revised c.v. that
21 we've marked as Exhibit 17, the first bullet point
22 references your membership on the Interdisciplinary
23 Peer Review Committee at Shady Grove Adventist
24 Hospital, and it also states that that committee
25 adjudicates all Category 3 and 4 cases in

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1 departments hospitalwide. What are Category 3 and 4
2 cases?
3 **A Those are events that are considered to be**
4 **serious events and potentially harmful or**
5 **life-threatening to patients. So if there's an**
6 **error in treatment, whether it be a medication error**
7 **or some other type of mishap, a misdiagnosis, a**
8 **complication of a procedure, they give a**
9 **categorization of severity, with 3 and 4 being the**
10 **worst, and 3 and 4 are largely predicated on whether**
11 **they are resulting in potential patient harm.**
12 **So, you know, the idea of the committee is**
13 **to take prior chiefs of different departments, put**
14 **us all together on a multidisciplinary basis, and to**
15 **look at those things from sort of hospitalwide**
16 **perspective so we can come up with ideas on how to**
17 **make things work better.**
18 Q In the professional memberships section it
19 mentions that you are a member of the AASLD Special
20 Interest Group, and it says, "acute on chronic liver
21 failure." Is that correct?
22 **A That's not a typo. Right. So that's a**
23 **new term of art that I think is actually quite**
24 **accurate, which is that there's an appreciation that**
25 **in patients with impaired liver function that you**

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1 **can then superimpose an acute injury on top of that**
2 **and that they have an additional susceptibility on**
3 **the basis of their underlying chronic liver disease.**
4 Q And then the other special interest group
5 listed is steatosis and steatohepatitis. What are
6 those?
7 **A Steatosis is the accumulation of fat in**
8 **your liver beyond a certain percentage amount of**
9 **actual fat droplets in the liver, and**
10 **steatohepatitis is when you have that fat in**
11 **conjunction with inflammatory cells, and**
12 **inflammation and fibrosis.**
13 Q Do you think that acute on chronic liver
14 failure, steatosis or steatohepatitis are involved
15 in any way in this case?
16 **A I think acute on chronic is pretty close,**
17 **not necessarily using the word chronic, but if you**
18 **substitute acute on pre-existing impaired liver**
19 **injury, then I think it does have relevance to this**
20 **case.**
21 Q What do you do -- there's a bullet point
22 entry on page three of the revised c.v. under the
23 Clinical Practice, Interests and Accomplishments
24 Section that says, "Special consultant to Centers
25 for Medicare/Medicaid Services, Office of the

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1 Inspector General for utilization of an enteral
2 nutrition." What do you do in that role?
3 **A That actually ties back to that**
4 **organization that we had discussed, FMAS, but we**
5 **only talked about one aspect of what they do. They**
6 **also act as a peer review consulting organization to**
7 **the Government so that if the Government has**
8 **questions about overutilization or underutilization**
9 **of certain services and surgeries or procedures or**
10 **medications, they will get an outside peer review**
11 **and FMAS assembles panels of expert physicians.**
12 **So in this case we were looking at the**
13 **utilization of feeding tube formulas in nursing**
14 **homes for Medicare to see if the appropriate**
15 **formulas were being used and if tubes were being**
16 **overused or underused or used correctly.**
17 Q On page four under the Research Section
18 there's a bullet point that references participation
19 in an NIH workshop entitled, DILI standardization of
20 nomenclature and causality assessment. Was that on
21 December 1st and 2nd of 2008?
22 **A Yes, that was. And that was actually one**
23 **of those conferences -- well, actually -- let's see.**
24 **Yes, in this one bullet point I have two things.**
25 **It's a little confusing. So the first one was an**

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1 **NIH workshop solely sponsored by the NIH; that was**
2 **December 2008. But then talking about those**
3 **meetings that I said were in March or April, which**
4 **are the tripartite meetings, that happened in**
5 **April of 2009, and that one was called, "Recent**
6 **Research Advances in DILI," 2009. So you see that's**
7 **actually two different conferences.**
8 Q What were the results of the conference in
9 December of 2008 that dealt with the standardization
10 of nomenclature and causality assessment?
11 **A Well, you know, a result kind of implies**
12 **that consensus was reached, and I think this was**
13 **more of an exploration of a problem. So they were**
14 **looking at some of the old conventional approaches**
15 **to assessing causation, and there are two main ones,**
16 **one is called the RUCAM, R-U-C-A-M, and I'm blocking**
17 **on what the other one is called, and that's a**
18 **scoring system. So they said well, how accurate are**
19 **these, and are they really sufficient and they do a**
20 **good job? And their conclusion was that each of**
21 **them had limitations, each of them was insufficient**
22 **in itself, and that what worked better in the eyes**
23 **of experts there was that when you got together a**
24 **panel of three hepatologists,**
25 **gastroenterologists/hepatologists and had them each**

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1 **independently review the cases, and then conference**
2 **call together and kick it around, then they, acting**
3 **as sort of an impaneled jury of three, could come up**
4 **with a more accurate causality assessment than any**
5 **of the previous scoring systems that existed. So**
6 **that was pretty much the conclusion.**
7 Q Has a new scoring system been developed?
8 **A Not really. So, I mean, right now, you**
9 **know, they have a system where they frequently do**
10 **these group of three impanelments, and, you know, if**
11 **a case comes to this organization called DILIN,**
12 **which is the DILI Network, then they'll review the**
13 **case; they'll ship it out to three people they'll**
14 **review it independently; then they'll conference**
15 **call and score it collectively. That's the way that**
16 **they think they get the best result. And most of**
17 **these liver experts when you ask them what they**
18 **think of RUCAM and the other one, they say either I**
19 **don't use them or they have limitations.**
20 Q RUCAM, is that an acronym for something?
21 **A It is.**
22 Q What does it stand for?
23 **A It's the first two words are the name of a**
24 **European drug company, which is Rous, R-O-U-S,**
25 **Uclef, U-C-L-E-F, Consensus something.**

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1 Q And you can't recall the name of the other
2 causation assessment testing tool?
3 **A Probably census on methodology. It slips**
4 **my mind.**
5 Q I'm going to mark as Exhibit 18 a
6 three-page document, unsigned, marked affidavit of
7 Neal Julie. When did you receive that?
8 **A When did I receive it? I think I signed a**
9 **copy and sent it, and I don't remember the exact**
10 **date on this. I'd have to look at my signed copy,**
11 **which is in the stack you have over there.**
12 Q Did you write Moody at the top?
13 **A Yes. Hang on one second. There you go.**
14 Q I'm not going to mark these as an exhibit
15 yet. There's a couple of documents that appear to
16 have something to do with Abbott Labs, but do they
17 have anything to do with this case?
18 **A Well, at this point I don't think Abbott**
19 **is really involved in this case.**
20 Q If Abbott were involved in this case, what
21 relevance would those particular documents have to
22 the case?
23 **A Well, it just shows that Abbott contacted**
24 **me and was interested in evaluating what, I guess,**
25 **they thought were qualified experts to**

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1 **potentially -- to be a medical director for their**
2 **antiviral global project on Hepatitis C, you know,**
3 **drug development.**
4 Q I'll mark the one with red writing on it
5 that says received 1/23/08 as Exhibit 19, and the
6 other, which is a three-page document which is a
7 composite document, two e-mails and one Internet
8 printout, as Exhibit 20.
9 May I see that blue folder, please? Mark
10 as Exhibit 21 a copy of the death certificate you
11 brought with you. I think there are two copies.
12 Did you review this in connection with the formation
13 of your opinions in this case?
14 **A Yes.**
15 Q What bearing does the death certificate
16 have on your opinions?
17 **A Well, it just is what it is, and, you**
18 **know, sepsis is one of the most common causes of**
19 **death in patients with advanced liver failure, and**
20 **also, you know, transplant recipients are at great**
21 **risk because of their immunocompromised,**
22 **immunosuppressed state.**
23 Q As Exhibit 22 I'll mark a copy of a
24 printout of a letter to the New England Journal of
25 Medicine dated April 22nd, 2009. Is that something

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1 that you relied upon in your review of this case?
2 **A Yes.**
3 Q What particularly did you rely on in that
4 letter?
5 **A Well, I mean, I just -- this is a case**
6 **report so basically -- and it's a letter actually.**
7 **So, you know, it's just a report of a case of liver**
8 **failure, fulminant liver failure, due to Lamisil.**
9 Q Are you responsible for the highlighting
10 and underlining?
11 **A Yes.**
12 Q There is a portion of the letter that is
13 highlighted and a subportion of that underlined
14 highlighted portion is, "Histologic examination of
15 the explanted liver revealed parenchymal submassive
16 necrosis and nearly complete disappearance of
17 hepatocytes with no evidence of chronic liver
18 disease. These findings are compatible with a
19 drug-related cause of disease." Why did you
20 highlight and underline that particular language?
21 **A Well, you know, usually that just means I**
22 **looked it over two different times and I had two**
23 **different marking devices at that those times. So**
24 **that's all.**
25 **You know, I think that basically this is**

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1 **useful information in terms of understanding the**
2 **potential patterns of Lamisil induced liver injury.**
3 **And why I highlighted it? It just was, you know,**
4 **the most important part of the text.**
5 Q I show you what I've marked as Exhibit 23,
6 a short report entitled, "Terbinafine induced
7 hepatic failure requiring liver transplantation."
8 Is that something you reviewed in connection with
9 this case?
10 **A Yes, it is.**
11 Q What bearing does that have on your
12 opinions in this case?
13 **A Well, on the basis of the history and the**
14 **matching of clinical history and the labs and the**
15 **like, this, to a reasonable degree of medical**
16 **certainty, is actually Mr. Moody that's being**
17 **written about here. So this is a narration of his**
18 **history.**
19 **You know, I have this article here. I**
20 **think it's a useful article. I don't rely on every**
21 **sentence, every word in these articles, but it does**
22 **describe in detail the clinical picture in this**
23 **case.**
24 Q In this clear plastic folder there's a lab
25 result reported December 17th, 2004, a surgical

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1 pathology consultation report dated August 5th,
2 2005, and another surgical pathology report dated
3 June 16, 2005. They're in a clear folder labeled
4 liver biopsy and labs. Are these things you pulled
5 out for your own use?
6 **A Yes. Those are just things that I copied**
7 **to have them readily on hand when we were having our**
8 **discussions.**
9 Q I'm just going to mark that as Composite
10 Exhibit 24. I'm going to put the exhibit sticker on
11 the clear cover because it has writing on it.
12 What do you have there?
13 **A This is the deposition of Allan Treadwell.**
14 Q And there's highlighting and tabs. Are
15 you responsible for both of those?
16 **A Yes, I am.**
17 Q What's in this stack here?
18 **A This is volumes one and two of the Young**
19 **deposition. Included with it is the Novartis**
20 **warning letter from 2001, but otherwise this is all**
21 **just the deposition of -- actually, let me correct**
22 **that. I'm not sure, things look like they might**
23 **have gotten switched, but this is the deposition**
24 **of -- oh, yeah, that's right -- of Timothy Young,**
25 **and on the top of that it has the letter, the Dear**

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1 **Doctor warning letter from May 2001 from Novartis.**
2 Q On the Dear Doctor warning letter there is
3 some highlighting and some underlining and some
4 circling. Are you responsible for the highlighting,
5 underlining and circling?
6 **A Absolutely.**
7 Q I'm going to mark this all as a composite,
8 which will be Exhibit 26. It consists of both
9 volumes of Dr. Young's deposition and Exhibit 1 to
10 Dr. Young's deposition, which was the Novartis May
11 2001 Dear Doctor letter concerning Lamisil tablets.
12 **A This is, I think, actually a duplicate of**
13 **part two of his deposition.**
14 Q There's also highlighting and tabbing
15 here. Are you responsible for that?
16 **A Yes.**
17 Q I'll mark this 2 as Exhibit 27.
18 What's on the CD there?
19 **A The CD is the records of Dr. Young from**
20 **Paces Ferry and South Fulton -- well, the South**
21 **Fulton are records from the patient in the last few**
22 **months of his life, and there's a list in there.**
23 Q And then there are two pages that appear
24 to have come out of some type of a spiral notebook
25 of some type. Is this your writing on these pages?

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1 **A I think so. Here I think that's just a**
2 **synopsis of, you know, dates, history. A summary of**
3 **things that were written in the medical record of**
4 **Dr. Young that I'm writing down, you know, as sort**
5 **of summaries of what he said, and a list of the**
6 **patient's prior liver enzymes before Lamisil, some**
7 **of the X-ray results, et cetera.**
8 Q What we'll do is one of those is
9 two-sided, the other is one-sided. We'll copy them
10 separately and mark them as exhibits 28 and 29
11 respectively. There are dates at the top of these
12 two pieces of paper. What do those dates reflect?
13 **A Those dates probably reflect the date that**
14 **I reviewed the CD. So these really represent just**
15 **my writing down what I'm reading from the record**
16 **historically, items in the history.**
17 Q And you took the notes on or about
18 July 11th, 2009?
19 **A Correct.**
20 Q And then that envelope that you have over
21 there that says Moody on it, is that something in
22 which you received materials?
23 **A Yes.**
24 Q Let me take a look at that real quick.
25 **A You know, actually, to tell you the truth,**

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1 **I'm sort of am a dedicated recycler, and I think**
2 **this is actually an envelope from something totally**
3 **unrelated.**
4 MR. STEEL: We don't use UPS Next-Day Air
5 so I can tell you that's not us.
6 THE WITNESS: Okay. Good. There you go.
7 MR. BAZINET: We will not mark that.
8 THE WITNESS: Then we've just got this.
9 MR. BAZINET: We're going to have a little
10 bit longer discussion about what's in the pink
11 folder so let's take a break because we've been
12 going about another hour, get those two little
13 sheets copied, and we'll come right back and get
14 back to it.
15 (A brief recess was taken from 11:33 to
16 11:40 a.m.)
17 BY MR. BAZINET:
18 Q All three of the handwritten pieces of
19 paper have been copied onto one page, which I've
20 marked as Exhibit 28. I've also marked the CD
21 itself as Exhibit 29.
22 Is this next folder we're about to look at
23 a collection of medical literature?
24 **A It is, and we've got 11 articles. Yes,**
25 **this is actually a two-page printed off the Internet**

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1 **of this article so I can clip them all together. So**
2 **that brings it down to ten.**
3 Q I'll mark as Exhibit 30 a case report
4 entitled, "Terbinafine-induced prolonged cholestasis
5 with reduction of interlobular bile ducts." What I
6 would like to know, please, is what bearing does
7 this piece of literature have on your opinions in
8 this case?
9 **A This paper does give a nice view of a**
10 **patient who was on three weeks of Lamisil, who**
11 **developed symptoms fairly similar to those**
12 **experienced by Mr. Moody within a month of starting**
13 **the drug, and in their conclusions they recommend**
14 **monitoring of liver enzymes as a way to potentially**
15 **avoid therapeutic misadventures.**
16 Q Does the article marked as Exhibit 30
17 discuss whether the patient discussed in the case
18 report had any type of pre-existing liver condition?
19 **A In this particular case, whether this**
20 **patient had pre-existing liver condition? Is that**
21 **the question?**
22 Q Yes.
23 **A I believe that they don't comment on**
24 **pre-existing liver condition in this case, but**
25 **another point that I took from this paper is that it**

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1 **describes a condition where you have reduction in**
2 **bowel duct number, which in its worse case is what's**
3 **called vanishing bile duct syndrome, which again was**
4 **experienced by Mr. Moody, and it shows the**
5 **association between this drug and that pathological**
6 **process.**
7 Q What is vanishing bile duct syndrome?
8 **A Well, vanishing bile duct syndrome is a**
9 **pathologist's descriptive disease, and what you see**
10 **in a normal liver biopsy is a certain ratio of bile**
11 **ducts to portal veins, and in vanishing bile duct**
12 **syndrome you get a process where the ducts start to**
13 **disappear. The thinking is that they're affected by**
14 **a toxic injury and obliterated by the body by an**
15 **inflammatory reaction and by scarring, and that the**
16 **bowel ducts just start to vanish. So when it's at**
17 **the extreme, it's vanishing bile duct syndrome, but**
18 **earlier biopsies tend to show reduction in the**
19 **number of bile ducts so it's a process that unfolds**
20 **over time.**
21 **Now, in the case of Mr. Moody you had two**
22 **liver biopsies so you could kind of see the process**
23 **unfold, and that's what it is. It's an uncommon**
24 **condition, but it's been described in certain types**
25 **of cholestatic drug-induced liver injury.**

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1 Q In your answer to the question about what
2 bearing this article had on your thinking in this
3 case, one of the things you said is that it showed
4 an association between vanishing bile duct syndrome
5 and terbinafine. Does it prove a causal connection
6 between ingesting oral terbinafine and developing
7 vanishing bile duct syndrome?
8 **A Well, let me just take that back for one**
9 **second. You know, this is actually stated in their**
10 **discussion as the first case described, and it's**
11 **from 1997 so this is pretty early on. So in the**
12 **medical literature, you know, we have kind of our**
13 **own way of assessing causation in terms of what we**
14 **consider to be established diseases. So one single**
15 **case report does not causation make, but you put**
16 **that together with a series of cases, and then**
17 **you've got a very strong case, especially a series**
18 **of cases with a very rare disease.**
19 **So the best analogy is when I worked with**
20 **Selikoff, you know, the association of mesothelioma,**
21 **which you almost never see, and asbestos exposure,**
22 **after a couple of cases you knew that they were**
23 **associated conditions and there was a causal**
24 **relationship. Same thing applies to this.**
25 Q The case report indicates that the patient

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1 was also taking a vasodilator, the name of which is
2 spelled N-I-C-E-R-G-O-L-I-N-E, nicergoline, and
3 fenofibrate. Are either of them independently
4 associated with any type of liver injury?
5 **A Well, the fibrates in theory could be. To**
6 **my knowledge, I haven't seen any cases of vanishing**
7 **bile duct syndrome with fenofibrate, but you can get**
8 **other types of liver effects.**
9 Q With respect to Samuel Moody, does the
10 diagnosis of vanishing bile duct syndrome appear
11 anywhere in his medical records?
12 **A I'd have to look at his liver biopsies.**
13 **If I could have that one folder there that's the**
14 **small one that says liver biopsies and labs. And**
15 **then also I'll need to probably look at the article**
16 **that we marked. You know, in terms of the use of**
17 **that particular buzz word, I think we're not going**
18 **to see it, but they say basically the same thing,**
19 **which is on the biopsy from August 2005 they say an**
20 **absence of bile ducts, which means the same thing.**
21 Q Are there any recognized or established
22 diagnostic criteria for arriving at the diagnosis of
23 vanishing bile duct syndrome?
24 **A There are, you know, and we could probably**
25 **pull it out of one of those articles in terms of,**

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1 **you know, the defined ratio and numbers of bile**
2 **ducts per high-powered field or low-powered field.**
3 **You could probably -- I could probably find it in**
4 **one of the other articles.**
5 Q When we get to the other article that we
6 can find it in, I'd like you to point it out to me.
7 Independently from your own memory, are you able to
8 tell me what the diagnostic criteria are for
9 vanishing bile duct syndrome?
10 **A I'd have to refer back to the article**
11 **since I am, you know, not a pathologist and so I**
12 **would not want to give you a wrong number.**
13 **If you want, while you're reading I could**
14 **flip through the stack and we could go to the right**
15 **place.**
16 **Okay. So I can answer that question if**
17 **you'd like.**
18 Q Okay. Let's hold onto that article, and
19 we'll discuss the definition of vanishing bile duct
20 syndrome in connection with that. I just want to
21 finish with this particular article.
22 **A Okay. For speed's sake do you mind if I**
23 **take my marking pen and just make a couple of new**
24 **marks?**
25 Q That's fine.

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1 **A But I won't use any Post-it notes. All**
2 **right. That's it.**
3 Q Twice in the article that we've marked as
4 Exhibit 30 it references the appearance of jaundice
5 prior to the onset of pruritus. Do you attribute
6 any medical significance to that?
7 **A Well, you know, I think that they**
8 **mentioned jaundice and pruritus in the same**
9 **paragraph so let's see if I can find -- is it**
10 **somewhere on this page where they attribute it to**
11 **coming before?**
12 Q The third sentence of the first paragraph
13 under the subheading case report says, "Jaundice
14 appeared during the first week followed by
15 pruritus." And then in the third sentence on the
16 third page of the article in the summary subsection
17 notes also that jaundice occurred first followed by
18 pruritus.
19 **A Well, I would say a couple of things. In**
20 **terms of tying this back to Mr. Moody, you know, in**
21 **my experience as a liver specialist, I've found that**
22 **it's not surprisingly -- it's surprising to me, but**
23 **pretty commonly jaundice is often noted by other**
24 **people. So, you know, patients, they just feel**
25 **fatigued, run down, lose their appetite, but they**

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1 **don't notice that they're jaundiced. And I think in**
2 **my experience, especially in patients who were**
3 **African American who have what doctors call muddy**
4 **sclera, where the sclera can sometimes have a little**
5 **bit of a brownish hue, jaundice can be easy to miss.**
6 **So the fact that in his case pruritus came**
7 **before the jaundice and in this case the jaundice**
8 **came a little before the pruritus, doesn't mean**
9 **anything to me. Also, his sister says that he, you**
10 **know, was wearing sunglasses a lot, and she didn't**
11 **notice it. So it wasn't until his jaundice was very**
12 **advanced, but I think that because of the reasons I**
13 **just mentioned, the relevance of which came first,**
14 **as long as they were both pretty close to each**
15 **other, doesn't really mean all that much to me. The**
16 **important thing in this case is that the pruritus**
17 **was a key and critical indicator that he was**
18 **experiencing cholestatic liver disease, and that**
19 **that was seen on the April 12th visit and that was a**
20 **very key warning sign of significant liver problems.**
21 Q When you said in your previous answer that
22 so long as the jaundice and the pruritus occurred
23 fairly close in time, what amount of time between
24 the occurrence of those symptoms do you consider to
25 be fairly close?

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1 **A It really depends on whether it's looked**
2 **for. So, you know, I mean, I think that here's the**
3 **thing, if you would have had a patient -- let's talk**
4 **about Mr. Moody. If when he came in on April the**
5 **12th with his itching and he had liver enzymes at**
6 **that time and they were normal, we would know that**
7 **he was not yet jaundiced. If he came in and didn't**
8 **have any liver enzymes checked, we don't really know**
9 **whether he was jaundiced or not. People don't**
10 **really show jaundice until their bilirubin exceeds**
11 **three, which is significantly abnormal, and if the**
12 **doctor is not paying much attention or the patient's**
13 **got muddy sclera, then the jaundice could have been**
14 **missed.**
15 **So really in his case it's an unknown**
16 **whether he had jaundice or not when he went in on**
17 **April 12th because nobody checked. So, you know,**
18 **that makes the question you were asking about how**
19 **much time is a significant amount of time something**
20 **I really can't answer because we have no way of**
21 **establishing when, in fact, he became jaundiced.**
22 Q When you use the term jaundice, are you
23 using it to signify a medical diagnosis of elevated
24 bilirubin or are you using it to describe an
25 observable condition involving either or both the

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1 yellowing of the sclera of the eyes and/or the skin?
2 **A I think that they can be used. It depends**
3 **on the circumstances, but, you know, both are true**
4 **in their own way. So, I mean, I think that**
5 **jaundice, most of the time people talk about it in**
6 **terms of the yellow eyes and the yellow color as a**
7 **clinical diagnosis, but in point of fact if your**
8 **bilirubin is supposed to be less than one and a half**
9 **and it's two and a half, then you do have jaundice;**
10 **it's just hard to detect.**
11 Q You mentioned also in part of your
12 description of the importance of the article we've
13 marked as Exhibit 30 the recommendation for
14 monitoring. Why did do you find that to be
15 significant?
16 **A Well, because I think that the drug is a**
17 **known hepatotoxin, and I think that Dr. Young**
18 **conceded that it was a known hepatotoxin, and he was**
19 **aware that it was a hepatotoxin and that his intent**
20 **was to have checked liver enzymes at six weeks,**
21 **which unfortunately wasn't done. And this article**
22 **points to how that is important and why that's**
23 **important.**
24 Q Did you read the article we've marked as
25 Exhibit 30 to indicate that the onset of the

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1 clinically observable symptoms in the patient to
2 whom that report relates occurred three weeks after
3 the patient first began taking oral terbinafine?
4 **A No. It was more like four weeks because**
5 **the patient only took it for three weeks, then**
6 **stopped it, and then a few days later the symptoms**
7 **began, but that was four weeks.**
8 Q Based on your understanding of the medical
9 records, how soon did Samuel Moody exhibit
10 clinically observable symptoms that might be
11 associated with jaundice or some type of decreased
12 liver function after he first began taking the oral
13 terbinafine?
14 **A Could you repeat the question for me,**
15 **please?**
16 Q Yes. On the basis of your review of the
17 medical records and your knowledge of the case, how
18 soon did Samuel Moody first exhibit observable
19 clinical symptoms that might be associated with
20 decreased liver function or liver injury after
21 Samuel Moody started taking the Lamisil?
22 **A Well, I mean, I think that, you know, to**
23 **have an observable finding you have to have -- it's**
24 **a two-party arrangement, you to have the finding and**
25 **you have to have the observer, right? You can't**

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1 **have one without the other. If there's no observer,**
2 **it's like the tree falling in the woods. So for**
3 **that first 12-week period that he went from middle**
4 **of January or January 11th till April 12th, there**
5 **was no competent medical observer. There was his**
6 **sister, but she wasn't a clinician.**
7 **So the only time where you had the**
8 **observer, really, was either people at work, and**
9 **they're not clinicians either so they don't know**
10 **what they're looking for, and April 12th. So the**
11 **first time when he manifested observable symptoms**
12 **was when the observer was present on the 12th. Now,**
13 **he may have been having symptoms a month and a half**
14 **before that, but there was no observer and there was**
15 **no observation made.**
16 Q On the bottom of the second page of the
17 article, which is page 1487, there's a paragraph
18 that continues onto the next page. The first
19 sentence of the paragraph is, "The mechanism of
20 hepatotoxicity of terbinafine is unknown." Is that
21 sentence true in the modern day?
22 **A Again, as you point out, this is 1997 so**
23 **this isn't the modern day. There is a lot more**
24 **understanding, and I have another paper here that**
25 **I'd be happy to share with you that goes into the**

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1 **mechanism or our understanding of the mechanism,**
2 **which -- I mean, that's kind of why I do what I do,**
3 **is to try and come up with insights and**
4 **understanding about why these bad things happen to**
5 **people's livers. So at that time yes, it was true;**
6 **in modern times we've learned a lot more, still not**
7 **100 percent complete.**
8 Q Are there persons or identified groups of
9 persons who are on the leading edge of research
10 concerning terbinafine induced liver injury?
11 **A I don't know who is out there doing such**
12 **work, and so I'd have to say I don't know.**
13 Q What is the article that you found that
14 discusses the diagnostic criteria for vanishing bile
15 duct syndrome?
16 **A So that article -- do you want to mark it**
17 **first? It's by somebody named Desmet.**
18 Q Yes. I'll mark it as Exhibit 31. It is
19 an article called, "Vanishing bile duct syndrome in
20 drug-induced liver disease."
21 What information in this article describes
22 the diagnostic criteria for vanishing bile duct
23 syndrome?
24 **A Well, let me read this from the article**
25 **because it's pretty clear. It will take a few**

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1 **minutes. "The typical hallmark of the chronic**
2 **stage in" -- we'll call it VBDS for short --**
3 **"vanishing bile duct syndrome, however, is a**
4 **decrease in number of interlobular ducts, termed**
5 **paucity of interlobular bile ducts or ductopenia.**
6 **The ductopenia may be of variable extent, remain**
7 **stabilized or progress continuously. Ductopenia is**
8 **diagnosed by estimating the percentage of portal**
9 **tracts devoid of interlobular ducts. Another way**
10 **consists in calculating the ratio of ducts to the**
11 **number of portal tracts, which in the normal liver**
12 **has values between 0.9 and 1.8. Ductopenia has a**
13 **severe reduction of at least half of the ducts, 50**
14 **percent reduction, or a ratio of less than 0.5. It**
15 **is clear, however, that less severe degrees of**
16 **ductopenia between zero and 50 percent may also**
17 **occur." So that's it.**
18 **And the other part of this article, too,**
19 **is they talk about how that's the chronic stage, but**
20 **they talk about how in the early form there is a**
21 **somewhat different pattern. And in the early**
22 **biopsies you see what we saw with Mr. Moody with a**
23 **parenchymal bilirubinostasis and a lymphocytic and**
24 **plasma cell infiltrate, but, you know, the ducts at**
25 **that point have not yet been destroyed. And then,**

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1 **you know, in other parts they go into other issues**
2 **about the significance of pruritus and jaundice, et**
3 **cetera.**
4 Q In your medical practice, have you ever
5 diagnosed a case of vanishing bile duct syndrome?
6 **A A few times, yeah.**
7 Q Have you ever diagnosed a case of
8 vanishing bile duct syndrome that you did not
9 attribute to a drug-related cause?
10 **A No.**
11 Q In your medical practice, to what drugs
12 have you attributed a decrease in the number of a
13 patient's intrahepatic bile ducts?
14 **A I think two of those were Chlorpromazine,**
15 **which was, you know, back in my training days right**
16 **around fellowship, and the other one was a Serzone**
17 **patient. So there's three.**
18 Q Can vanishing bile duct syndrome originate
19 from causes other than drugs?
20 **A I'd have to actually go back to the**
21 **literature and review that question. I don't know**
22 **the answer. I think that's clearly the minority,**
23 **and I don't know how often that occurs, if at all.**
24 Q One of the drugs in this article by Desmet
25 that we have marked as Exhibit 31 that has been

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1 involved in more than one reported case of vanishing
2 bile duct syndrome is erythromycin esters, and do
3 you consider erythromycin esters to be close enough
4 to chlarithromycin that chlarithromycin might be a
5 suspect and a potential cause of vanishing bile duct
6 syndrome?
7 **A Yes, I would agree that it is similar**
8 **enough.**
9 Q Very briefly, from a perspective of a
10 gastroenterologist, is there any difference in
11 evaluating chlarithromycin for potential
12 hepatoxicity and evaluating chlarithromycin for
13 potential hepatoxicity?
14 **A Is there any difference?**
15 Q Yes, from the gastroenterologist's
16 perspective.
17 **A Maybe if you could clarify the question.**
18 **I'm not sure.**
19 Q Sure. What I'm trying to get an
20 understanding of is whether you would evaluate
21 erythromycin and chlarithromycin the same way in
22 terms of their potential for causing some type of
23 injury to the liver of any type.
24 **A Yes. I mean, I think that you would look**
25 **at it in terms of your general process in a similar**

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1 **way, but I think what you need to do then is also**
2 **look at what's the known history with that given**
3 **particular individual drug. And so, for instance,**
4 **if you look at the erythromycin family, there's a**
5 **second cousin drug called Ketek, K-E-T-E-K, you**
6 **might have heard of, that is immensely hepatotoxic,**
7 **but it's related, although not intimately related,**
8 **to erythromycin so we know that one is particularly**
9 **bad.**
10 **We know erythromycin is bad because**
11 **there's a bunch of literature out there that reports**
12 **it's bad, but all of this literature we've discussed**
13 **so far predates the existence of chlarithromycin so**
14 **they're not going to have anything to say about**
15 **clarithromycin because it didn't exist yet. So your**
16 **radar has to be up, the process has to be the same,**
17 **and in this particular case chlarithromycin as a**
18 **contributing factor on top of the cholestatic injury**
19 **initiated by Lamisil is a significant contributing**
20 **factor, probably, in the irreversible liver disease**
21 **that Mr. Moody ended up suffering from.**
22 Q And what was it that caused Samuel Moody's
23 liver disease to become irreversible?
24 **A You know, we haven't gotten into some of**
25 **the newer discoveries about mechanisms of the injury**

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1 **for Lamisil, but to just lay it out in a simple**
2 **form, in general you have somebody who's got a liver**
3 **injury in evolution, which is cholestatic liver**
4 **injury from the Lamisil, and it manifests itself in**
5 **terms of his anorexia, his fatigue, his pruritus,**
6 **and it's already started up by the time he's coming**
7 **off of Lamisil. Then on top of that you have a drug**
8 **of the erythromycin family that's going to tend to**
9 **cause toxic metabolites to accumulate in the bile**
10 **duct in the biliary system, and it's secreted by the**
11 **liver, and the concentrations in the bile ducts**
12 **itself are pretty high; and then you're going to now**
13 **take a liver that's already got a cholestatic**
14 **injury, so you've got impaired hepatocytes and**
15 **you've got impaired bile duct epithelium, and you're**
16 **now going to add another level of poison into that**
17 **system, and that tips you over the edge.**
18 Q Other than providing the diagnostic
19 criteria for vanishing bile duct syndrome, what else
20 does this article marked Exhibit 31 by Desmet add to
21 your evaluation of the case?
22 **A Well, I think that it does go into the**
23 **description of the early biopsy findings, which is**
24 **on the bottom right on page 232, and then the later**
25 **biopsy findings, which is on the left-hand side of**

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1 **page 33. And then, as you pointed out, I think as a**
2 **good observation, it does list under table one that**
3 **the erythromycin esters are drugs that have been**
4 **implicated in vanishing bile duct syndrome, which,**
5 **you know, confirms that he should not have gone on**
6 **that drug in terms of his condition in April.**
7 **And then, you know, it just kind of**
8 **mentions major form, minor form, and the fact that a**
9 **lot of times you can reverse the process, unless you**
10 **progress to the major form, which, you know,**
11 **unfortunately it went down the road in the major**
12 **form in the case of Mr. Moody.**
13 Q At what time did Samuel Moody progress to
14 the major form of vanishing bile duct syndrome?
15 **A By major meaning irreversible liver**
16 **disease that was, you know, going to obliterate all**
17 **of his bile ducts and lead to liver failure, I would**
18 **say during the course of his Biaxin therapy in**
19 **April.**
20 Q Anything else about this article by Desmet
21 that we've marked as Exhibit 31 that bears on your
22 opinions?
23 **A No. But I would like to see the pharmacy**
24 **records for one second, if I could. It's in a blue**
25 **sleeve, one of the blue sleeves. Thank you.**

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1 **You can go ahead. I'm listening.**
2 Q What's the next article over there in that
3 stack?
4 **A Well, let me just move to the article that**
5 **gets into considerations of mechanisms. So next**
6 **article is entitled, "Drug metabolite profiling and**
7 **elucidation of drug-induced hepatotoxicity," by**
8 **Dr. Tang, T-A-N-G -- actually and Merck.**
9 Q I'll mark that as Exhibit 32. So I don't
10 have to ask you in connection with each article, are
11 you responsible for the highlighting and any writing
12 on these articles?
13 **A Yes, I am. And that's for everything, all**
14 **the articles that follow.**
15 Q What bearing does this article by Tang
16 have on your opinions?
17 **A Would it be possible -- because this**
18 **article, and it has like a companion article, so we**
19 **could talk about them both together.**
20 Q We'll mark the companion article as
21 Exhibit 33. The companion article is entitled,
22 "Defining targets for investigating the
23 pharmacogenomics adverse drug reactions to
24 antifungal agents."
25 What bearing do those two things have?

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1 **A So, you know, just to keep it fairly**
2 **brief, what they do is they look at things in a**
3 **mechanistic way and they talk about terbinafine.**
4 **One of the articles mentions prior reports of**
5 **decreased interlobular bile ducts, and they both**
6 **describe how there's a metabolite of the drug which**
7 **is conjugated to something called GSH, and that**
8 **these metabolites are actually an aldehyde,**
9 **A-L-D-E-H-Y-D-E, which are toxic. The conjugate**
10 **then binds, as mentioned, and they then call this**
11 **thing TBF dash A dash SG, and then this conjugate is**
12 **transported from the liver cells into the bile duct.**
13 **And the bile duct has a very powerful**
14 **concentrating capacity because there's actually a**
15 **transporter unit called MRP-2 that basically pumps,**
16 **like a sump pump, it pumps the drug, this conjugate,**
17 **out into the bile ducts, concentrating it in the**
18 **bile, and it then has the potential to bind and**
19 **cause direct toxicity to the bile duct epithelium**
20 **and trigger an inflammatory response in the region**
21 **of the bile ducts because of the damage that it**
22 **generates.**
23 **So these two articles, you know, take it**
24 **from the previous date in '97, when we don't really**
25 **know the mechanism, to giving a good biochemical**

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1 **clarification of a potential mechanism that was put**
2 **in motion wile this patient was on Lamisil from**
3 **early January till sometime in March, and that**
4 **explains it pretty nicely.**
5 Q Before your review of this case, what was
6 the extent of your knowledge about this particular
7 biomechanical mechanism as it relates to
8 terbinafine?
9 **A I had a global general understanding of**
10 **the, you know, bile acid pumps and the way that bile**
11 **kinetics operate in liver cells. As far as the, you**
12 **know, aldehyde formation, things like that, I**
13 **learned about that when I read about this case.**
14 Q Are you familiar with the isoenzymes of
15 which terbinafine is a substrate?
16 **A I think it's some kind of squalene**
17 **related -- as I recall it has something to do with**
18 **squalene something which is present in fungi, and it**
19 **seems to block it in the fungus and not so much in**
20 **the human.**
21 Q With respect to enzymes in the P450 system
22 in the liver, are you familiar with the particular
23 enzymes which terbinafine is the substrate?
24 **A I'd have to look it up. I mean, various**
25 **drugs use various, you know, P450 components so I'm**

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1 **not sure. You know, I'm sure it's probably in one**
2 **of those papers.**
3 Q I do note that at least there appears that
4 one of the authors of the article that we have
5 marked as Exhibit 33 is from Maryland. Do you know
6 anyone who's written this article?
7 **A I do.**
8 Q Who do you know?
9 **A Steve Chanock, C-H-A-N-O-C-K.**
10 Q Is Steve Chanock a medical doctor?
11 **A He is, I think, but he's pure research, I**
12 **believe.**
13 Q What is the focus of his research, if you
14 know?
15 **A You know, I don't. And I didn't really --**
16 **it was just kind of an amazing surprise to me that I**
17 **saw his name on the article, nor did I discuss it**
18 **with him, but he does research. I think his field**
19 **is pediatric oncology, but I think he now runs a lab**
20 **and spends most of his time doing bench research at**
21 **a very high level.**
22 Q There is on the second page of the article
23 that we've marked as Exhibit 33, which is the
24 article by Dr. Chanock, or at least of which he is
25 one of the authors, there is a particular paragraph

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1 that is bracketed using a red pen. Is the area of
2 the article that's bracketed with the red pen the
3 part of the article that describes the mechanism of
4 injury associated with terbinafine?
5 **A Yes.**
6 Q And in the article that we've marked as
7 Exhibit 32, which is the drug metabolite profiling
8 article, on page 414 there is some language that is
9 highlighted and then also some other language that
10 is bracketed and has two stars next to it. Does
11 that also describe the mechanism of injury?
12 **A Yes.**
13 Q The drug metabolite profiling article that
14 we've marked as Exhibit 32, does that make any
15 particular discussion of terbinafine?
16 **A Yes, they do actually. It's mentioned**
17 **over here in the left-hand column where it says,**
18 **"Terbinafine is an antifungal agent known to cause**
19 **cholestatic hepatotoxicity. In a case report**
20 **prolonged cholestasis was accompanied by decrease in**
21 **bile ducts."**
22 Q And so we can have an understanding going
23 forward, in medical terminology what does
24 cholestasis mean?
25 **A Cholestasis is a condition where you have**

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1 **a problem with bile exports so you have a problem**
2 **with the liver pumping out bilirubin and bile and**
3 **bile acids from the liver into the bile ducts and**
4 **then out into the G.I. tract. And so what happens**
5 **is you don't have as much liver cell death, but what**
6 **you do get is you get a backup of a lot of these**
7 **things that the liver is meant to excrete, and it**
8 **just doesn't excrete them so they start to build up**
9 **and you get yellow skin, your skin starts to itch,**
10 **your alkaline phosphatase and GGT get significantly**
11 **elevated. Those are the characteristics of**
12 **cholestasis.**
13 Q Other than describing the mechanism by
14 which terbinafine induced liver injury may occur,
15 what other things do these two articles we've been
16 discussing add to your analysis of and opinions in
17 this case?
18 **A That's pretty much it. You know, they**
19 **actually go ahead and in the diagram above, in**
20 **Figure 3, they map out the biochemical diagram of,**
21 **you know, what the agents are that they have found**
22 **to be the hepatotoxic factors, but other than that,**
23 **that pretty much covers it.**
24 Q What's the next article in the pile?
25 **A The next article on terbinafine, and then**

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1 we'll be pretty much done with that drug -- well,
2 there's two actually -- is first just briefly in an
3 article entitled, "Drug-Induced Cholestasis."
4 Q I'll mark this as Exhibit 34. What
5 bearing does this article, "Drug-induced
6 Cholestasis," have on your opinions?
7 A Basically they give sort of a clinical
8 synopsis of the clinical patterns of injury with
9 terbinafine, and they make the point that mild ALT
10 changes occur in about 10 percent of treated
11 patients, but then the significant hepatotoxicity is
12 a rare reaction.
13 And the point here is that in most of
14 these patients or almost all of these patients
15 before you get really, you know, bad and obvious
16 clinical injury, you get mild ALT elevations. And
17 then there's a bunch of people who get the mild
18 elevation, and they never progress to the really bad
19 disease, but the mild elevation -- and that's the
20 point of monitoring -- occurs and gives the doctor
21 the opportunity to stop the drug before things go
22 from bad to worse, which unfortunately did not take
23 place with Mr. Moody. So it's just all here marked
24 in red.
25 Q Other than the portion of this article on

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1 page 298 that you have bracketed in red, is there
2 anything else in this particular article,
3 "Drug-Induced Cholestasis," by Velayudham,
4 V-E-L-A-Y-U-D-H-A-M, that bears on your opinions?
5 A No.
6 Q What's the next article?
7 A These are -- I guess, let's just move to a
8 different -- well, let's stay with this and just
9 kind of finish it up. These are two other case
10 reports of patients who had terbinafine induced
11 liver injury, and we can maybe mark those as a group
12 and I'll talk about the two together. And that will
13 be it for case reports.
14 Q I'm going to mark the letter entitled,
15 "Terbinafine hepatotoxicity resulting in chronic
16 biliary ductopenia and portal fibrosis," as Exhibit
17 35, and I'll mark as Exhibit 36 the case report
18 entitled, "Terbinafine associated hepatotoxicity."
19 What bearing does Exhibit 35 have on your
20 opinions in this case?
21 A Okay. This is a letter that describes a
22 patient who had, again, a reduction of interlobular
23 bile ducts with an accompanying liver biopsy
24 supporting a pattern of injury which was the kind of
25 injury seen in Mr. Moody, and in this particular

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1 article they point out that you can see this type of
2 injury even in patients who have no pre-existing
3 liver disease. And it instructs the readers that
4 clinicians using this agent should monitor serum
5 alkaline phosphatase levels in patients who develop
6 liver function test abnormalities while taking the
7 drug.
8 Now, in this case it's an unusual case
9 because this is really a long-term follow-up a
10 couple of years after the fact that showed this
11 progression, you know, from the time of the injury
12 to a liver biopsy done 20 months after the first
13 liver biopsy where the obliteration of bile ducts
14 had occurred.
15 Q Does the letter discuss any medications
16 that were co-administered with the terbinafine?
17 A It does not. It does not.
18 Q What bearing does the article we've marked
19 as Exhibit 36 have on your opinions in this case?
20 A This article by Ajit, A-J-I-T, first it's
21 going back to before. They report also that the
22 mechanism appears to be this formation of TBF-A, the
23 aldehyde formed by liver enzymes that has been
24 proposed to be a direct hepatotoxin. So they
25 comment on that, and then they go into the report of

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1 their case, which was a patient who had the onset of
2 abdominal pain -- I'm sorry, strike that, please --
3 the onset of severe fatigue, some dark urine,
4 generalized pruritus, no comments on jaundice, one
5 month after starting the use of Lamisil; and the
6 biopsy showed bile duct damage, and the patient
7 slowly improved over time.
8 And they again advocate that even
9 asymptomatic patients, quote, hepatic function tests
10 should be performed periodically in patients taking
11 terbinafine for longer than six weeks, close quote.
12 So that's pretty much the summary of what it has to
13 say.
14 Q Other than just the summary of what these
15 articles have to say, Exhibit 35, the letter, and
16 Exhibit 36, the case report, what do they mean in
17 the context of your opinions in this case?
18 A Well, they speak to the one case with the
19 obliteration of bile ducts over time. The other
20 case has the pruritus described before any
21 description of jaundice so it's pruritus and
22 fatigue, which fits Mr. Moody well. The onset of
23 symptoms is within a month of initiation of therapy,
24 which is also relevant to this case, and the
25 importance of monitoring.

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1 Q I note that one of the authors of the
2 letter we've marked as Exhibit 35 is a Frank Anania,
3 a medical doctor associated with the University of
4 Maryland School of Medicine. Do you know him?
5 **A I do. I know him very vaguely. I think I**
6 **spoke to him once in 20 years.**
7 Q Did your conversation with him have
8 anything to do with drug-induced hepatic injury?
9 **A No.**
10 Q What's the next article you have?
11 **A The next article is just a very brief**
12 **thing from a dermatology book called "Dermatology,"**
13 **and it just gives the definition of onychomycosis**
14 **with the differential diagnosis of it.**
15 Q We'll mark this as Exhibit 37. It's a
16 two-page composite exhibit, one page consisting of
17 the title page of the book. The second page
18 consisting of copies of pages 426 and 427 of the
19 book. The handwriting on the title page of the book
20 with your name, is this a book that you own?
21 **A Yes.**
22 Q How did it come to be that you own a
23 dermatology book?
24 **A Well, it's probably so old that I may have**
25 **gotten it back in my ER days. Does it have a year**

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1 **on it? And I have a hard time throwing away books.**
2 Q Possibly 1980?
3 **A There you go. So it's just a leftover**
4 **from my days in residency and in emergency medicine.**
5 Q And what bearing on your opinions in the
6 case do these two pages from the dermatology book
7 have?
8 **A It just describes the disease well and the**
9 **differential diagnosis, which is clearly important**
10 **since other diseases can look like onychomycosis.**
11 Q What other diseases can look like
12 onychomycosis?
13 **A I think there's a yellow nail syndrome. I**
14 **think psoriatic nail disease. Trauma. I'm blanking**
15 **on the others.**
16 Q Trauma is a precursor in many cases to the
17 development of onychomycosis, true?
18 **A It can be, yeah.**
19 Q Have you ever diagnosed a case of yellow
20 nail syndrome?
21 **A I've seen it, you know, but I don't think**
22 **I was primarily involved in its treatment. So, I**
23 **mean, I've seen it, but I think it was probably when**
24 **I was doing some dermatology at UCSF during my**
25 **residency.**

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1 Q Have you ever diagnosed a case of
2 psoriatic nail disease?
3 **A No. Other things that can cause it -- I'm**
4 **just looking here -- contact dermatitis, lichen**
5 **planus, P-L-A-N-U-S, and nail-bed tumor.**
6 Q Have you ever had the occasion to
7 diagnosis any of those three conditions?
8 **A No.**
9 Q What's next?
10 **A Next is an article from the American**
11 **Family Physician Journal, published by AAFP,**
12 **entitled, "Treating Onychomycosis," by Philip**
13 **Rodgers, R-O-D-G-E-R-S.**
14 Q I will mark that as Exhibit 38. What
15 bearing does that piece have on your opinions in
16 this case?
17 **A Well, based on the descriptions that they**
18 **give, the article demonstrates the point that you**
19 **need to really do a KOH to establish diagnosis**
20 **because, you know, you have a 50-50 chance, really,**
21 **at baseline of being right in the diagnosis of**
22 **onychomycosis and that the definitive test is the**
23 **KOH study. In the case of Mr. Moody, I would say**
24 **that it is more likely than not that he did not**
25 **really have onychomycosis.**

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1 Q Why do you say that?
2 **A Let me break it down. First of all,**
3 **according to that paper it's only 50-50 to begin**
4 **with. Secondly, in the medical record -- in the**
5 **electronic medical record compiled by Dr. Young he**
6 **puts down the diagnosis of tinea pedis, which means**
7 **that he's either charting incorrectly, or that it**
8 **was the wrong diagnosis to use Lamisil for, or some**
9 **of the other reason that he offers. That's the**
10 **second part of it.**
11 **The third part of it is that I believe,**
12 **according to the records, Mr. Moody only has nails,**
13 **toenails, on one foot, and in Dr. Young's record I**
14 **think at one point he describes fungal infection on**
15 **both feet. So if the guy's got no toes on his one**
16 **foot, then he can't have onychomycosis on that foot**
17 **because he has no toenails to have a toenail fungus.**
18 **So he's got to be at least wrong about one foot. So**
19 **if you're starting from 50-50 and then you, you**
20 **know, apply the logic that I just laid out, then I**
21 **think it's more likely than not that he did not have**
22 **onychomycosis at all.**
23 **May I see the packet that is the marked**
24 **exhibit of the claim? If you just give me that**
25 **stack, I promise to keep it organized, but I just**

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1 **want to refer to something.**
2 **So just to expand on that, Dr. Young, in**
3 **his January 11th note, 2005, noted a, quote, fungal**
4 **like lesion, both feet, close quote, and diagnosed**
5 **him with tinea pedis and seborrhea. There's no way**
6 **he could have onychomycosis on one of his feet**
7 **because he had no toenails on one of his feet. So**
8 **if the lesion he described is on both feet, it**
9 **couldn't have been onychomycosis.**
10 Q What other bearing on your opinions does
11 this article from the American Family Physician
12 have?
13 **A Again, they recommend that liver enzymes**
14 **should be, quote, obtained before terbinafine is**
15 **initiated and repeated every four to six weeks**
16 **during treatment, period. Terbinafine should be**
17 **discontinued if the ALT or AST levels become**
18 **elevated to two or more times normal, close quote.**
19 **So that's the only other element.**
20 Q What's the next article in the stack?
21 **A The next article is -- and it's the**
22 **last -- is called, "Hepatic side effects of**
23 **antibiotics" by Westphal from 1994.**
24 Q I'll mark that as Exhibit 39. What
25 bearing does this article have on your opinions in

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1 this case?
2 **A This article is again going back 17 years**
3 **now so this is an earlier time with more incomplete**
4 **knowledge. And in this article this really deals**
5 **with what we talked about before, which is the**
6 **macrolide antibiotics, and they talk about**
7 **erythromycin estolate first, but then they also say,**
8 **quote, A number of well-documented cases of**
9 **hepatotoxicity associated with the other**
10 **erythromycin derivatives have also been described,**
11 **close quote. So it's not just one particular, you**
12 **know, variety of the drug.**
13 **And then later on they comment on how**
14 **erythromycin has intrinsic hepatotoxic potential so**
15 **it's not what some people in the drug field want to**
16 **call idiosyncratic, and they say that it's probably**
17 **unstable metabolites, and that at times there can be**
18 **a drug drug interaction where one drug can**
19 **potentiate the hepatotoxicity of the macrolide. So**
20 **that is really all that you can get from this very**
21 **old article.**
22 Q Does the article undertake to describe the
23 nature of the drug drug interaction in terms of
24 whether it's a protein binding reaction or a
25 competition reaction for liver based isoenzymes or

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1 anything like that?
2 **A I think that what they invoke here is that**
3 **you take one drug which is -- in other words, it's**
4 **not so much an interaction at a P450 site, which is**
5 **metabolic, but what it is is that you have**
6 **cholestasis of one drug, one cholestatic drug, on**
7 **top of which you put another cholestatic drug so**
8 **it's like a clogged sewer line, you know, it's**
9 **really more of a mechanical limitation of flow out**
10 **of the liver than a metabolic pathway. That's what**
11 **they invoke.**
12 Q In part of your answer previously you used
13 two words, one being idiosyncratic and the other
14 being intrinsic. What are the differences between
15 those two terms?
16 **A Well, there's been a lot of spin applied**
17 **to the term idiosyncratic so it's really lost a lot**
18 **of its meaning, but idiosyncratic, as defined by**
19 **Zimmerman, was not seen in animal studies, not dose**
20 **dependent, not predictable and tended to occur late.**
21 **Those are, I think, four of the main criteria that**
22 **he utilized in his definition.**
23 Q When you say tends to occur late, what do
24 you mean by that?
25 **A Like, you know, not within a few weeks but**

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1 **more like after several months. And, you know, I**
2 **mentioned the, quote, unpredictable issue.**
3 Q And what is the word intrinsic to your
4 mind intended to describe when one uses it in the
5 context of a drug reaction?
6 **A Well, intrinsic implies that it's dose**
7 **dependent, that it can be reproducible in animal**
8 **models, that, you know, basically if you give enough**
9 **of the drug to any person, you can induce an injury,**
10 **but, you know, I think I kind of get to the topic of**
11 **the deterioration of the term idiosyncratic**
12 **hepatotoxic injury in terms of the impact, I think,**
13 **of litigation on that whole topic in my article. So**
14 **let me just read you a few sentences because I think**
15 **it gets summed up pretty well.**
16 Q Which article is that?
17 MR. STEEL: Tell him the exhibit number.
18 THE WITNESS: Exhibit Number 4.
19 BY MR. BAZINET:
20 Q What portion of that article bears on the
21 difference or discussion of idiosyncratic versus
22 intrinsic reaction to a drug?
23 **A Right. And I'm looking to see if I can**
24 **find the place where I wrote that. Okay. Let's**
25 **see. Here's part of it, quote, Another lesson from**

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1 **the troglitazone experience is that there are a few**
2 **important distinctions seen with mitochondrial**
3 **toxicity. It is not truly consistent with a rigid**
4 **idiosyncratic toxicity paradigm. Synergy with other**
5 **liver diseases can occur.**
6 **Basically I'm not finding the part, but**
7 **the important thing to note is that a lot of times**
8 **the term idiosyncratic means that there's just been**
9 **no mechanism identified and nobody knows how it**
10 **works, and the lack of identification of a mechanism**
11 **of injury then throws it into this waste category of**
12 **idiosyncratic, when, in point of fact, further**
13 **investigation can frequently lead to the discovery**
14 **of the toxic pathway. Just like we discussed with**
15 **terbinafine between 1997 and 2008, you know, those**
16 **two different papers, where you elucidate a**
17 **mechanism and it no longer fits into the old rigid**
18 **definition of idiosyncratic.**
19 **So an intrinsic toxin, you know, is dose**
20 **dependent; it should have a toxic effect on a lot of**
21 **people if you give them enough of it; it's**
22 **predictable; it should be in quicker onset of**
23 **occurrence. But, you know, that is a definition**
24 **that is very limited, and it's been kind of badly**
25 **misused.**

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1 Q Take a look at your case report for a
2 moment. If you look at the first paragraph on page
3 37 in the discussion subheading, is that what you
4 were looking for discussing intrinsic versus
5 idiosyncratic hepatotoxic --
6 **A Which paper are you on? Because I might**
7 **be looking at the wrong one.**
8 Q The case report.
9 **A Oh, the case report. No. Actually that**
10 **was not the paper I was looking at, but I'll take a**
11 **look at it. Left side or right?**
12 Q Page 37, first paragraph under the
13 discussion subheading.
14 **A Right. And that's kind of what I**
15 **summarized.**
16 Q So what you're trying to communicate in
17 that sentence that's in this article is what you
18 just told me a second ago about?
19 **A Well, you know, this is really kind of --**
20 **this paragraph was written by one of my coauthors**
21 **and, you know, I think that it's kind of not 100**
22 **percent. If I had written this paragraph myself, I**
23 **don't think I would have put in the last part -- the**
24 **last portion of that sentence. What I'm really**
25 **trying to convey is that a lot toxicity reactions**

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1 **occur in a minority of patients. It's unpredictable**
2 **if you don't use the right predictive models, you**
3 **know, and it gets called idiosyncratic because it's**
4 **sort of an easy out in terms of explaining away an**
5 **injured patient.**
6 **But, you know, if you look at something**
7 **like, let's say, alcohol abuse, if you have a room**
8 **full of 1,000 heavy drinkers for years and years,**
9 **only 15 percent of those people are going to get**
10 **cirrhosis of the liver; the other 85 percent won't.**
11 **Does that mean that those 15 percent are**
12 **experiencing an idiosyncratic reaction to alcohol?**
13 **Nobody would say that. But it's still just a**
14 **minority that has the injury so there are going to**
15 **be some host factors, some genetic factors, but I**
16 **think that idiosyncratic as a term, I'm not a**
17 **believer that it's very useful.**
18 MR. BAZINET: We've been going another
19 hour and a half. Let's take a five-minute break.
20 THE WITNESS: Okay.
21 (A brief recess was taken from 1:03 to
22 1:11 p.m.)
23 BY MR. BAZINET:
24 Q I want to ask you about your opinions in
25 this case in more detail. I cataloged them earlier.

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1 I'm not going to go through that.
2 **A Okay.**
3 Q The first standard of care opinion that
4 I've written down that you gave me is that you
5 believe that Dr. Young breached the standard of care
6 by failing to determine whether Samuel Moody had
7 onychomycosis; is that correct?
8 **A That's correct.**
9 Q Is it your opinion that he breached the
10 standard of care in that regard by failing to get a
11 KOH test?
12 **A Well, I think he needed a KOH test or he**
13 **needed to have, you know, kind of really detailed**
14 **clear, well-documented medical record giving a, you**
15 **know, picture perfect description clinically of**
16 **onychomycosis for it to have been acceptable.**
17 Q What would, to your mind, a sufficiently
18 detailed description to meet the standard of care
19 have included?
20 **A Well, I mean, first of all, there's no**
21 **way, like I said, that he could have had**
22 **onychomycosis on both feet since he only had**
23 **toenails on one foot. So that in itself is hugely**
24 **suspect. Second, he had an electronic medical**
25 **record, and, you know, with any computer program**

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1 **there's the capacity to free-text. I could have**
2 **typed in that name, I'm sure, in his system and put**
3 **the correct diagnosis to the patient. Tinea pedis**
4 **is unacceptable. And the description of the**
5 **toenails, maybe even an illustration and, you know,**
6 **a clear note that describes graphically what he was**
7 **treating.**
8 Q Do you believe that the KOH test and the
9 documentation and description that you have just
10 described to me were alternatives or did they have
11 to be done together?
12 **A Well, I think as a clinician that a KOH**
13 **should have been done just on the basis of that AFP**
14 **article saying it was 50-50 just by looking. So I**
15 **think KOH would have been the appropriate -- a**
16 **dermatology referral would have been the appropriate**
17 **step, and then they would have the capacity to do**
18 **the KOH.**
19 Q The second standard of care breach that
20 you talked about at the beginning of the deposition
21 was what you perceived as deficiencies in
22 Dr. Young's documentation regarding diagnosis and
23 treatment results. Is that what you just described
24 to me or is that something else?
25 **A Well, that's part of it, but there's more.**

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1 **So he could have free-texted the correct diagnosis;**
2 **he could have documented his findings on physical**
3 **exam more accurately, and he should have; he should**
4 **have put in a recommendation, as I do and as most**
5 **EMR's require you to do, that you want to get a**
6 **follow-up visit or that you don't want to get a**
7 **follow-up visit. And if he wanted the patient back**
8 **in six weeks, it should have been charted as such.**
9 **If he wanted to get lab results or lab tests**
10 **ordered, it should have been charted and it should**
11 **have been done. On follow-up visits in April when**
12 **he saw the patient, he didn't even comment on how**
13 **the toenails looked after several months of**
14 **treatment, which was also unacceptable.**
15 Q The third criticism that you had with
16 respect to the standard of care concerned
17 Dr. Young's intent to check liver enzymes. What is
18 your criticism in that area?
19 **A Well, his statement that he intended to**
20 **treat isn't really backed up by the medical record**
21 **because there's no follow-up appointment, there's no**
22 **written note saying that he planned to check,**
23 **there's no contact by his office with the patient,**
24 **and it didn't get done. He offered an explanation**
25 **after the fact that he thought the patient was not**

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1 **compliant, but, again, the pharmacy records refute**
2 **that claim. So the patient was on drugs, and if he**
3 **intended to check liver enzymes, he should have done**
4 **so.**
5 Q The pharmacy records show that the
6 prescriptions for medications, including
7 prescriptions Biaxin and Lamisil, were filled,
8 correct?
9 **A Correct.**
10 Q The pharmacy records do not show that
11 Samuel Moody actually took the drugs after the
12 prescriptions were filled, true?
13 **A That's true.**
14 Q In connection with your review of the case
15 or otherwise, have you had the occasion to look at
16 the product inserts for either Biaxin XL or oral
17 Lamisil as published in the PDR or otherwise?
18 **A I think probably I did back in 2008, but I**
19 **haven't looked at it in the last three years.**
20 Q The check of the product insert, was that
21 in specific reference to this case or was it in
22 reference to something else in medical malpractice?
23 **A This case.**
24 Q Do you know from what year you looked at
25 the product insert?

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1 **A It probably would have been from my PDR in**
2 **2006 or 7, which is what I would have had around at**
3 **the time.**
4 Q Would it be fair to say that when you
5 looked at it, you looked at the most recent version
6 of the PDR that was then available to you?
7 **A Yes.**
8 Q In connection with your review of the case
9 or otherwise, have you had the occasion to look at
10 any of the historical product inserts for either
11 oral terbinafine, Lamisil or Biaxin XL?
12 **A No.**
13 Q Do you know whether at any time there was
14 a recommendation in the product insert for Lamisil
15 for periodic testing?
16 **A There was, as I understand it, before**
17 **2001.**
18 Q Do you know anything about why that
19 recommendation was removed from the product insert?
20 **A I have no firsthand knowledge, and so I**
21 **don't.**
22 Q Part of that last question was based on
23 the premise that the recommendation about the
24 periodic testing had been removed. From your review
25 of the more recent product insert, as published in

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1 the PDR, did you find any recommendation by the
2 manufacturer about periodic testing relating to oral
3 terbinafine?
4 MR. STEEL: You mean other than the KOH?
5 You said periodic testing.
6 MR. BAZINET: KOH isn't done periodic.
7 I'll ask the question again.
8 BY MR. BAZINET:
9 Q In your review of the product inserts
10 published in the PDR after 2002, did you see any
11 recommendation for periodic liver function testing
12 after the initial test that's recommended before
13 prescription of the drug?
14 **A That language about the monitoring**
15 **interval afterwards was taken out, but I think also**
16 **there was the language put in, in what I guess was a**
17 **black box or equivalent thereto, that, you know,**
18 **that there was serious liver risks of the drug and**
19 **that, you know, close monitoring or close oversight**
20 **should be taken to look for signs and symptoms of**
21 **liver disease, et cetera, without any particular**
22 **stipulation as to frequency of testing and frequency**
23 **of labs.**
24 Q Is it your position that a black box
25 warning has been placed on oral terbinafine tablets

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1 relating to liver injury?
2 **A I'd have to see. I don't know if it meets**
3 **the criteria of black box or if it was just, you**
4 **know, in the warning category so it might have --**
5 **I'd have to look at the PDR and see.**
6 Q I'll mark as Exhibit 40 a printout of the
7 product labeling for Novartis Lamisil tablets with a
8 revision date of January 2004. Take the time to
9 look at that and let me know when you're ready to
10 talk about it.
11 **A All right. Okay. I'm ready.**
12 Q Do you see any black box warning at all on
13 the product insert?
14 **A No. And I did correct myself, in all**
15 **fairness, so no.**
16 Q Do you believe that the recommendations
17 set forth in product inserts establish a standard of
18 care for physicians?
19 **A I think they outline some general**
20 **parameters, and as far as actually establishing a**
21 **standard of care, I think that is based on more than**
22 **just the PDR. You know, this is sort of a**
23 **negotiated document between the drug companies and**
24 **the FDA, and I don't think that they are complete**
25 **and comprehensive in terms of giving all the**

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1 **recommendations that doctors need to follow.**
2 Q Do you think that this particular product
3 insert for Lamisil with a revision date of 2004 is
4 deficient in any way?
5 MR. STEEL: I'm going object to the form
6 of that because I don't understand what you mean by
7 deficient. Are you relating it back to the standard
8 of care? Are you relating it to what to report to
9 the FDA? I just don't understand the question.
10 Deficient in any way is my problem.
11 BY MR. BAZINET:
12 Q Do you think that this product insert for
13 Novartis Lamisil tablets with the revision date of
14 January 2004 contains all of the information that a
15 doctor needs to know before prescribing Lamisil
16 tablets to a patient?
17 **A No, I don't think it does.**
18 Q What should be in here that's not in here?
19 **A Well, I think -- you know, if I was**
20 **writing this, I think they should put in a mention**
21 **of pruritus as a symptom, and I think that it would**
22 **be helpful to give explicit recommendations about**
23 **monitoring.**
24 Q What type of recommendations about
25 monitoring do you believe should be in the product

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1 insert?
2 **A Well, I think we'd have to go back into**
3 **the previous PDR, I think, mentioned liver enzymes**
4 **every four to six weeks or every six weeks. I think**
5 **that that was appropriate.**
6 Q What is your basis for that thinking?
7 **A The literature that I read, my knowledge**
8 **of the toxicity of the drug, the prior presence of**
9 **that information in the PDR. I mean, more likely**
10 **than not that language was pulled out of the PDR**
11 **with the enthusiastic urging of the pharmaceutical**
12 **manufacturer.**
13 Q One of the other criticisms of Dr. Young's
14 compliance with the standard of care that you had
15 was that he failed to document something in a
16 follow-up appointment. What was it that he failed
17 to document?
18 **A Well, he didn't -- is this what you are**
19 **reading back from the list from before?**
20 Q Yes.
21 **A So that he failed to document something on**
22 **a follow-up appointment?**
23 Q Maybe it's he failed to document a
24 follow-up appointment. Is that what you intended to
25 communicate to me?

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1 **A Well, yeah, I think that was one of my**
2 **criticisms is that if he had an intention, as he**
3 **stated, to see the patient back in six weeks and to**
4 **check liver enzymes in six weeks because he was**
5 **aware of the hepatotoxicity of this medication, then**
6 **it should have been charted, it should have been**
7 **scheduled, and it was neither.**
8 Q To your mind, does the standard of care
9 require a physican to write the scheduling of future
10 appointments in a patient's medical chart?
11 **A Well, in the context of an EMR it is**
12 **standard practice to do so.**
13 Q Do you use electronic medical records in
14 your office?
15 **A I do, yes.**
16 Q Who manufactures the EMR system you use?
17 **A EClinicalWorks.**
18 Q Do you have any knowledge of the
19 manufacturer of the electronic medical records
20 system that Dr. Young was using at the time that he
21 was treating Samuel Moody?
22 **A No.**
23 Q Do you have any familiarity with that
24 system at all?
25 **A Well, you know, I do know a fair amount**

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1 **about EMR-type systems and, you know, what they**
2 **generally consider themselves capable of doing, and**
3 **scheduling functions are certainly a central part of**
4 **good medical practice. So, you know, there is -- in**
5 **my system, you know, there's a screen you really**
6 **can't get past without determining whether you're**
7 **going to do a follow-up or you're not going to do a**
8 **follow-up. You need to enter something there.**
9 **He may not have had that, but still, in**
10 **terms of good charting, if you have a patient,**
11 **you're putting them on a potentially toxic drug,**
12 **you're going to want to monitor their response to**
13 **that drug and monitor them for side effects, and**
14 **then you just type in RTO in six weeks. You know,**
15 **if you use abbreviations, that's like 12 keystrokes.**
16 Q The next of your criticisms that you
17 listed off to me at the beginning of the deposition
18 was that you believe Dr. Young failed to document
19 his treatment. What did you mean by that?
20 **A Well, he failed to bring the patient back**
21 **to take a look at the toes to describe whether there**
22 **had been any impact of treatment and to perform the**
23 **monitoring, which he himself admitted he knew he**
24 **wanted to do and that he intended to do.**
25 Q The next criticism that you listed to me

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1 at the beginning of the deposition was that on
2 April 12th, 2005, Dr. Young failed to diagnose
3 cholestatic liver injury. And we can look at --
4 here's the stack of exhibits that we have
5 established in this case. Please take out any
6 records that you want to, maybe Dr. Young's medical
7 records, so we can discuss what symptoms you believe
8 showed cholestatic liver injury on April 12th, 2005.
9 **A You want to fire up the laptop and we'll**
10 **go into the CD.**
11 MR. STEEL: Here it is right here.
12 THE WITNESS: Good. Even better.
13 What was your question again?
14 BY MR. BAZINET:
15 Q What factual data are recorded in
16 Dr. Young's April 12th, 2005, note that lead you to
17 believe that Samuel Moody had symptoms of liver
18 injury on that date?
19 **A Primarily it was the pruritus and itching.**
20 Q Are itching and pruritus synonymous?
21 **A Yes. But I was just putting that in the**
22 **record for clarification to nonmedical personnel.**
23 Q Do you know what part of Samuel Moody's
24 body was itching?
25 **A Let's see. No.**

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1 Q Do you know how long he had had the
2 itching?
3 **A It doesn't say.**
4 Q Did you note in the comment section that
5 Mr. Moody reported red scratchy eyes?
6 **A Yes.**
7 Q Had you considered in your evaluation of
8 this case that the electronic entry for itching
9 slash pruritus related to the red scratchy eyes?
10 **A I've never in my life in 25 years of**
11 **practice ever heard a doctor refer to itching eyes**
12 **as pruritus, ever.**
13 Q Did you notice also that Mr. Moody
14 reported that his symptoms worsened when he cut the
15 grass?
16 **A I did.**
17 Q Did you consider in your analysis that the
18 itching was related in any way to the grass cutting?
19 **A I did.**
20 Q Did you rule out grass cutting as a
21 potential cause of the itching?
22 **A How would one rule that out?**
23 Q Other than the itching and pruritus, what
24 other factual matter is recorded in Dr. Young's
25 April 12th, 2005, note that informs your conclusion

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1 that Samuel Moody had some type of liver injury on
2 that date?
3 **A That is the main issue. Let me just go**
4 **back for a second here. I'm looking through the**
5 **record as we speak. I'm sorry, what was the**
6 **question again?**
7 MR. BAZINET: Can you read it back?
8 (The reporter read the pending question.)
9 THE WITNESS: All right. I'm trying to
10 get to a note here. I'm trying to get to the
11 January note.
12 Okay. To answer your question, that is
13 the primary symptom.
14 BY MR. BAZINET:
15 Q At this point in time, April 12th of 2005,
16 before Dr. Young prescribed and before Samuel Moody
17 took the Biaxin, if one assumes that Mr. Moody had
18 the liver injury like you've described, was it
19 reversible at this point in time?
20 **A Yes.**
21 Q What methods could have been undertaken to
22 reverse the liver injury on April 12th of 2005,
23 assuming the liver injury existed?
24 **A Well, it would have required avoidance of**
25 **all other hepatotoxic medications, careful**

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1 **monitoring and follow-up care, close supervision of**
2 **his liver enzymes over time. He might have been**
3 **treated with Urso, U-R-S-O, or other potentially**
4 **beneficial drugs to try and see if that would help**
5 **improve his cholestatic liver disease. That would**
6 **be primarily what you would do. Gastroenterology**
7 **referral.**
8 Q In your review of this case, have you
9 undertaken to look at Samuel Moody's pharmacy
10 records to see if he was taking any other
11 potentially hepatotoxic drugs other than the
12 Lamisil?
13 **A I did.**
14 Q Did you find in looking at those --
15 MR. STEEL: At what point in time? I'm
16 sorry.
17 MR. BAZINET: I'm about to get to that.
18 BY MR. BAZINET:
19 Q Did you find in looking at those pharmacy
20 records that Mr. Moody had taken any potentially
21 hepatotoxic drugs within the calendar year prior to
22 April the 12th of 2005?
23 **A Prior to April 12th?**
24 Q Yes.
25 **A Well, you know, he was using ketoconazole**

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1 **shampoo, but that was just being used on his head so**
2 **he wasn't using it systemically. He was using**
3 **Lotrel, which is a compound drug. Neither of those**
4 **would be, I think, significant contributing factors**
5 **to his progressive liver disease.**
6 Q The two drugs that you just mentioned, the
7 Lotrel and the ketoconazole shampoo, are they
8 associated with liver injury?
9 **A Well, I'm not sure whether ketoconazole**
10 **shampoo has been associated or not. You know,**
11 **generally if you're just using it topically on your**
12 **head, the absorption systemically is not all that**
13 **high. So, you know, he did have an underlying skin**
14 **condition so he might have gotten a little of the**
15 **drug into his system, but he should probably not**
16 **have had enough to induce significant toxicity.**
17 Q And going back in time in your analysis,
18 how did you undertake to determine that prior to
19 April 12th of 2005 Samuel Moody did not have some
20 pre-existing liver disease or liver injury?
21 **A Basically that is just on the basis of an**
22 **ultrasound, I think, that he had, and let's see if I**
23 **can go back to these records here. He had an**
24 **ultrasound, which was normal. Well, this is --**
25 **actually, scratch the ultrasound because that was**

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1 **subsequently. But he had some liver enzyme tests**
2 **done in December of '04, which showed an AST of 13,**
3 **ALT of 12, normal bilirubin, normal platelet count,**
4 **normal albumin. So he had completely normal liver**
5 **enzymes at that time, which was predating his**
6 **therapy.**
7 Q Are there any situations known to medicine
8 where one can have normal lab values, particularly
9 normal liver enzymes, and have some type of ongoing
10 liver disease or liver injury?
11 **A Well, yes, you can have people who've got**
12 **fatty liver, what we call NAFL, N-A-F-L, and they**
13 **can have normal liver enzymes and they can have**
14 **abnormal looking liver biopsies.**
15 Q What are the diagnostic criteria for the
16 fatty liver?
17 **A There's a certain percentage of fat when**
18 **you do a biopsy. It's like a biopsy-driven**
19 **diagnosis.**
20 Q Other than the fatty liver disease, can
21 one have apparently normal liver enzymes on a lab
22 test, but have a liver disease or liver injury?
23 **A Sure. It's possible.**
24 Q Other than looking at the lab results from
25 December of 2004, what other steps did you take to

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1 determine whether prior to April 12th of 2005 Samuel
2 Moody had any type of pre-existing liver disease or
3 liver injury?
4 **A There wasn't really that much clinical**
5 **information available. So outside of liver enzymes**
6 **and his medical records, there was really very**
7 **little additional information available.**
8 Q Did I understand you to say earlier that
9 part of your thinking in this case is that the
10 Lamisil initiated a cholestatic liver injury and
11 that the Biaxin somehow aggravated it?
12 **A That is correct.**
13 Q How did the Biaxin, to your mind,
14 aggravate the liver injury that was caused by the
15 Lamisil?
16 **A Well, the Lamisil caused a cholestatic**
17 **liver injury, which was manifested by the pruritus**
18 **symptoms that the patient had. Whether or not the**
19 **patient had other findings like jaundice really is**
20 **not known because we don't have a reliable physical**
21 **exam on which to rule in or out that possibility,**
22 **and if his eyes were red, it would make it hard to**
23 **see if his eyes were yellow. So, you know, we have**
24 **symptoms as of April indicative of cholestatic liver**
25 **injury.**

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1 **If the drug had been stopped and no other**
2 **hepatotoxic drugs had been added, it wouldn't have**
3 **been a situation where you were, you know, pouring**
4 **gas on a fire, and the Biaxin, which had its own**
5 **potential hepatotoxicity, was then added in for a**
6 **ten-day course, which caused the superimposed**
7 **cholestatic injury on a liver that already had**
8 **sustained a substantial cholestatic injury. So you**
9 **had a synergistic toxic effect of those two agents**
10 **that led to his liver failure.**
11 **Now, when I said before was it likely that**
12 **he would have recovered in April? It was more**
13 **likely than not that he would have recovered. It's**
14 **more likely than not he wouldn't have needed a**
15 **transplant if he got no other insults after**
16 **April 12th, but it's not 100 percent. I mean, there**
17 **still would have been a possibility that he would**
18 **have gone on to liver failure.**
19 Q On the basis of what available data -- and
20 I'm not restricting this question to what's
21 available in the April 12, 2005 note; I'm asking
22 about all the data that's available to you through
23 any medical records of Samuel Moody or otherwise.
24 What data indicates that to you that if the Biaxin
25 had not been given, then more likely than not Samuel

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1 Moody could have recovered from the cholestatic
2 liver injury caused by the Lamisil?
3 **A Well, he had -- you know, looking at the**
4 **literature that's available, he didn't have the**
5 **rapid onset within four weeks of really clinically**
6 **severe and obvious liver disease so his was more of**
7 **a gradual onset, and that would suggest that the**
8 **nature of the injury would have, you know, been less**
9 **fulminant -- well, that's a bad word. Let's not use**
10 **fulminant. It's likely that the injury would have**
11 **been less extensive than in some of those papers**
12 **that we discussed earlier. So he had a liver**
13 **injury, but it wouldn't have gone as far, and more**
14 **likely than not he would have turned a corner and**
15 **probably would have recovered without a liver**
16 **transplant.**
17 Q Is there a body of medical literature that
18 discusses or undertakes to discuss the nature or
19 extent of liver injury from which a liver can
20 recover to essentially normal function?
21 **A It's really variable. So you really can't**
22 **say, you know, across the board and break it out**
23 **into statistics. You know that some people do and**
24 **some people don't recover.**
25 Q Other than the gradual onset of the

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1 symptoms that you just described to me in connection
2 with the answer to the last question, are there any
3 other factors or data that to your mind indicates
4 that if Samuel Moody had not been prescribed and
5 taken the Biaxin that he would have recovered?
6 **A Repeat the question.**
7 Q Other than the gradual onset of symptoms
8 that you just described to me, are there any other
9 factors or data that indicates to you that if Samuel
10 Moody had not taken the Biaxin he would have
11 recovered from the cholestatic liver injury caused
12 by the Lamisil?
13 **A That's the main indicator.**
14 Q Are there any other indicators whatsoever,
15 even if they're minute?
16 **A I think that we don't really have enough**
17 **information about what his clinical status really**
18 **was because labs were not obtained or drawn in --**
19 **you know, in late February there were no labs drawn**
20 **in six weeks, and there were no labs drawn**
21 **April 12th. So it's really hard to know just how**
22 **bad his numbers were at either of those points in**
23 **time because we don't have either of them.**
24 Q In part of your answer to one of my
25 questions a few minutes ago you described, I

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1 believe, that the Lamisil and the Biaxin had a
2 synergistic toxic effect on the liver. What was the
3 process of that synergistic toxic effect?
4 **A Well, they're both drugs that have the**
5 **capacity to cause cholestatic liver injury so the**
6 **Lamisil in and off itself was causing significant**
7 **cholestasis and significant bile duct -- hold on.**
8 Q Are you waiting on me?
9 **A Yes.**
10 Q No. You go ahead. I'm listening.
11 **A Is that right?**
12 Q Yes.
13 **A Okay. Well, so the Lamisil had, you know,**
14 **initiated a significant bile duct injury, more**
15 **likely than not, within the first few weeks. The**
16 **bile duct injury progressed over time, and as it**
17 **progressed you had a patient who already had severe**
18 **cholestasis by the time April 12th rolled around.**
19 **And Dr. Young said that as of April 12th he wouldn't**
20 **have given somebody with an impaired liver Biaxin.**
21 **He just wouldn't have done that because he knew**
22 **Biaxin has hepatotoxicity, and he would not give a**
23 **hepatotoxic drug like Biaxin to a patient with an**
24 **impaired liver. And I agree, he's correct about**
25 **that, and that's the appropriate decision and the**

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1 **appropriate statement that he made.**
2 **Then you take somebody who's got a**
3 **cholestatic problem and you give them a drug that's**
4 **hepatotoxic and toxic to the biliary system, and**
5 **it's largely excreted through that same biliary**
6 **system, and so these toxic metabolites are then**
7 **slowly moving through this damaged liver and damaged**
8 **bile duct epithelium, and because of that fact they**
9 **are able to cause more toxic injury in the very same**
10 **bile ducts that already are reeling from the effects**
11 **of the Lamisil.**
12 Q And the particular biological mechanism of
13 this injury is what you bracketed in red in the two
14 articles that we discussed a couple hours ago?
15 **A Well, that's, you know, looking at**
16 **biochemical breakdown of what the mechanism is in**
17 **terms of toxic metabolites being produced, being**
18 **exported by MRP2 into the bile ducts and then**
19 **causing damage.**
20 Q When you used the word synergistic in the
21 term synergistic toxic effect, are you intending to
22 communicate and describe what is sometimes known as
23 a synergistic effect between two concomitantly
24 administered medications?
25 **A Well, these are sequentially administered,**

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1 **aren't they?**
2 Q Right. But what I'm trying to get at is,
3 how are you using the term synergistic in this
4 particular phrase?
5 **A I am saying that there's convergence of**
6 **two injurious agents working on the same pathway one**
7 **after the other. The first one causes severe**
8 **damage; the second one provides the death blow.**
9 Q And when you say the same pathway, are you
10 describing the P450 system in the liver?
11 **A Not at all.**
12 Q What are you describing?
13 **A I'm describing an excretion pathway.**
14 Q Is there a medical term that is generally
15 used to refer to that particular excretion pathway?
16 **A Well, you know, to use an analogy in terms**
17 **of kidney disease where it's, you know, easier to**
18 **quantify because kidney function is easier to**
19 **measure in terms of creatinine clearances and things**
20 **like that, if you have somebody who's diabetic and**
21 **has renal impairment and you give them an**
22 **hepatotoxic drug like some of the antibiotics that**
23 **are excreted through the kidney, because their**
24 **kidneys are damaged, they don't excrete as**
25 **efficiently. The drugs are exposed to the kidney**

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1 **microtubules for a longer period of time so that**
2 **they have longer time to work their damage, and**
3 **those patients are much more susceptible to go on to**
4 **kidney failure as a result of that exposure. It's**
5 **the same process. It's just common sense.**
6 Q Is it your opinion that once Samuel Moody
7 took the first dose of Biaxin that his fate was
8 essentially sealed and that his liver injury was not
9 going to be able to heal?
10 **A You know, I think whether it's the first**
11 **dose or the fourth dose or the tenth dose, we can't**
12 **really parse it that fine. I think it was the**
13 **Biaxin on top of the pre-existing liver injury from**
14 **the Lamisil that was the one-two punch.**
15 Q In your analysis of this case, have you
16 assumed that Samuel Moody took the entirety of both
17 Biaxin prescriptions that were given to him?
18 **A No.**
19 Q In your consideration of this case, what
20 have you assumed about Samuel Moody's taking of the
21 Biaxin?
22 **A I'm assuming he took some of it, and I**
23 **can't quantify how much of it.**
24 Q If you assume that Samuel Moody suffered
25 liver injury secondary to Lamisil, like you've

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1 opined, is there some amount of Biaxin that you
2 believe that Samuel Moody could have taken without
3 suffering irreversible liver injury?
4 **A That is not really a scientifically**
5 **knowable quantification.**
6 Q From your review of the records, after
7 Mr. Moody went to Crawford Long Hospital for the
8 first time, did it appear to you that he got
9 somewhat better before his discharge?
10 **A Well, you're talking about -- so that was**
11 **the first time he was in, which was back, I guess,**
12 **in June?**
13 Q On or about June 14th, 2005.
14 **A Right. You know, I think the problem with**
15 **these patients that you see with cholestatic liver**
16 **injury is that they're jaundiced, and they look**
17 **awful and they feel bad, and their numbers, you**
18 **know, fluctuate a little bit. So the bilirubin may**
19 **go up a little bit and then it comes back down**
20 **again, and it's possible for doctors to think that**
21 **someone's getting better when they're really not.**
22 **So I'm not sure if I answered your question, but**
23 **that's my observation.**
24 Q From your review of the medical records
25 yourself, and taking into account the lab results

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1 and those types of things that were done at the
2 hospital, did it appear to you that Samuel Moody's
3 liver function was improving in mid-June of 2005
4 during his stay at Crawford Long Hospital?
5 **A Well, it was stabilizing a bit, and that**
6 **would make sense, right, because at that point**
7 **you've removed all the hepatotoxins. The Lamisil is**
8 **long gone. The Biaxin finally is gone. So the**
9 **liver is valiantly trying to regenerate and recover,**
10 **but its regenerative capacity is finite and**
11 **unfortunately it wasn't sufficient in this case.**
12 Q I'd like you to assume that Samuel Moody
13 was admitted to Crawford Long Hospital on June 14th,
14 2005, spent a couple days in the hospital, and then
15 was discharged on June 16th of 2005, after having a
16 liver biopsy but before the liver biopsy results
17 were returned. Are you in any way critical of the
18 fact that he was discharged before the liver biopsy
19 was back?
20 **A Not really. That was an understandable**
21 **course of action.**
22 Q Are you aware that after his discharge
23 from Crawford Long Hospital on June 16th of 2005,
24 Samuel Moody returned to work at the railroad for a
25 period of time?

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1 **A Yes.**
2 Q Do you think that his return to work at
3 the railroad in any way aggravated his liver
4 condition?
5 **A No.**
6 Q Do you think that by the time he was
7 discharged from Crawford Long on June 16th of 2005,
8 that it was essentially predetermined that he was
9 going to have liver failure?
10 **A As of June 16th, 2005?**
11 Q Yes.
12 **A I think that, you know, in the eyes of the**
13 **clinicians, you know, they're looking at it going**
14 **forward, and, you know, in a population-based sense**
15 **most people with this kind of condition get better;**
16 **some people don't get better. In the case of**
17 **Mr. Moody, he was destined, more likely than not, to**
18 **go to liver failure; but they didn't know that**
19 **because, I mean, you know, if they had 20 people**
20 **with liver failure who looked just like him, had the**
21 **same numbers just like him, most of those people**
22 **demographically would get better. He would not.**
23 Q I want to ask you some questions about
24 your review of this case. You have some hard copies
25 of Dr. Young's records with you and also have a CD

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1 with some records that we haven't looked at. Is the
2 hard copy records that you have essentially a
3 printout of the complete set of the records that are
4 on the CD?
5 **A I doubt that they're the complete set so**
6 **they're probably like the most, you know, pertinent**
7 **excerpts.**
8 Q In your review of this case, did you
9 review all of the records that you have printed out
10 from Dr. Young's office?
11 **A In my review did I review all of these?**
12 Q No. The records that you brought with you
13 that have been printed out from Dr. Young's office.
14 **A Did I review all the records that I**
15 **printed out? Is that what you're saying?**
16 Q All of Dr. Young's records that you have
17 printed out and brought with you, did you review all
18 of those?
19 **A Yes.**
20 Q If there are indeed records that are on
21 the CD that were not printed out in hard copy, did
22 you review those as well?
23 **A I did.**
24 Q Did you review records from Crawford Long
25 Hospital?

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1 **A Yes.**
2 Q Did that relate both to a June and
3 July 2005 admission?
4 **A I believe so.**
5 Q Did you review the records you brought
6 with you from Piedmont Hospital?
7 **A Yes.**
8 Q Have you reviewed any records from an
9 institution in Florida called the Florida Institute
10 for Neurologic Rehabilitation?
11 **A I don't think I did.**
12 Q Have you reviewed the deposition of
13 plaintiff Eunice White?
14 **A I did.**
15 Q Have you read the whole thing or selected
16 portions?
17 **A I speed-read through a lot of it, and I**
18 **read slowly through some of it.**
19 Q Which portions of Eunice White's
20 deposition did you read through slowly?
21 **A Her descriptions of what his symptoms were**
22 **like at home between December and June.**
23 Q Any other portions of the deposition that
24 you read through slowly?
25 **A I read through, you know, the course of**

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1 **his hospitalizations, his status after his liver**
2 **transplant and -- you know, that's what I remember**
3 **of it.**
4 Q Have you read both volumes of Dr. Young's
5 deposition?
6 **A Yes.**
7 Q Did you read both of those volumes in
8 their entirety?
9 **A I did.**
10 Q Did you speed-read any portions of
11 Dr. Young's deposition?
12 **A Well, ultimately I went back and read it**
13 **all in detail.**
14 Q Have you read the deposition of Dr. Alan
15 Treadwell of San Francisco?
16 **A I did.**
17 Q Did you speed-read any portions of that?
18 **A Probably some of it, yeah.**
19 Q What portions did you read more slowly?
20 **A His opinions regarding monitoring for the**
21 **liver enzymes, his opinions regarding the workup of**
22 **onychomycosis, his history of Lamisil use and the**
23 **role of Lamisil. Those are the main things I**
24 **focused on.**
25 Q Are there any portions of Dr. Treadwell's

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1 testimony with which you do not agree?
2 **A I think that, you know, in terms of the**
3 **diagnosis of the onychomycosis, you need to have the**
4 **KOH stain or you need to have totally bulletproof,**
5 **you know, clinical description and documentation in**
6 **the chart that you know this is onychomycosis, which**
7 **is what I told you earlier which I don't think he**
8 **said.**
9 Q Do you know personally any of Samuel
10 Moody's treating physicians that are reflected in
11 his various medical records that you've reviewed?
12 **A Do I know any of them personally? No.**
13 Q Do you know of any of them?
14 **A No.**
15 Q Have you interviewed any persons
16 associated with this case?
17 **A No.**
18 Q Have you reviewed any type of radiological
19 films or other radiological studies?
20 **A No.**
21 Q Have you reviewed any pathology slides in
22 connection with this case?
23 **A No.**
24 Q The articles that you brought with you and
25 that we've marked as exhibits in this case, do they

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1 represent the sum total of the medical research that
2 you have done for the specific purpose of forming
3 your opinions in this case?
4 **A They do.**
5 Q Have you reviewed any information, records
6 or documents that you haven't brought with you
7 today?
8 **A No.**
9 Q Have you spoken with any of your
10 colleagues about this case?
11 **A No.**
12 Q Do you think that you need to conduct any
13 further research for the purpose of finalizing your
14 opinions in this case?
15 **A No.**
16 Q Do you consider the opinions that you have
17 given me in the deposition to be fully formed?
18 **A Yes.**
19 Q At the beginning of the deposition we
20 tried to catalog your opinions concerning
21 Dr. Young's compliance with the standard of care,
22 and then I asked you some follow-up questions about
23 those not long ago. At any time during this
24 deposition, have you thought of additional
25 criticisms that you have not told me about in some

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way?
**A I think we covered it in terms of our questions and answers in the past, but, again, Dr. Young stated an intention to do a six-week follow-up which would include performance of liver enzyme testing in this patient, and that that should have been done, was not done. But I guess we've covered that.**
**But I guess, to add to that, had that been done, more likely than not there would have been mild enzyme elevations that would have led to a more prompt discontinuation of the terbinafine.**
Q How is it that you can say that if intermittent testing had been done earlier the enzyme would have been elevated?
**A Just on the basis of the literature that I've seen, the enzyme elevations appear to come within the first month. And, like I said, his was a milder onset, but we know that in various literature four to ten percent of people will have mild liver enzyme abnormalities, and that is a harbinger of bad things to come. So it's likely he would have had that.**
Q In your review of this case, have you considered the possibility that Samuel Moody's liver

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injury could have been caused by some type of chemical to which he was exposed at work?
**A You know, I think there's no evidence -- that's kind of speculative so I didn't go down that road, but nor do I have a history of his -- a detailed history of his chemical exposures.**
Q What do you know about what Samuel Moody did for work?
**A I know he worked for the railroads, but I don't know the nature of the work he did there.**
Q Have you been provided with any of his records from the railroad that detailed the particular job descriptions that he had or anything like that?
**A No.**
Q In your research that you conducted for this case, did you search for any medical literature that concerned the prescription of terbinafine and chlarithromycin either concomitantly or in close succession to one another?
**A I didn't come across any literature in that regard.**
Q When one is undertaking to evaluate liver injury like the liver injury at issue in this case, does the patient's history of alcohol use figure

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into the analysis at all?
**A Yes.**
Q How does it figure in?
**A Alcohol is an hepatotoxin.**
Q What is your understanding of Samuel Moody's history of alcohol use?
**A That it was not excessive.**
Q When you say not excessive, what type of frequency and volume are you expressing?
**A A few drinks a week.**
Q When you say a few drinks a week, what type of number are we talking about?
**A Six or seven.**
Q When you're evaluating liver injury in a case like this, does the patient's smoking history have any bearing on the analysis?
**A Not much.**
Q Can it have some?
**A In a case like this not really at all.**
Q Why not?
**A Because smoking doesn't really play much of a role in terms of liver disease.**
Q In considering a case like this of liver injury, does the patient's weight or body mass index figure into the analysis at all?

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**A It does.**
Q How does that figure in?
**A You know, obesity is a risk factor for NAFL, N-A-F-L.**
Q How would you classify Samuel Moody by weight or body mass index?
MR. STEEL: At what point in time?
MR. BAZINET: In April of 2005.
THE WITNESS: Markedly obese.
BY MR. BAZINET:
Q Is there a body of medical literature that connects or undertakes to connect a patient's obesity to the fatty liver disease you discussed earlier?
**A Yes.**
Q What are the conclusions to be drawn from that literature?
**A Well, you know, people who are markedly obese are more prone to develop NAFL, and that some have steatosis and some have what's called NASH, N-A-S-H. On the basis of his enzymes, it looked like he had steatosis, which in itself doesn't carry a bad prognosis and does not infer, like, progression to cirrhosis.**
Q When you're evaluating a case of liver

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1 injury like this, does the patient's use of caffeine
2 beverages figure into the analysis at all?
3 **A You know, only a little bit in terms of**
4 **altering some metabolism, perhaps, of some other**
5 **drugs.**
6 Q Have you undertaken to evaluate Samuel
7 Moody's caffeine use and how it may have impacted on
8 his liver condition?
9 **A No.**
10 Q When one looks into a case of liver injury
11 like this, does the patient's level of physical
12 activity figure into the analysis at all?
13 **A It doesn't really figure in to an analysis**
14 **about a case like this, no.**
15 Q Why not?
16 **A Well, it may have impact on somebody's**
17 **general health, but it won't really have impact on**
18 **whether they develop liver failure from hepatotoxic**
19 **drugs or not.**
20 Q When one is considering a case of liver
21 injury like at issue in this case, does the
22 patient's family history matter?
23 **A Yes.**
24 Q How does it matter?
25 **A Well, if there's a liver history of**

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1 **certain types of liver diseases, then you'd be**
2 **concerned that maybe this patient has that**
3 **underlying condition.**
4 Q Other than a history of liver disease, is
5 there any other history of disease that could bear
6 on a case of liver injury like this?
7 **A Not so much really, no.**
8 Q To your review of the records, did you
9 find any history of liver disease in Samuel Moody's
10 family?
11 **A Not that I recall.**
12 Q So I can understand this when I go back
13 and read it later, is it your opinion that there was
14 not what is commonly thought of as a drug drug
15 interaction between the terbinafine and the
16 chlarithromycin?
17 **A Well, I mean, drug drug interaction has**
18 **kind of like connotes a very simple concept, right?**
19 **You got two drugs and they interact. So in that**
20 **common sense definition, yes, there was a drug drug**
21 **interaction, but you're talking about -- if you want**
22 **to narrow it down to a precise type of drug drug**
23 **interactions that are sort of the interaction**
24 **du jour, then, right, we can talk about that one.**
25 Q Do you think that there was any

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1 competition at any time between the terbinafine and
2 the chlarithromycin for a protein-binding site?
3 **A No.**
4 Q Do you think that the chlarithromycin in
5 any way inhibited any enzymes in the P450 system of
6 the liver that caused the level of free terbinafine
7 to be increased?
8 **A That would require going backwards in**
9 **time. So no.**
10 Q What about vice versa, do you think there
11 was any interaction at all between the terbinafine
12 and the chlarithromycin that in any way increased
13 level of free chlarithromycin?
14 **A I think that, you know, a toxic injury**
15 **is -- toxicity is determined by dose and duration,**
16 **right? So let's talk in terms of radioactivity in**
17 **Fukushima. You know, if you happen to be in**
18 **Fukushima and you're there for five minutes, you**
19 **have one exposure. If you're there for five days**
20 **five miles from the site, you got a lot more**
21 **exposure.**
22 **The effect that the Lamisil had is by**
23 **impairing and damaging the excretory mechanism of**
24 **the biliary system in this patient between January**
25 **and April, and leaving it damaged. That allowed the**

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1 **toxic byproducts of erythromycin to just sit and**
2 **marinate within the patient's liver -- hepatocytes**
3 **and biliary system for a much longer time with a**
4 **much more prolonged exposure allowing for a lot more**
5 **damage to arise.**
6 Q Have you ever seen any of Novartis'
7 commercials for oral Lamisil?
8 **A Yes.**
9 Q Have you ever had any patients in your
10 practice request a prescription for oral terbinafine
11 based on the commercial?
12 **A No.**
13 MR. BAZINET: Let's take a five-minute
14 break because I think I'm done or nearly done.
15 (A brief recess was taken from 2:25 to
16 2:31 p.m.)
17 BY MR. BAZINET:
18 Q A few follow-up questions.
19 **A Okay.**
20 Q I'm looking at the pharmacy records that
21 we've marked as Exhibit 15, and there are several
22 prescriptions for Cialis that are in and around the
23 time that we've been talking about, February of 2005
24 to June of 2005. Do you think that the Cialis had
25 any impact at all on Samuel Moody's liver function?

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1 **A I don't think it had a substantial impact**
2 **on his liver function.**
3 Q Do you think it had any impact, even if
4 the impact was not substantial?
5 **A I don't think it had any clinically**
6 **significant impact, but it might have had some**
7 **biochemical impact of no consequence.**
8 Q I show you what we've marked as Exhibit
9 28. I want to understand the purpose of some of
10 these notes. In the note in the upper left-hand
11 corner does that say 2002 hemoptysis?
12 **A Yeah, hemoptysis, H-E-M-O-P.**
13 Q What's written after that?
14 **A Got pulmonary workup.**
15 Q And then this other PMH?
16 **A Past medical history. Should I read that**
17 **for you?**
18 Q Yes.
19 **A "Seborrheic dermatitis, decreased libido,**
20 **sleep apnea, hypertension, high cholesterol" --**
21 **should I keep going?**
22 Q No. And then what you've recorded from
23 then on is a time line of sorts of certain events?
24 **A Right.**
25 Q We have marked as one of the exhibits in

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1 this case the affidavit that you signed in
2 connection with the complaints that have been filed
3 in this lawsuit as Exhibit Number 9. The opinions
4 that you have expressed to me throughout the
5 deposition today, are they different in any way from
6 the opinions you've expressed in that affidavit?
7 **A No. They're basically the same.**
8 Q The medical literature that you brought
9 today to the deposition, was all of that the result
10 of your own research?
11 **A Yes.**
12 Q Before you signed the affidavit that
13 you're holding in your hand, how much time had you
14 spent reviewing the case?
15 **A That was four years ago. I really can't**
16 **break it down. I really can't.**
17 Q When one is undertaking to evaluate a case
18 of potential liver injury like at issue in this
19 case, does whether the patient usually took their
20 medications with food figure into the analysis?
21 **A It depends. You know, drugs have variable**
22 **bio-availability depending on whether they're given**
23 **with meals or apart from meals so it will depend**
24 **drug to drug.**
25 Q What about with terbinafine?

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1 **A I don't recall.**
2 Q What about with chlarithromycin?
3 **A I don't recall.**
4 Q When one is undertaking to evaluate a case
5 of potential drug-induced liver injury like this
6 case, does the time of day at which the patient has
7 taken the medication make any difference?
8 **A It can make little differences, yes.**
9 Q What differences can be occasioned by the
10 time of day at which the patient takes the
11 medication?
12 **A It's more about whether they're taking it**
13 **with other concurrent medications and, you know,**
14 **whether they're taking it at the right interval.**
15 **So, you know, if you have a drug that needs to be**
16 **taken every eight hours, do you take it every eight**
17 **hours or is there four hours and then 12 hours, that**
18 **kind of thing. So the time of day, I guess, really**
19 **is not as important as whether you follow the dosing**
20 **interval directions correctly.**
21 Q In performing the research that you did
22 for this case, did you use Ovid?
23 **A No.**
24 Q Did you use MD Consult?
25 **A I don't think so.**

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1 Q Did you use Up-To-Date?
2 **A No.**
3 Q Did you use any type of electronic or
4 online resource?
5 **A I think I just searched PubMed with**
6 **particular searches in mind, and then I went through**
7 **my library of literature on hepatotoxicity.**
8 Q I know that you've given me the names of
9 some textbooks earlier, Yamada being one and --
10 **A Sleisenger.**
11 Q Sleisenger being the other one. Besides
12 those two textbooks, what else is in your library in
13 literature concerning hepatotoxicity?
14 **A Well, you know, I have a lot of copies of**
15 **seminars on liver disease. I have -- there's**
16 **something, I think, called Liver Clinics. I'm not**
17 **sure if that's the correct name for it. I've got**
18 **some other books about liver -- a book on liver**
19 **immunology by guy named Veirling, V-E-I-R-L-I-N-G.**
20 **There's a couple of other books. There's a book on**
21 **cholestasis. There was one of those Liver Clinics**
22 **books. That's about it.**
23 MR. BAZINET: Do you want to read and sign
24 your deposition?
25 THE WITNESS: Probably be a good idea.

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1 MR. BAZINET: Any notary is fine. That's
2 all I have.
3 (Signature having not been waived, the
4 deposition of NEAL L. JULIE, M.D. was concluded at
5 2:40 p.m.)
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1 CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC
2
3 I, Stephany L. Jerome, the officer before
4 whom the foregoing proceedings were taken, do hereby
5 certify that the foregoing transcript is a true and
6 correct record of the proceedings; that said
7 proceedings were taken by me stenographically and
8 thereafter reduced to typewriting under my
9 supervision; and that I am neither counsel for,
10 related to, nor employed by any of the parties to
11 this case and have no interest, financial or
12 otherwise, in its outcome.
13
14 IN WITNESS WHEREOF, I have hereunto set
15 my hand and affixed my notarial seal this 7th day of
16 August, 2011.
17
18 My commission expires August 3, 2015.
19
20
21
22
23 _____
24 NOTARY PUBLIC IN AND FOR
25 THE STATE OF MARYLAND

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