UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA

THE UNITED STATES OF AMERICA, ET AL.	*	
versus	*	Case No. 9:14-cv-230
BLUEWAVE HEALTHCARE CONSULTANTS, INC., ET AL.	*	January 26, 2018

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REPORTER'S OFFICIAL TRANSCRIPT OF THE JURY TRIAL - DAY NINE
HELD BEFORE THE HONORABLE RICHARD M. GERGEL
UNITED STATES DISTRICT JUDGE
January 26, 2018

Appearances:

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Appearances:

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Proceedings recorded by mechanical stenography using computer-aided transcription software.

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9:11AM (Call to order of the Court.)

9:11AM **THE COURT:** Good morning. Okay. Any matters we need to -- please be seated. I'm sorry.

9:11AM Any matters we need to address before we bring in the jury?

9:11AM **MR. LEVENTIS:** I don't think so, Your Honor.

9:11AM **MR. KASS:** I'm sorry, Your Honor, very briefly. I don't think this will be an issue today, but I understand we have two treating physicians coming in, and just a reminder that we did not receive any patient files for them. So I'm hopeful that won't be an issue, but I thought --

9:11AM **THE COURT:** I doubt that's going to be an issue.

9:12AM **MR. COOKE:** They're very well aware.

9:12AM **THE COURT:** Very good.

9:12AM Defense, anything we need to address?

9:12AM **MR. COOKE:** Nothing, thank you.

9:12AM **THE COURT:** And I believe Mr. -- what was the gentleman's name?

9:12AM **MR. LEVENTIS:** Mr. Carnaggio.

9:12AM **THE COURT:** Let's bring him in. Let's go ahead and bring him in, get him back on the stand, and then I'll bring the jury in.

9:12AM (Pause.)

9:12AM **THE DEPUTY CLERK:** He'll be right in.

9:12AM **THE COURT:** And I believe we had finished the

direct --

MR. COOKE: Yes.

THE COURT: -- and then the cross was about to commence, Mr. Leventis; is that right?

MR. LEVENTIS: Yes, Your Honor.

THE COURT: Let's bring in the jury.

(Whereupon the jury entered the courtroom.)

THE COURT: Please be seated.

Mr. Leventis, cross-examination?

MR. LEVENTIS: Thank you, Your Honor.

THOMAS ANTHONY CARNAGGIO,

a witness called on behalf of the defendants, being first duly sworn, was examined and testified as follows:

CROSS-EXAMINATION

BY MR. LEVENTIS:

Q. Good morning, Mr. Carnaggio. I'm James Leventis. I represent the United States. We've met before, haven't we?

A. Yes, we have. Yes.

Q. So I'd like to first go back to the beginning of your testimony yesterday. It sounds like you and Cal Dent have known each other for long time; is that right?

A. Correct.

Q. I think you said since about 2007. So 10 years, roughly?

A. Correct. Yes.

Q. Then you guys worked together at Berkeley. You worked

9:15AM 1 together at Berkeley HeartLab.
9:15AM 2 **A.** We did, yes.
9:15AM 3 **Q.** He convinced you to come over to BlueWave; is that right?
9:15AM 4 You worked with him at BlueWave?
9:15AM 5 **A.** That's correct.
9:15AM 6 **Q.** In fact, you guys then went into business together with a
9:15AM 7 business called Hisway?
9:15AM 8 **A.** Correct. Yes.
9:15AM 9 **Q.** You're 50-50 owners in Hisway?
9:15AM 10 **A.** Correct.
9:15AM 11 **Q.** So any money coming in, you guys split up 50-50; right?
9:16AM 12 **A.** Yes.
9:16AM 13 **Q.** And you have a lot of clients together; is that right?
9:16AM 14 **A.** Correct. Yes.
9:16AM 15 **Q.** Heritage Medical is one that came up yesterday?
9:16AM 16 **A.** Yes.
9:16AM 17 **Q.** I believe there's a Dr. Alam at Keowee. You guys share
9:16AM 18 that client as well?
9:16AM 19 **A.** Say that again.
9:16AM 20 **Q.** Dr. Alam, a Keowee partner?
9:16AM 21 **A.** Yes, yes. Uh-huh.
9:16AM 22 **Q.** That's one of the top HDL clients; right?
9:16AM 23 **A.** I think he was, yes.
9:16AM 24 **Q.** So you guys spent a lot of time together and you've
9:16AM 25 learned a lot from him, haven't you?

9:16AM **A.** I have, yes.
9:16AM **Q.** And you testified yesterday about a pro forma that you emailed to a Dr. Nancy Netter in 2012 on Cal's behalf. Do you remember that?
9:16AM **A.** I do, yes.
9:16AM **Q.** And that pro forma projected the annual total P&H dollars the practice could make; right?
9:16AM **A.** Correct, yes.
9:16AM **Q.** Let's pull up Exhibit 1004.
9:16AM Peter, if you wouldn't mind blowing up the top section there for me. So this is from you to Nancy Netter. You copied Cal Dent. It's in April of 2012, and the subject is HDL Singulex pro forma for Dr. Netter and Dr. Phillips. Did I read that correctly?
9:17AM **A.** Yes, you did.
9:17AM **Q.** And then down in the body of the email, it says, "Cal asked me to forward the attached pro forma"; is that right?
9:17AM **A.** Correct.
9:17AM **Q.** So let's turn to the pro forma.
9:17AM Thanks, Peter. If you would maybe blow up the top part here so we can read it better.
9:17AM So in this chart you guys made, it says "projected annual total P&H dollars based on the last eight weeks"; right?
9:17AM **A.** Yes, that's what it says.
9:17AM **Q.** And looking down here at the bottom, you're showing this

practice at -- currently they make $27,746. And you were -- under your proposal, they would then make $33,344; is that right?

A. Yes, that's what it says.

Q. Okay. And I think you testified yesterday that you had never heard someone call the fees illegal; is that right?

A. Call which fees?

Q. The process and handling fees.

A. No. I hadn't heard them at that time, no.

Q. Do you recall an attorney for a doctor's office telling you that the process and handling fees were illegal?

A. I don't recall that.

Q. Okay. Let's look at Exhibit 7011.

MR. LEVENTIS: It's not in evidence yet, Your Honor, so we can just show it to the witness.

May I approach, Your Honor?

THE COURT: You may.

BY MR. LEVENTIS:

Q. Take a look at that for me, Mr. Carnaggio.

(Pause.)

Q. Mr. Carnaggio, does this appear to be an email from you to Cal Dent that starts up there towards the top?

A. It does.

Can you give me just one more second just to finish reading it.

9:20AM **Q.** Sure.
9:20AM **A.** I just want to make sure I understand what the email is speaking to.
9:20AM **Q.** Sure.
9:20AM (Pause.)
9:21AM **A.** Okay.
9:21AM **THE COURT:** Mr. Leventis, reask your question.
9:21AM **BY MR. LEVENTIS:**
9:21AM **Q.** Mr. Carnaggio, this appears to be an email from you to Cal Dent; is that correct?
9:21AM **A.** Correct.
9:21AM **MR. LEVENTIS:** Your Honor, I'd like to move Exhibit 7011 into evidence.
9:21AM **THE COURT:** Is there an objection?
9:21AM **MR. COOKE:** No objection.
9:21AM **MR. ASHMORE:** No objection.
9:21AM **THE COURT:** Plaintiffs' Exhibit 7011 admitted without objection.
9:22AM **MR. LEVENTIS:** Thank you, Your Honor.
9:22AM **BY MR. LEVENTIS:**
9:22AM **Q.** Mr. Carnaggio, let's look here. So the part that says, "From Tony Carnaggio" -- the date is January 8th, 2013 -- "to Cal Dent." The subject is "Question." It says, "Cal, please see the below -- please see below."
9:22AM Do you see that?

9:22AM **A.** I do.
9:22AM **Q.** Then we'll go down to the next part of the email. This is from a MaryNell Waldrup to you, Tony Carnaggio. It says "Tony, please read the below message from MDVIP."
9:22AM What is MDVIP?
9:22AM **A.** MDVIP is a -- is a -- it's concierge medicine. It's a company that has concierge medicine physicians.
9:22AM **Q.** Okay.
9:22AM **A.** That, you know, the patients pay a monthly fee.
9:22AM **Q.** It says, "And please share your thoughts with me and help me comfortably understand why MDVIP's attorneys would come to this conclusion. Thanks, MaryNell."
9:23AM Do you see that?
9:23AM **A.** I do, yes.
9:23AM **Q.** Let's turn to the next page and see what it says. This is from John Lee, sent Tuesday, January 8th, 2013, to MaryNell Waldrup.
9:23AM "I have to warn you that our lawyers" -- I believe that should be "have" or "has" -- "concluded that the $20 draw fee is illegal. I thought that you should know."
9:23AM Do you see that?
9:23AM **A.** I do.
9:23AM **Q.** Let's turn back to the front page. It looks like at the top here, the very top, Cal Dent then forwards this on to Tonya Mallory, doesn't he?

9:23AM **A.** Yeah, that's what it says. Uh-huh.
9:24AM **Q.** Mr. Carnaggio, did you lose any physician clients because you stopped offering process and handling fees?
9:24AM **A.** Did I lose -- it's possible.
9:24AM **Q.** And do you recall that BlueWave would send you emails about accounts that were dropping off?
9:24AM **A.** Typically, yeah. Sure.
9:24AM **Q.** And do you recall that BlueWave would ask you to explain why these accounts were dropping off, why they were not ordering anymore? Do you remember that?
9:24AM **A.** Sure.
9:24AM **Q.** Do you remember what you said?
9:24AM **A.** Well, every -- every case was different. Could be that the doctor was out of the country for, you know, a month. It could be the fact that they didn't have a phlebotomist in their office. There was always -- you know, every circumstance was a little different.
9:24AM **Q.** Weren't there doctors that told you, "I quit ordering because you stopped giving me process and handling fees"?
9:25AM **A.** It's possible.
9:25AM **Q.** Okay. In fact, it happened, didn't it?
9:25AM **A.** It's possible. I can't recall a specific example.
9:25AM **Q.** Okay. Let's look at Exhibit 7012.
9:25AM **MR. LEVENTIS:** Your Honor, may I approach the witness?

9:25AM **THE COURT:** You may.
9:25AM **BY MR. LEVENTIS:**
9:25AM **Q.** I'll have you take a look at this, Mr. Carnaggio.
9:25AM (Pause.)
9:25AM **A.** Okay.
9:25AM **Q.** So, Mr. Carnaggio, this appears to be an email exchange between you, Cal Dent, and Tiffany Nelson; is that correct?
9:26AM **A.** Yes, it does.
9:26AM **MR. LEVENTIS:** Your Honor, we would move Exhibit 7012 into evidence.
9:26AM **THE COURT:** Is there an objection?
9:26AM **MR. COOKE:** No objection.
9:26AM **MR. ASHMORE:** No, sir.
9:26AM **THE COURT:** Plaintiffs' 7012 admitted without objection.
9:26AM **BY MR. LEVENTIS:**
9:26AM **Q.** Let's start down at the bottom. The email from Tiffany Nelson, she's a BlueWave employee, isn't she? She has a BlueWavehealth.com email address?
9:26AM **A.** Yes, it appears to be.
9:26AM **Q.** It was sent on Wednesday, September 17th, 2014. This was after you stopped paying process and handling fees; is that correct?
9:26AM **A.** Okay.
9:26AM **Q.** To Tony Carnaggio. Subject is "Singulex dropped clients."

"Below is a list of Singulex dropped clients. Please reply with a reason for the loss of client."

And you see there they have a series of North Carolina and South Carolina practices; is that correct?

A. That's correct.

Q. That you were responsible for; right?

A. That's correct.

Q. And what did you give for the reason that they -- you lost those clients?

Let's go up to the top. A little bit lower, Peter, please. It's Tony's email. There we go.

So on September 17th, 2014, at 1:51, Tony Carnaggio wrote P&H for all of them, didn't you?

A. That's what it says, yes.

MR. LEVENTIS: No further questions, Your Honor.

THE COURT: Mr. Ashmore?

MR. ASHMORE: No questions, Your Honor.

THE COURT: Anything on redirect?

MR. COOKE: Again, briefly, Your Honor.

THE COURT: Yes.

MR. COOKE: Can I trouble you to put 7011 back up. Could you highlight just the top half of that? Thank you.

REDIRECT EXAMINATION

BY MR. COOKE:

9:28AM **Q.** Mr. Carnaggio, do you remember the inquiry that was made to you by the MDVIP practice?
9:28AM **A.** I don't -- I don't recall. And it's a little confusing on this, because the MDVIP attorneys that came back, you know, they work -- MDVIP worked very closely with Cleveland HeartLab. Matter of fact, they really wanted their clients to utilize Cleveland HeartLab. And Cleveland HeartLab paid a P&H fee of $20, I think it was.
9:28AM **Q.** Was that -- was that a concierge practice?
9:28AM **A.** It was, yes, sir.
9:28AM **Q.** And was that a customer of yours?
9:28AM **A.** It was, yes.
9:28AM **Q.** Okay. And you say that they used Cleveland HeartLab which paid a $20 P&H fee?
9:28AM **A.** That's correct.
9:28AM **Q.** Okay. This occurred in January of 2013. And what did you do with the information when you got it?
9:28AM **A.** I just forwarded it on.
9:28AM **Q.** To Cal?
9:28AM **A.** To Cal, yes.
9:28AM **Q.** And then can you tell from here what Cal did with it?
9:29AM **A.** He sent it on to Tonya.
9:29AM **Q.** Okay. To HDL?
9:29AM **A.** HDL, correct.
9:29AM **Q.** And they had attorneys.

9:29AM 1 **A.** That's correct.
9:29AM 2 **Q.** All right. And was that typically what would happen, if
9:29AM 3 legal questions arose, it would be referred to HDL's attorneys?
9:29AM 4 **A.** That's correct.
9:29AM 5 **Q.** On this last exhibit about the dropped clients, I believe
9:29AM 6 you described yesterday that, by September of 2014, a number of
9:29AM 7 things had happened.
9:29AM 8 Do you remember articles coming out in The Wall
9:29AM 9 Street Journal?
9:29AM 10 **A.** Absolutely.
9:29AM 11 **Q.** And do you remember --
9:29AM 12 **THE COURT:** Mr. Cooke, don't lead your client.
9:29AM 13 **MR. COOKE:** Okay. I'm sorry.
9:29AM 14 **THE COURT:** Don't lead the witness.
9:29AM 15 **MR. COOKE:** All right.
9:29AM 16 **BY MR. COOKE:**
9:29AM 17 **Q.** What other things had happened during that time that your
9:29AM 18 customers found disturbing that were associated with process
9:29AM 19 and handling?
9:29AM 20 **A.** Well, the fraud alert came out. That was the big one.
9:29AM 21 When the fraud alert came out and then negative press in The
9:29AM 22 Wall Street Journal and those things, I mean, a lot of
9:29AM 23 physicians, they just kind of took a step back and said, "Hey,
9:30AM 24 you know, we don't want to -- we don't want to be put on that
9:30AM 25 spot."

9:30AM 1 **Q.** When the special fraud alert came out from the Office of
9:30AM 2 Inspector General, are you referring to the June 25, 2014,
9:30AM 3 fraud alert?
9:30AM 4 **A.** That's correct.
9:30AM 5 **Q.** And did that become well known in the medical community?
9:30AM 6 **A.** Absolutely, yes.
9:30AM 7 **Q.** Thank you.
9:30AM 8 **A.** But it was still important to note that a lot of those
9:30AM 9 physicians are still ordering today.
9:30AM 10 **MR. COOKE:** Thank you.
9:30AM 11 **THE COURT:** Thank you. You may step down. Thank
9:30AM 12 you, Mr. Carnaggio.
9:30AM 13 (Witness excused.)
9:30AM 14 **THE COURT:** Call your next witness.
9:30AM 15 **MR. COOKE:** We'd call Dr. Tauqueer Alam.
9:31AM 16 **THE DEPUTY CLERK:** Please place your left hand on the
9:31AM 17 Bible, raise your right. State your full name for the record,
9:31AM 18 please.
9:31AM 19 **THE WITNESS:** Tauqueer Alam.
9:31AM 20 **THE DEPUTY CLERK:** Could you spell your name for the
9:31AM 21 record?
9:31AM 22 **THE WITNESS:** T-a-u-q-u-e-e-r.
9:31AM 23 **THE DEPUTY CLERK:** Thank you.
9:32AM 24 (Witness sworn.)
9:32AM 25 **THE DEPUTY CLERK:** Thank you. You may be seated.

TAUQUEER ALAM,

a witness called on behalf of the defendants, being first duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. COOKE:

Q. Good morning, Doctor. I'm Dawes Cooke. I think we met this morning.

A. Yes, sir.

Q. And you know that I represent BlueWave and Mr. Dent and Mr. Johnson; correct?

A. Yes.

Q. Do you know them, by the way?

A. I have seen them before, the attorneys, in previous depositions.

Q. Okay. I'm actually referring to the two larger gentlemen on the end there. Do you know them?

A. Yes, I do.

Q. Okay. What do you do for a living?

A. I'm a physician in Seneca, South Carolina. I practice medicine there.

Q. What's the name of your practice?

A. Keowee Primary Care & Internal Medicine.

Q. Could you tell us about your educational background, please.

A. I did my medical school from India; Bombay, India. And I

9:33AM 1 did my residency from there.
9:33AM 2 And back in 1992, I came to New York Medical College,
9:33AM 3 and I finished my residency there. I finished in '96. And
9:33AM 4 soon after that, I started a practice in Seneca, South
9:33AM 5 Carolina.
9:33AM 6 **Q.** And the name of it is what?
9:33AM 7 **A.** Keowee Primary Care & Internal Medicine.
9:33AM 8 **Q.** And can you describe that practice for us?
9:33AM 9 **A.** I -- in 1996, I started this practice towards -- in
9:33AM 10 August. And it was a solo practice. And soon after I started
9:33AM 11 the practice, I joined the hospital which is maybe a mile away
9:33AM 12 from my practice. That's Oconee Memorial Hospital. I joined
9:33AM 13 end of '96. And I practice -- I saw my patients, inpatients,
9:33AM 14 and they were admitted.
9:33AM 15 I also -- in '98, I became the chief of staff in the
9:34AM 16 hospital. After two years of work, physicians saw me doing
9:34AM 17 things. And I was chief of staff for four years.
9:34AM 18 After four years, I came off the position of chief of
9:34AM 19 staff. Then, in a year, they reelected me back and put me as
9:34AM 20 chief of staff for another four years.
9:34AM 21 I also continued my private practice. I used to see
9:34AM 22 patients in my office during the office hours. Early in the
9:34AM 23 morning, I used to go and take rounds in the hospital. If
9:34AM 24 there were any admissions, I would go after 5:00, complete my
9:34AM 25 admissions. If there's emergency in between, I would go to the

hospital and see those patients.

I continued the solo practice until, I think, late '90s, early 2000s, when other providers started joining me, some nurse practitioners, PA. And now we are a group of eight or nine providers together.

Q. And, in addition to yourself, you mentioned others -- other nurse practitioners and so forth. What is a nurse practitioner?

A. A nurse practitioner is also a practitioner. They're medical providers. They're nurses who have done their master's program and have done a nurse practitioners program after that. And they -- they -- basically, they can see patients independently under a physician's supervision. If they have questions, they ask us. If they want us to step in and see patients with them, we do that. So they -- they -- for -- for -- so they basically can see patients independently as well as under a physician over them. If they're a complex patient, then they want that input, and we look at these patients.

Q. You have to be present in the building, but you don't have to see each patient?

A. Yes. For a nurse practitioner, I don't have to be present in the building, but I have to be available for them if they have any questions, or I have to be available if their patients are sicker and they want me to see the patients.

Q. Are you the only MD, medical doctor, in the practice?

9:36AM **A.** No, we were three MDs. One of them recently retired. So we are two MDs in the group. We are looking for another one to join us.

9:36AM **Q.** What is your patient demographic?

9:36AM **A.** Going back to 1996 when I -- you have to understand, Seneca is a rural area. The only hospital up there is Oconee Memorial Hospital, which was a 105-bed hospital. And when I joined in there, there was no subspecialties available in that local area. And the physician -- patients had to go to the nearest area, which is Greenville or Anderson, which is at least an hour, hour and a half drive from there.

Being in the local area, the services were very limited. The -- it's also still now it's a health professional shortage in the area. So there's shortage of physicians and professionals in that area. At that time, it was much more acute.

9:37AM I had trained in New York Medical College, and, you know, the hospital where I trained in, there were over 160 ER visits in a year. We used to manage patients. As chief resident, I had done a lot of cardiac care, intensive care work. And even with my training in India as a -- in residency, I had done a lot of those things.

9:37AM So when I came, I could -- the patients, when they came into the emergency room or were sicker, they used to be sent to Greenville Memorial Hospital or Anderson Hospital

because there was nobody to manage them. Right around that time before I came, the hospital actually was able to get a part-time cardiologist from Canada to practice there. So he was their part-time doctor, Dave Newton.

So, half the time, he was not on call and the ER was trying to find him. If he was not on call, they were stuck with patients with acute MI, strokes, and other things sending them there. So I ended up managing these patients because I had the experience to do that.

And the more I did, the more ER would call me, and the more the hospital would call me to manage the patients on the ventilators and other things. And it ended up in a way that I used to be working in the hospital for, you know, sometimes on the weekends 10, 15 hours, 12 hours. And on the weekdays, I'd be -- after my office, I would be there five, six hours managing these patients.

So as things went about, I actually started getting these patients back to my office who were sicker patients, who had multiple medical problems. And that's what an internist is about. They manage adult patients with multiple medical problems.

As -- as the years passed by, my name got out into the community as this was a person who manages diabetes, hypertension, heart disease, strokes. We don't have to go to Greenville. We don't have to have all these specialties

available. So I ended up seeing these patients. And, in my practice, 95 to 98 percent of my practice is highly complex patients. And I still follow them. I don't see cough, cold, flu. I don't see these kinds of patients, because, you know, there are urgent cares, there are other places where they can get these kind of treatment. So my office pretty much, when I see patients, they're all highly complex patient with multiple medical problems.

I still get requests, at least six or eight every day, for these kinds of patients to be admitted to the practice.

Q. Thank you, Doctor.

A. And that's how our practice, even our nurse practitioners and other physicians there, ended up seeing these kinds of patients. And we are probably one of the largest practices in Seneca who see these patients. I don't think any patients in Oconee County -- or any physicians in Oconee County can manage these kinds of patients.

The specialists from out of area, like Greenville, when they see patients and they wonder diabetes, hypertension, hyperlipidemia, they actually refer back to our office, even though, the patients, they go and get established there so they can get care there.

Q. Thank you. Doctor, let me just remind you, as we discuss your practice, do not discuss any particular patients. All

9:40AM 1 right? You can talk about your general practice and your
9:40AM 2 philosophies about medicine, but don't use any anecdotes of
9:40AM 3 specific patients. You've done fine so far; I just wanted to
9:40AM 4 caution you about that.
9:40AM 5 Understand?
9:40AM 6 **A.** Yes, sir.
9:40AM 7 **Q.** At some point in your career, did you become interested in
9:40AM 8 preventive cardiovascular medicine?
9:40AM 9 **A.** I have done that right from the start of my practice. I
9:40AM 10 wouldn't call it preventive cardiovascular; I'd call it as
9:40AM 11 disease management, because once you have diabetes, once you
9:40AM 12 have hypertension, once you have heart disease, once you've had
9:40AM 13 an event or stroke or heart attacks or those things, then you
9:41AM 14 have to be managed through these diseases. There's no going
9:41AM 15 back with it.
9:41AM 16 So, yes, if you want to call it as preventative or
9:41AM 17 you want to call it as a long-term management of disease,
9:41AM 18 that's what I -- I ended up doing -- I mean, I do. And that's
9:41AM 19 what I've been doing for -- since '96.
9:41AM 20 **Q.** Could you describe what, if any, role advanced lipid
9:41AM 21 testing and genetic testing has had in your practice?
9:41AM 22 **A.** The -- when you have complex patients, you have to have
9:41AM 23 certain kind of -- of lab testing or certain kind of other
9:41AM 24 testing to identify patients at high risk or patients who are
9:41AM 25 already at high risk. Are they being well taken care of or are

they at a risk of having a second event or a third event?

So whenever you see these, you risk-stratify patient; and whenever you risk-stratify patients, you need all the tools at your disposal to identify that; and if you don't identify that, then you're going to land up with the same problem, is they're going to have another event. This patient is going to have another ER visit or hospital stay. More -- it's higher chances of morbidity, higher chances of mortality. Everything going up much more high. Once you have an ER visit, once you're admitted to the hospital, you're fighting against mortality and morbidity.

So if you can prevent that -- to prevent, that you have to risk-stratify patients; and when you risk-stratify patients, you have to have these tools. These tools -- there are certain tools like regularly checking blood sugar levels with an A1C, regularly checking lipids, advanced lipids. Very important because if -- if a person -- half of the heart attack and stroke occurs in patients with normal cholesterols. So if you just go by the regular lipid panels, then you're going to miss half the patients who have events. So to identify -- subidentify these patients, you have to go ahead and do these advanced lipid panels to find out.

Also, there are certain things that is genetic testings in patients which are necessary. Why genetic test? Because certain genotypes are very high risk for heart disease

and strokes. Certain genotypes are moderate risk, certain genotypes are low risk. If you identify these patients with certain genotypes, you can actually see that, if they are high risk, you have to be more aggressive with their treatment and get them to normal values as much as possible. And that's how these advanced testing helps.

You know, 30, 40 years ago, if you told me patient was a diabetic and, you know, checking blood sugars was great, I would say great. But 20 years ago, if you told me diabetic, I would next ask you, what's the A1C level? Because that gives me an average of the level over the last three months of a patient. And, based on the A1C level, I can identify patients who are controlled, not controlled, and these things.

Same thing with lipids. 25 -- 30, 40 years ago, you told me just cholesterol level was fine. Then 30 years ago, 25 years ago came lipid panels where you had cholesterols, you had triglycerides, you had HDL, you had LDL, those things, you could do that and identify for the subclasses.

Now you have advanced lipid panels, which can actually give you actual particle numbers, particulate matters, whether these are atherogenic particles, that means they can form plaques, or they don't form plaques. The good particles, are there enough of those there or not enough of those there?

So these are the panels which will help you guide treatment; and if they're not, then you fine-tune it further.

9:45AM **Q.** Did you at some point become a -- I'll just use the term "customer" of a company called HDL?
9:45AM **A.** What do you mean by "customer"?
9:45AM **Q.** Somebody that -- I wasn't sure the right word to use. Did you start ordering tests from HDL?
9:45AM **A.** I've always ordered advanced lipid panel. Right in the early '90s, there used to be -- I don't remember clearly, but there used to be company somewhere based in North Carolina where we used to order advanced lipid panel where it broke down the LDL particle numbers and certain other things.

I remember I used to sit down with David Newton -- he was a cardiologist -- and we used to go over these things. And certain patients which were admitted to the hospital, we used to send it to the hospital. Used to go to North Carolina.

So we were one of those early users, and me, Dave Newton used to sit down and discuss things and how to manage these patient.

9:45AM **Q.** Is that LipoScience, by the way?
9:45AM **A.** It -- I think it was NMR, LipoScience, or something like that it was. And it was the lab testing VIP. I vaguely remember that, because it used to be -- Dave Newton passed away a few years ago, but very good memories. We used to sit down and used to go over.

So, anyway, after that came, I think we started reading these things. But those are very raw data they used to

give us. So interpretation was difficult in the sense you had to take those raw data, interpret it according to the patient, and then go and do it.

I think after that, certain other labs came about which were doing it, and I think we went to Berkeley HeartLab. And they did that. But the good thing was we didn't have to interpret the raw data. They gave us in a very nice -- in a way that interpretation was very easy on these tests.

For others, became easy and to correlate it to patient, to explain it to the patient when we give those, it was easy for us to do that. And I think after Berkeley got sold to -- if I'm not mistaken to Quest -- Quest did not have the same kind of aim or goal where Berkeley had, and that test results started deteriorating. And they went into another format of it which was not easy to interpret everything.

So then I think it got sold to Celera or something like that. There were two or three companies. So we got frustrated with the results we were having. And then I think we moved over -- there was two or three companies at that time, and we moved over to HDL.

Q. And what about Singulex? Did you start ordering labs from Singulex?

A. Yes, we did. Singulex. And, in fact, I still do right now.

Q. What were the Singulex tests used for?

9:47AM 1 **A.** Singulex tests was -- again, it was about inflammatory
9:47AM 2 markers. It was about highly sensitive troponins. So these
9:47AM 3 tests, we ordered from there.
9:47AM 4 To explain that, I probably have to go back and -- in
9:47AM 5 my practice where we see patients, at least -- at least 80
9:48AM 6 percent of my patients, I would say, are either diabetics or
9:48AM 7 prediabetics. Why do I say that? Because I see high-risk
9:48AM 8 population. Those are the patients I see.
9:48AM 9 A third of the population in this country are obese.
9:48AM 10 At least another third of it, if they're not obese, they're
9:48AM 11 overweight. These are the people who have problems with
9:48AM 12 diabetes, insulin resistance. So these are the patients who
9:48AM 13 actually seek help and come.
9:48AM 14 And if they don't, they will get events at certain
9:48AM 15 amount of time, they will go to the ER with those events, and
9:48AM 16 then they find out that the metabolic profiles are not in order
9:48AM 17 and they'll send back to the physician.
9:48AM 18 So these are the kinds of people whom I see in the
9:48AM 19 office. When I say 80 percent of patient are diabetic or
9:48AM 20 prediabetic, it's very important, because these are the
9:48AM 21 patients who actually have events. If you are -- I'm not even
9:48AM 22 talking about a diabetes. If you are a prediabetic, you are at
9:48AM 23 least seven times more atherogenic -- that means seven times
9:49AM 24 more likely to deposit plaques -- than a person who is
9:49AM 25 non-prediabetic. It's that important.

9:49AM And so -- so measuring insulin levels, measuring the lipid levels, also diabetes, what we call it is have silent ischemias. That means they may have a heart attack without any signs and symptoms. So they get what we call a silent.

To identify the silent ischemias is very difficult. One thing, you can wait until a patient gets an event. If he gets a chest pain or gets some sharpness event or pain and they end up at the doctor's office or emergency room and then start treating patients, so the emergency room will order typically certain blood test, certain profiles, and they will also order a cardiac profile.

A cardiac profile would include, again, several tests: CPK, myoglobulin, MB fractions of CPK, and a troponin I. A troponin I is very important. If the troponin I is elevated, that means you are actually having acute coronary syndrome or a heart attack, which is both equal, and they will immediately admit you to the hospital. They will, 99 percent of the time, end up doing a cardiac catheterization or maybe 1 to 5 percent of the time stress test if you have risk factors. But those patients are actually having a heart attack. That's how we identify them.

Now, what Singulex does is this troponin I, they have a very high-sensitive troponin I. They're hundred times more sensitive than what is done at the -- at any labs, at any hospital. So you can actually identify these patients at the

very, very early stage if they're having microischemia. That means they're having ischemias and you don't identify -- their levels of measuring this are very, very sensitive. So if you get these test in diabetics and they have elevated troponins at that time, you are pretty sure that this patient is going to have an event in the near future.

So you either take care of it now -- either you take care of the medical management and also do appropriate testing for them to identify if they're having blocked arteries or not blocked arteries, and you get them to a cath lab, without going to an emergency room, without having an event.

So that's how it helps us to, again, identify patient, in selective patients.

Q. And, Doctor, I wasn't allowed to tell you this, but we've already had -- the jury has already heard a fair amount of medical testimony about the details and the science. So if I rush you along, it's not because we're not interested; it's just because we're covering something that we've already --

A. Please.

Q. Is that all right with you?

A. That's fine.

Q. Are you familiar with the requisition forms that were provided by HDL and by Singulex?

A. Yes.

Q. Did they contain different panels of tests that are

9:52AM 1 available?
9:52AM 2 **A.** Yes.
9:52AM 3 **Q.** Were you required to order a whole panel if you didn't
9:52AM 4 think all of the tests in that panel were necessary?
9:52AM 5 **A.** I think I could pick and choose from the panels what I
9:52AM 6 wanted and I could make my own panels what I prefer.
9:52AM 7 **Q.** Did you create your own panels?
9:52AM 8 **A.** Yes, I did.
9:52AM 9 **Q.** And then would those go on registry with the laboratory so
9:52AM 10 that they would know what you want to order?
9:52AM 11 **A.** Yes, I did.
9:52AM 12 **Q.** And I -- is it true that you also did other testing in
9:52AM 13 your facility?
9:52AM 14 **A.** Yeah. I had my own lab. And, again, if you give me a
9:52AM 15 couple of minutes to explain that.
9:52AM 16 **Q.** Yeah. This is actually -- I do want to focus on that.
9:52AM 17 You -- you have your own laboratory; is that correct?
9:52AM 18 **A.** Yes, I do have my own. And that, again, came out of
9:52AM 19 necessity more than anything else. Again, in a rural area
9:52AM 20 where we live, there's only couple of places where you can
9:52AM 21 collect the blood, is either at the hospital or there's a
9:53AM 22 LabCorp center where you can collect blood.
9:53AM 23 It's a rural area. It's not most up-to-date area.
9:53AM 24 And the kind of testing that we order and the kind of blood
9:53AM 25 work that we want certain things, half the time the patient was

back in the office; the results were not back in the office. So patient is waiting. We're trying to call the lab. We are trying to do things, and the results are not available. They used to fax it. Take another half hour, 45 minutes.

Sometimes we didn't get the results. Half the time patients, 15, 20 percent of the time, whatever we had actually ordered to the lab was not -- you know, was not -- the certain tests were missing or certain tests were done extra because there are certain people sitting in the hospital lab, they didn't put in the entry right or they ordered the wrong tests, so we got those results.

So it had become to a point where managing these chronic patients was becoming a problem. So at that point we made a decision in the office, why not have our own lab do these tests? So we started doing a lab -- I think it was in the early 2000s or mid 2000s, somewhere there. We started doing -- started our own laboratory out of necessity, and we started doing the labs there.

So a lot of -- it's a moderate complex lab. When we started this lab, we got a COLA certification, and that COLA certification is the same kind of certification that the hospital or any kind of reference lab, like Quest, LabCorp, need maintain that.

What that means is we have certain quality assurances to do. COLA, they -- they send us samples from, you know,

different places to run it at our lab. And you have to have -- every two or three months we get these. And we have to have at least 80 percent correlation on these tests to maintain that license. That means -- so when we get these -- we send the results, and they see if this correlates.

Now, our lab has 100 percent correlation. So whatever we do we do with a gold seal of quality assurance out there.

So why is it important? Because, if I get a lab result, I need to make sure that that's what the true reflection of that patient's profile is, number one. And, number two, when I sit down, I change medications, I do long-term treatments, that it is based upon values that reflect the true -- true nature of the disease.

So we've done this lab. We have our own lab. We have a couple of very highly competent lab techs in there. We have phlebotomists in there which do that.

Q. Okay. Does that laboratory serve just your Keowee practice?

A. Yes.

Q. Do they stay busy?

A. They are busy.

Q. Would they be busy even if they weren't doing HDL and Singulex testing?

A. Yes.

9:55AM 1 **Q.** Approximately how many patients do you see a week?
9:56AM 2 **A.** It varies. I think I see anywhere from, you know, 18, 20
9:56AM 3 to 25, 30 patients. Probably around 25 on an average I would
9:56AM 4 probably see in a day. You have -- you know, we see -- I see
9:56AM 5 patients for four and a half days a week, so you can do the
9:56AM 6 numbers. It's probably around 125 -- 100 to 125 patients a
9:56AM 7 week I see.
9:56AM 8 **Q.** 100 to 125?
9:56AM 9 **A.** Uh-huh.
9:56AM 10 **Q.** Was that -- was that the case back in 2010 through 2014?
9:56AM 11 **A.** Yes.
9:56AM 12 **Q.** Of those patients, how many of them, approximately --
9:56AM 13 generally, how many advanced lipid studies would you have
9:56AM 14 ordered? I'm referring now back to the 2010 through 2014, '15
9:56AM 15 range.
9:56AM 16 **A.** I don't remember the numbers exactly, but I probably
9:56AM 17 ordered at least 25 to 50 percent of the patients.
9:57AM 18 **Q.** 25 to 50 percent of the patients?
9:57AM 19 **A.** Uh-huh.
9:57AM 20 **Q.** So let me -- let me understand. Did you -- what criterion
9:57AM 21 would you use to decide whether to order a test -- an advanced
9:57AM 22 lipid test or a -- anything offered by HDL or Singulex for a
9:57AM 23 patient?
9:57AM 24 **A.** I mean, these were very high-risk patients anyway. So,
9:57AM 25 you know, your criterias are, are they risk of heart disease?

Are they risk of stroke? Any kind of vascular diseases.

So if they're at risk of vascular disease, have they had an event or have they not had an event? So these are the criteria. Are they diabetics or nondiabetics? Are they prediabetics? If they're a diabetic, if they have had an event or if they -- if -- if -- they're genotype, I would probably end up ordering them.

Now, if you remember, I told you at least 80 percent of my patients are diabetic and prediabetic. So if an initial evaluation a patient came in first time was seeing me with an event that has diabetes, has, you know, has hyperlipidemia, clearly, I would do one on the patient to at least have a baseline when I started with to see what's happening, to see their genotype.

Q. In your opinion, could you have justified doing testing with HDL and Singulex on more patients than you did?

A. I can if I wanted to. I mean, I could have done on at least 70, 80 percent of the patients if I wanted.

Q. Is that because they had risk factors?

A. Yes.

Q. And, again, what percentage of your patients would you say have risk factors for cardiovascular disease?

A. Of the 25 patients or 125 patient -- 100, 125 patients I see?

Q. Yes.

9:58AM **A.** Pretty much most of them. At least 80, 90 percent of them.
9:58AM **Q.** But yet you did the testing on 25 to 50 percent?
9:58AM **A.** Because they are -- they're probably at a much higher risk. They have -- the risk factor is when you say we quantify them into low, moderate, or high risk. I would say moderate and high risk, probably 80 percent of the patients would fall into moderate to high risk.
9:59AM **Q.** At some point did you -- were you invited to become a member of the HDL advisory -- physician's advisory board?
9:59AM **A.** Yes, I was.
9:59AM **Q.** What is that?
9:59AM **A.** Well, it was a group of physicians who were -- who would sit down together and who would see that the utility of these tests and interpretation of these tests, and if -- if these panels could be laid out in a different way, if there were more tests coming in to look at these tests, whether there would be -- we would be able to utilize -- utilize it with the patients or not. So those are the kinds of things we used to discuss.

Also sitting around with physicians and looking at these, we would get -- it's a good peer-to-peer where we could discuss things at a different level in terms of advanced lipid panels.

10:00AM **Q.** Now, did you begin using HDL tests because they put you on

10:00AM 1 the advisory board, or did they put you on the advisory board
10:00AM 2 because you were using their tests?
10:00AM 3 **A.** No, no. I was using HDL before that, I think. And --
10:00AM 4 yeah, I was using advanced lipid panel much before that.
10:00AM 5 **Q.** Okay. Could we bring up this -- are you familiar with
10:00AM 6 process and handling fees?
10:00AM 7 **A.** Yes.
10:00AM 8 **Q.** What I'm showing you is a -- an exhibit that the
10:00AM 9 government has been using, and it shows some of the physicians,
10:00AM 10 the amount of process and handling fees that they -- or that
10:00AM 11 their practices received over a period of years.
10:00AM 12 Do you see Keowee Family Care up there with your
10:01AM 13 name?
10:01AM 14 **A.** Uh-huh.
10:01AM 15 **Q.** And there's a -- a line for Singulex, and then there's a
10:01AM 16 line down here for HDL.
10:01AM 17 **A.** Yes.
10:01AM 18 **Q.** And does that -- do you have any way of knowing whether
10:01AM 19 that accurately reflects the amount of process and handling
10:01AM 20 fees that your practice received over those years?
10:01AM 21 **A.** Yeah, after I see those numbers, probably is. I have not
10:01AM 22 looked at these numbers those years.
10:01AM 23 **Q.** Okay. Well, let's assume that that's accurate. Does that
10:01AM 24 number shock you or surprise you in any way?
10:01AM 25 **A.** No.

10:01AM **Q.** Let's talk about what your office has to do in order to process and handle specimens for HDL and Singulex.

Would you -- would you walk the jury, please, through the process of what your practice is asked to do for the laboratory with regard to processing and handling.

10:02AM **A.** You know, as I have a full-scale lab in the office which is COLA certified, moderate complexity lab, so I have lab technicians in there who are working, the phlebotomists who are working. So the -- you know, I won't be able to say exactly what everything, but I know in overview how things happen when you collect these labs.

So a phlebotomist will collect these labs. These labs are actually going to specialty tubes because there are certain fractionated particles, genetic testing to be done. I think there are four or five tubes, something like that, in there which has to be -- these tubes are actually shipped by the companies to our office because they have to go into certain specialty tubes.

So storage, they have to go get from the storage. They have to collect those blood. After they collect the blood, it goes to the lab.

Now, before going to the lab, they have to fill out certain specialty forms which was sent by the lab. And these forms are a little bit extensive forms. They ask for certain things. They even ask for the weight, the height of the

patient so that they can do a BMI on the patient. So those have to be also measured prior to collecting the blood work.

These forms are extensive. Patients have to sign it. Phlebotomist has to sign it. And so -- so transcribing the form, writing the weight, the height, measuring the weight, height, all of this done by the phlebotomist.

Then the phlebotomist collects the blood, goes to the lab. The lab has to spin this blood, make sure it is labeled correctly, make sure it is stored correctly. And if it -- and after they do that, the -- the lab is then shipped -- I think by FedEx or one of these ship -- shipping agencies.

Now, if they're not shipped because the FedEx is already, then they have to store it in a certain controlled environment. And then the next day it has to be shipped.

So there's multiple layers of handling this and multiple people handling it and people who are paid at different levels -- phlebotomists, lab technicians.

So this is in short. I'm sure there are other processes which is done by the -- by the phlebotomist and lab techs which I'm not --

Q. All right. Do you believe that a $3 draw fee and a $17 process and handling fee fully compensates you for the expense that you have incurred to process and handle HDL's specimens?

MR. KASS: Objection, Your Honor. Lack of foundation.

10:04AM **THE COURT:** Overruled.

10:04AM **THE WITNESS:** I don't think because ours is a very special circumstance where a phlebotomist and very highly paid lab technician handles those things. So our cost of doing things is very high. I think -- I think -- what you said? $3 and $17?

10:05AM **BY MR. COOKE:**

10:05AM **Q.** For --

10:05AM **A.** It's still -- it still would not compensate entirely for what we do.

10:05AM **Q.** How about for the process and handling fees that you received from Singulex? Did that fully compensate you for the cost --

10:05AM **A.** Not with the phlebotomist and with the lab technician handling all these specimens in a very certified manner, in a COLA-certified manner.

10:05AM **Q.** Doctor, you've testified that you actually have a laboratory. Did you ever ask that -- that you be paid the $25 lab-to-lab fee that HDL would pay to a laboratory?

10:05AM **A.** You know, I did not even know about it, that these kinds of things -- I think when I look -- I look at science. When I look -- when -- I have always ordered advanced lipid panels before even these companies were there. I've ordered during these companies were there. What they pay -- it's been seven, eight years, ten years since all these things have happened. I

don't remember specifically asking about the price, you know, talking about this pricing.

I think we started doing it because of the science, and I think these prices were -- when these were signed were signed by the office managers at that time, and they got -- I did not even know about these numbers until all these cases came up and I had to compile these numbers when I saw and I had to submit it. Then I looked at these numbers.

So, really, when you're asking me these questions, yes, it was done by the office. Was it done by office manager, signed by them, certain papers they got me are signed by. $20, $25. It was not about all about that. It was about the science that we used it, and that's how we've used it.

Q. Do you offer -- do you order more tests because of the fact that you're being compensated the process and handling?

A. Absolutely not.

Q. Would you ever do that?

A. Never.

Q. Let's talk about what HDL and Singulex may have tried to get you to do.

Did you -- who were the sales representatives that you dealt with?

A. There were many sales representatives I've dealt with over the years. I don't remember -- I do remember because Cal used to be in Berkeley HeartLab, and then he transitioned into, I

10:07AM 1 think, HDL. So those -- Tony, I remember, because he called
10:07AM 2 until, you know, the last few years.
10:07AM 3 **Q.** Tony Carnaggio?
10:07AM 4 **A.** Yes. There used to be Mr. -- Mr. Kung. He was there. I
10:07AM 5 think he went with Cleveland HeartLab or Boston Heart lab at
10:07AM 6 one point.
10:07AM 7 **Q.** How did they convince you to switch from Berkeley HeartLab
10:07AM 8 to HDL and Singulex?
10:07AM 9 **A.** Oh, no. At that time we were looking because Berkeley got
10:07AM 10 bought out by Celera Genomics, which was a genomic company.
10:07AM 11 They didn't have these kind of things. The lab just started
10:07AM 12 deteriorating. The way we got the results started not up to
10:08AM 13 par. The health coaches were gone where patients could call
10:08AM 14 and discuss the labs with the health coaches. Then it got sold
10:08AM 15 to Quest with further deterioration.
10:08AM 16 So we are actually looking for some other place where
10:08AM 17 we could send these. And there were certain options. I think
10:08AM 18 at that time there was Boston Heart lab and Cleveland HeartLab
10:08AM 19 and HDL came about then. So the transition was going to
10:08AM 20 happen, because -- so it happened with HDL.
10:08AM 21 **Q.** Did any of the sales representatives for HDL or Singulex
10:08AM 22 tout or promote process and handling fees as a reason for you
10:08AM 23 to use HDL or Singulex?
10:08AM 24 **A.** No.
10:08AM 25 **Q.** Did they provide you with clinical information about the

10:08AM tests that were being offered?
10:08AM **A.** Yes, they did. And I was pretty much well aware of these clinical information. But most important was how these labs would be reported to us, because, ultimately, you have to sit down with the patient and go over these labs. And that's the key to it, because the patients have to understand this lab well to understand their treatment plans.
10:09AM **MR. COOKE:** Your Honor, we have an exhibit. It's -- it was premarked as Exhibit 524. But it's a very large spreadsheet. But I'm mindful that we like paper exhibits and not just electronic. We've taken a subset of that that has some numbers for Dr. Alam. And these are the sales numbers, week-by-week sales numbers. And I believe there's no objection.
10:09AM **THE COURT:** Is there any objection?
10:09AM **MR. KASS:** No objection.
10:09AM **THE COURT:** How about Mr. Ashmore?
10:09AM **MR. ASHMORE:** No objection.
10:09AM **THE COURT:** BlueWave 525?
10:09AM **MR. COOKE:** It's 524.
10:09AM **THE COURT:** I'm sorry. BlueWave 524, admitted without objection. Please proceed.
10:09AM **MR. COOKE:** May I hand this copy --
10:09AM **THE COURT:** You may. Yes, sir.
10:09AM **BY MR. COOKE:**

10:09AM **Q.** Take a moment to took at that, if you would, Dr. Alam, and we have highlighted your orders beginning in 2013 and running through 2014.

Would you take a moment just to leaf through that and see if that appears to be reasonable representation of your ordering practices.

A. Can I ask you a few questions?

THE COURT: No.

THE WITNESS: No?

THE COURT: Sorry, Doctor, he gets to ask the questions; you get to give the answers.

THE WITNESS: I just want to make sure what I'm seeing is what it is.

THE COURT: If he can't identify it, he can't testify about it. You can't explain it to him.

MR. COOKE: Okay. Well, it's in evidence.

THE COURT: Right.

THE WITNESS: Is it daily? Is it weekly? How does it go by this?

MR. COOKE: Can I answer that?

THE COURT: Go ahead and answer that question.

BY MR. COOKE:

Q. Just read the legend on it, and you'll see it looks like weekly. It's pretty small writing.

A. Okay. Yes, sir.

10:11AM **Q.** Take your time.
10:11AM **A.** Yes, sir.
10:11AM **THE COURT:** Please proceed.
10:11AM **BY MR. COOKE:**
10:11AM **Q.** All right. And we have put together a --
10:11AM Can you put this up?
10:11AM **THE COURT:** Any -- you want to put this in? What do you want to do?
10:11AM **MR. COOKE:** I'm just going to use it as a demonstrative.
10:11AM **THE COURT:** No problem.
10:11AM There's no objection?
10:11AM **MR. KASS:** No objection.
10:11AM **THE COURT:** Mr. Ashmore?
10:11AM **MR. ASHMORE:** No objection.
10:11AM **THE COURT:** Very good. Please proceed.
10:11AM **BY MR. COOKE:**
10:11AM **Q.** Dr. Alam, we've taken the liberty of translating that data into a graph. And if you look at the screen in front of you, do you see that?
10:12AM **A.** Yes, sir.
10:12AM **Q.** Let me ask you this question: Did you -- did you change your ordering practices when you no longer received process and handling fees from HDL and Singulex?
10:12AM **A.** No, I haven't. And I still keep on ordering them.

10:12AM **Q.** All right. And when I showed you this this morning, did
10:12AM you make a comment about what it would show if I extended it
10:12AM even farther into the future?
10:12AM **A.** I still use advanced lipid panel, and I use Boston Heart
10:12AM lab. And pretty much I think it's the same, or if not more,
10:12AM because I've gotten busier since 2014.
10:13AM **Q.** Did you complain to the folks at BlueWave or HDL or
10:13AM Singulex that they were no longer compensating you for
10:13AM processing and handling their specimens?
10:13AM **A.** I didn't even know that they stopped giving it in June
10:13AM 2014 until I'm seeing this.
10:13AM **Q.** Okay. All right. Well, if you had known that, would you
10:13AM have stopped ordering from them?
10:13AM **A.** No.
10:13AM **MR. KASS:** Objection, Your Honor.
10:13AM **THE WITNESS:** I mean, it's the utility of the tests.
10:13AM **THE COURT:** Overruled.
10:13AM **THE WITNESS:** It's the utility of the tests. And, as
10:13AM you see, I still -- even after that, 2014, I still kept on
10:13AM ordering that. And I still use advanced -- and if you have a
10:13AM snapshot before this with either Boston or -- with Berkeley
10:13AM HeartLab or with -- before that with NMR LipoSciences, it would
10:13AM probably show the same data.
10:13AM **MR. COOKE:** Your Honor, I think I would like to offer
10:13AM just the hard copy of this as an exhibit, if we may.

10:13AM **THE COURT:** Very good.
10:13AM Any objection?
10:13AM **MR. KASS:** No objection.
10:13AM **MR. ASHMORE:** No objection.
10:13AM **THE COURT:** What number is that?
10:13AM **MR. COOKE:** Give me a number.
10:14AM **MS. MASON:** 524-1.
10:14AM **MR. COOKE:** 524-1.
10:14AM **THE COURT:** BlueWave 524-1 admitted without objection.
10:14AM **BY MR. COOKE:**
10:14AM **Q.** In addition to the personnel that handled the processing and handling of blood specimens in your office, do you have to dedicate space to that as well?
10:14AM **A.** Can you ask me that again?
10:14AM **Q.** Yeah.
10:14AM In addition to -- you talked about the people that work in your laboratory and handle the processing and handling of specimens. In addition to the people, do you have to devote space -- that is, office space -- to that function?
10:14AM **A.** Yes, you do, because there's a lot of -- there's those boxes that come for storage to be mailed out. It's quite an elaborate box. It's a big-sized box that has to be -- so all those has to be stored at clinics and then used. Because if you see, you know -- you know, our volumes are at least -- I've

10:15AM 1 been using 20, 25 in a week. So when you -- you can count
10:15AM 2 those things as storage space.
10:15AM 3 Also, when the tubes are collected, you have to
10:15AM 4 separate those tubes out, whether it's going to be used by our
10:15AM 5 lab or it's going to be mailed out. So it has to have a
10:15AM 6 separate desk area, space area with the phlebotomist and with
10:15AM 7 the -- with the lab -- in the lab for the lab tech to operate
10:15AM 8 with it.
10:15AM 9 **Q.** And in addition to that, do you have to have space for the
10:15AM 10 specimens to be drawn, for the phlebotomist to work?
10:15AM 11 **A.** Yes, we have a dedicated space for that.
10:15AM 12 **Q.** And does that also include equipment such as your
10:15AM 13 refrigerator and your --
10:15AM 14 **A.** Yes.
10:15AM 15 **Q.** -- centrifuge?
10:15AM 16 **A.** I mean, I didn't go into great details of this, but, yes,
10:15AM 17 it does.
10:15AM 18 **Q.** I'm catching you off guard, but any rough guess of the --
10:16AM 19 excuse me -- estimate of the amount of square footage?
10:16AM 20 **A.** I'm not sure about it. I won't be able to answer that.
10:16AM 21 **Q.** That's all right. Thank you very much.
10:16AM 22 **A.** Thank you.
10:16AM 23 **THE COURT:** Cross-examination, Mr. Kass?
10:16AM 24 **MR. KASS:** Thank you, Your Honor. I have too much
10:16AM 25 paper.

10:16AM 1 **CROSS-EXAMINATION**

10:16AM 2 **BY MR. KASS:**

10:16AM 3 **Q.** Good morning, Dr. Alam. How are you?

10:16AM 4 **A.** I'm doing good. Good morning to you, sir.

10:16AM 5 **Q.** I'm just going to grab that one if you don't mind.

10:16AM 6 Thank you for your time this morning, sir. We have

10:16AM 7 not met before. My name is Michael Kass, and I represent the

10:16AM 8 United States. You may recall my colleague, James Leventis,

10:16AM 9 from your deposition in --

10:16AM 10 **A.** Yes, I do.

10:16AM 11 **Q.** -- March of last year? Sure. Okay.

10:16AM 12 Couple of questions. Let's start with this: Now,

10:16AM 13 Dr. Alam, you are not a cardiologist; correct?

10:16AM 14 **A.** Yes.

10:16AM 15 **Q.** Right. Yes as in you are not a cardiologist?

10:16AM 16 **A.** Yes, I'm not a cardiologist.

10:16AM 17 **Q.** Yeah, it gets confusing on the record.

10:16AM 18 And you never did a fellowship in cardiology;

10:17AM 19 correct?

10:17AM 20 **A.** Yes, I never did a fellowship.

10:17AM 21 **Q.** Never did a fellowship. And you never did a fellowship in

10:17AM 22 interventional cardiology; is that correct?

10:17AM 23 **A.** Yes, sir.

10:17AM 24 **Q.** Meaning you never did a fellowship?

10:17AM 25 **A.** Yes.

10:17AM **Q.** And you were not board-certified as a specialist in any
10:17AM area; is that right?
10:17AM **A.** Yes, sir.
10:17AM **Q.** Meaning you are not --
10:17AM **A.** I am not board-certified in any specialty area.
10:17AM **Q.** And you have not published any peer-reviewed articles in
10:17AM any medical journal; is that correct?
10:17AM **A.** That's correct.
10:17AM **Q.** Now -- and, earlier, Mr. Cooke was asking you about all
10:17AM the steps that go into process and handling and what's -- you
10:17AM know, how much you thought that cost.
10:17AM You never did your own study to investigate the cost
10:17AM or time involved in process and handling; correct?
10:17AM **A.** Yes, I have not done my own study.
10:17AM **Q.** And I believe you testified earlier that you weren't
10:17AM really knowledgeable about the process and handling fees at the
10:17AM time; is that right?
10:17AM **A.** Yes.
10:17AM **Q.** And I think you said, if I understood you correctly, that,
10:18AM you know, those agreements were signed by your office manager?
10:18AM **A.** Yes.
10:18AM **Q.** You weren't in the loop; right?
10:18AM **A.** Yes, some were signed by them. Some, they put the paper
10:18AM in front of me and I signed it.
10:18AM **Q.** Good. Okay. That's what I wanted to talk about. Let's

start with this one.

MR. KASS: May I approach, Your Honor?

THE COURT: You may.

MR. KASS: Thank you.

BY MR. KASS:

Q. Do you recognize this document?

A. Yes, I do.

Q. Okay. And this is a --

MR. KASS: Your Honor, I'd like to move into evidence United States Exhibit 1063, please. 1063.

THE COURT: Any objection?

MR. COOKE: No objection.

MR. ASHMORE: No objection.

THE COURT: Plaintiffs' 1063 admitted without objection.

MR. KASS: And if we could just zoom in, Peter, on the top part of that first page if you don't mind.

BY MR. KASS:

Q. Okay. Is this a process and handling agreement between your practice and Health Diagnostic Laboratory?

A. It does.

Q. And if you don't mind turning to the second page, let's look down at the signatures on that. At the top of that, do you see Tonya Mallory's signature?

A. Yes.

10:19AM **Q.** And she was the president and CEO of Health Diagnostic Laboratory at the time?
10:19AM **A.** Yes.
10:19AM **Q.** And you knew Ms. Mallory; right? You met her a couple of times?
10:19AM **A.** Yes, I did.
10:19AM **Q.** Okay. And then underneath that, it appears that Tanweer signed this. I believe Tanweer is your brother?
10:19AM **A.** Yeah, he was the office manager at that time.
10:19AM **Q.** He was the office manager at the time. And I believe you testified, in your deposition with my colleague Mr. Leventis, that he signed this on your behalf; correct?
10:19AM **A.** Yes.
10:19AM **Q.** And he signed this, it appears to be, on or around November 19th, 2010; correct?
10:19AM **A.** Yes.
10:19AM **MR. KASS:** Actually, could we just go back to that first page. And if we zoom it on the second paragraph, numbered paragraph 2. Sorry, the one above that. It's numbered paragraph 1. Great.
10:20AM **BY MR. KASS:**
10:20AM **Q.** And this talks about a process and handling fee of $17; right? You see that?
10:20AM **A.** Yes.
10:20AM **MR. KASS:** Your Honor, may I approach?

10:20AM
THE COURT: You may.
BY MR. KASS:
Q. Dr. Alam, do you recognize this document?
A. Yes, I do.
MR. KASS: Your Honor, I'd like to move into evidence United States -- or Plaintiffs' Exhibit 1336, please.
THE COURT: Any objection?
MR. COOKE: No objection.
MR. ASHMORE: No objection.
THE COURT: Hold on just a second.
MR. KASS: Sorry.
THE COURT: Plaintiff 1336 admitted without objection.
Please proceed.
BY MR. KASS:
Q. And, Dr. Alam, this is a process and handling agreement with Singulex; correct?
A. Yes.
Q. Okay. Great.
And if we could turn to page 2, Peter. I just want to look at the signatures. Could we zoom in on those.
Okay. It appears to be signed at the top by Philippe Goix.
A. Yes.
Q. And were you aware that he was the president and CEO of

Singulex?
A. I don't remember it, but I'm sure he is.
Q. Fair enough. And underneath that, that is your signature; correct?
A. Yes.
Q. Okay. And you signed this on or around -- it looks like -- August 10th, 2010?
A. Yes, I did.
Q. Great.
Can we go back to the first page, Peter.
And it looks like -- if you zoom in on paragraph A -- this relates in part to a processing and handling fee of $10; correct?
A. Yes.
Q. Great. And let's go to that demonstrative that Mr. Cooke showed us earlier. I think that's PDX 14 or 15.
So, you know, just to get a sense of how the money adds up, if we --
Could we scooch that over a little bit to the right.
MR. PHANEUF: No.
MR. KASS: No?
MR. PHANEUF: Sorry.
MR. KASS: Okay. We'll make do.
BY MR. KASS:
Q. It appears to be here, sir -- please correct me if I'm

10:22AM wrong -- you received $122,000 -- or excuse me -- your practice
10:22AM received $122,634 in process and handling fees from Singulex
10:22AM between 2010 and 2013; right?
10:22AM **A.** Yes, it shows that.
10:22AM **Q.** Right. And I believe your testimony earlier was that you
10:22AM thought that was accurate?
10:22AM **A.** Yes.
10:22AM **Q.** Okay. And then if you look down a couple of rows, it
10:22AM appears to reflect that your practice received $409,473 between
10:22AM 2010 and 2014 from Health Diagnostic Laboratory; right?
10:22AM **A.** Yes.
10:22AM **Q.** And I believe it was your testimony earlier that that
10:22AM number appears to be accurate to you; right?
10:22AM **A.** Yes.
10:22AM **Q.** During your deposition, my colleague Mr. Leventis asked
10:23AM you what happens with this money with your practice. He asked
10:23AM you about the mechanics of how it was paid, and you testified
10:23AM that checks came into the practice and were deposited; correct?
10:23AM **A.** Yes.
10:23AM **Q.** And you testified that once deposited, the money would be
10:23AM used to pay overall expenses and employee salaries, including
10:23AM your own; correct?
10:23AM **A.** Right.
10:23AM **Q.** I'm sorry?
10:23AM **A.** Yes.

10:23AM **Q.** Yes. And you said -- and I quote -- "and after that, whatever the profits are generated goes to the owner of the practice"; right?
10:23AM **A.** Yes.
10:23AM **Q.** Right. And Mr. Leventis said, "Okay. So after expenses are paid, the rest goes to you as the owner?"
10:23AM And you answer "Yes."
10:23AM **A.** Yes.
10:23AM **Q.** And that's because you own 100 percent of the practice; correct?
10:23AM **A.** Yes, I do.
10:23AM **Q.** You own 100 percent of Keowee Practice?
10:23AM **A.** Yes.
10:23AM **Q.** And everything that I just said, does that sound about right to you?
10:23AM **A.** It does.
10:24AM **Q.** I'd like to talk about a couple of your other financial arrangements with Health Diagnostic Laboratory. Mr. Cooke asked you earlier about the medical advisory board that you were on with Health Diagnostic Laboratory?
10:24AM **A.** Yes.
10:24AM **Q.** And am I correct in saying that Health Diagnostic Laboratory paid you somewhere between 2,000 and $2,500 each month to serve on that board; is that right?
10:24AM **A.** Yes.

10:24AM 1 **Q.** And about how long were you on that board receiving 2,000
10:24AM 2 to 2,500 a month?
10:24AM 3 **A.** I don't exactly remember, but I'm sure they must have the
10:24AM 4 years.
10:24AM 5 **Q.** I believe you said in your deposition maybe two or three
10:24AM 6 years. Does that sound about right?
10:24AM 7 **A.** Maybe, yeah.
10:24AM 8 **Q.** And during that time, Health Diagnostic Laboratory was
10:24AM 9 paying you 2,000 to $2,500 a month?
10:24AM 10 **A.** Yes.
10:24AM 11 **Q.** Very briefly, talking about some of the tests that you
10:24AM 12 ordered from Health Diagnostic Laboratory, you worked with
10:25AM 13 Health Diagnostic Laboratory. You ordered tests from them
10:25AM 14 between about 2010 and 2014; correct?
10:25AM 15 **A.** Yes.
10:25AM 16 **Q.** And initially you ordered a pretty broad panel from them;
10:25AM 17 right?
10:25AM 18 **A.** The assessment panels, yes.
10:25AM 19 **Q.** And some of the tests that were on that panel that you
10:25AM 20 ordered from HDL were tests that you were also running
10:25AM 21 internally at your own laboratory inside your practice;
10:25AM 22 correct?
10:25AM 23 **A.** Yeah, we took those tests out from HDL so -- because we
10:25AM 24 were doing it ourself, so we started running it in our own
10:25AM 25 office.

10:25AM **Q.** Right.
10:25AM **A.** Because it's a moderately complex lab, you could do that. And -- yes.
10:25AM **Q.** Sir, please continue. I apologize.
10:25AM **A.** Go ahead.
10:25AM **Q.** Right. So just to put a finer point on that, so, at one point, you were ordering these broad panels of tests from Health Diagnostic Laboratory. And at the same time as you were ordering those broad panels of tests from Health Diagnostic Laboratory, some of those tests that were in those broad panels were tests that you were running in your own in-house lab; right?
10:26AM **A.** Yes.
10:26AM **Q.** Okay. And, eventually, you removed some of those tests from the HDL panel?
10:26AM **A.** Yes.
10:26AM **Q.** But not for a while; right?
10:26AM **A.** No, I think if we ran it, we removed it immediately, because we don't want to have the test running twice.
10:26AM **Q.** Well, that's interesting, because, in your deposition last year with my colleague Mr. Leventis, he was talking about some of those tests, and you said that those tests weren't removed from your panel until 2012 or 2013; isn't that right?
10:26AM **A.** Maybe there might be some misunderstanding or maybe there might have been a small overlap by the time the messages got

10:26AM through, but if -- the same test should not be done twice at two different places.
10:26AM **Q.** I agree, sir, but for a while there was an overlap, wasn't there?
10:26AM **A.** Maybe. I'm not sure about it, but maybe there was.
10:26AM **Q.** Okay.
10:26AM **MR. KASS:** No further questions. Thank you.
10:26AM **THE WITNESS:** I have one thing on that, the last thing that he showed on the computer.
10:27AM **THE COURT:** Go ahead. Put it up.
10:27AM **BY MR. KASS:**
10:27AM **Q.** Was this the Singulex --
10:27AM **A.** Yeah, Singulex and the HDL. And I wanted to clear this out with the jury and the judge. When you see those numbers up there -- can we go ahead and put it up?
10:27AM **THE COURT:** Just put it up.
10:27AM **THE WITNESS:** And when you see those numbers up there, these numbers are a period of four or five years. And if you look at each and every year, yes, there is payments of 17,000, 84,000 on there. You have to realize that, each year, these phlebotomists and these lab technicians, they are highly paid, and they are paid out. If you look at a five-year aggregate number, yes, it looks high, 409,000. But if you expense it out, there's not much profits in there. There's not much things what you're looking at.

10:27AM **BY MR. KASS:**

10:27AM **Q.** But there is some profit in there, isn't there?

10:27AM **A.** Well, it's a whole thing. I mean, the lab, everything else, there are other areas in our practice. There are 50 or 60 employees. There are other areas in our practice, like, we do x-rays. It is a money-losing business. We lose money on that. So there is -- I mean, it's going to be -- which is a little bit more profit, which compensates for it. But it is overall a care given in a -- a rural environment, where you have all these things available at one place to do that, and that's how you make the practice profitable. Otherwise, this practice was sinking.

There is some amount of profit, but not a whole lot of profit. And there are certain years where there is not much -- if you look at year 2010, I'm sure we lost money on that.

MR. KASS: Thank you, sir. No further questions.

THE WITNESS: Thank you.

THE COURT: Mr. Ashmore?

MR. ASHMORE: No questions, Your Honor.

THE COURT: Let me just ask you a question.

Would you put that chart back up just for a moment, please?

I see in 2012 and in 2013, under HDL, your practice received 104,000 in process and handling fees in 2012,

and 107,000 in 2013; is that correct?

THE WITNESS: Yes, sir.

THE COURT: Why does it drop to 65,000 in 2014?

THE WITNESS: I think they stopped paying the process and handling. And after that, we still continued. And we still continue using that. So it's really not the process and handling we're going after.

THE COURT: Thank you, sir. I appreciate the explanation.

Anything further occasioned by --

MR. COOKE: Nothing.

THE COURT: Very good. You may step down.

THE WITNESS: Thank you, Your Honor. Should I leave these papers here?

THE COURT: Yes, you can leave it right there.

(Witness excused.)

THE COURT: Call your next witness.

MR. GRIFFITH: Your Honor, we -- we call -- we have the option of doing a deposition or a witness. I don't know what -- if you prefer one or the other.

THE COURT: How long will the deposition take?

MR. GRIFFITH: We haven't timed it. I would think at least 30 minutes.

THE COURT: Let's take our morning break, if we could, please.

10:30AM (Whereupon the jury was excused from the courtroom.)
10:30AM **THE COURT:** Any matters we need to address? Please be seated.
10:30AM **MR. LEVENTIS:** Thank you, Your Honor.
10:30AM **THE COURT:** Let's take about a 10-minute break. And, Mr. Griffith, it's entirely y'all's call about who you call, how you do that.
10:30AM (Recess.)
10:49AM **THE COURT:** Please be seated. Who are you planning to do next?
10:49AM **MR. GRIFFITH:** Your Honor, BlueWave is going to call a live witness, Burt Lively.
10:49AM **THE COURT:** Good, a live witness named Lively.
10:49AM Any other matters we need to address?
10:49AM **MR. COOKE:** I have one thing, Your Honor.
10:49AM **THE COURT:** Yes, sir?
10:49AM **MR. COOKE:** I think we have maybe a -- an evidentiary issue brewing. All of the government exhibits that begin in what we call the 700 series that begin with a 7, those are all exhibits that were never identified on the pretrial disclosures. And the government evidently takes the position that exhibits that they use for cross-examination don't have to have been identified. And we don't agree with that.
10:49AM **THE COURT:** Well, let me say this: Exhibits that can be -- are used for impeachment do not have to be identified if

10:49AM you're -- if you're talking -- as potential exhibits.
10:50AM I presume they got them from -- how did they get
10:50AM these documents?
10:50AM **MR. LEVENTIS:** Yeah, for example, today, Your Honor,
10:50AM those were produced by BlueWave. That's what we're using.
10:50AM **THE COURT:** Right. I don't think you have to
10:50AM identify as an exhibit something for impeachment. That's not
10:50AM my understanding.
10:50AM **MR. COOKE:** I believe our pretrial order was to
10:50AM disclose all exhibits that you intend to use, and so --
10:50AM **THE COURT:** Well, you don't know whether you're going
10:50AM to use them until someone gets on the stand and says something,
10:50AM if you impeach them with it. I've never heard limiting
10:50AM impeachment because there's no way to forecast what somebody is
10:50AM going to say.
10:50AM **MR. COOKE:** If it's truly a surprise -- I mean, we
10:50AM identified every exhibit that we thought we might use.
10:50AM **THE COURT:** Well, first of all, you haven't objected.
10:50AM So I'm going to put --
10:50AM **MR. COOKE:** I'm not objecting so far.
10:50AM **THE COURT:** I understand, and I will say if it's used
10:50AM for impeachment, it's -- and it's based on something somebody
says on direct, they were not required to list it as an
exhibit. If something does not fall into that category, then I
think you have a legitimate point.

10:51AM **MR. COOKE:** Well, Your Honor, then, for the record, I would formally request that we be given any exhibits that the government presently believes it might use.

10:51AM **THE COURT:** No, that's not the way impeachment works, Mr. Cooke. That's -- I've never heard such a thing. You don't know until they speak. I can understand you would prefer to not have your clients impeached, but it goes both ways. You can impeach the government witnesses in the same way.

10:51AM **MR. COOKE:** Well, impeaching and surprising are two different things, and we have a lot of things in place to keep us from being surprised.

10:51AM **THE COURT:** Impeachment is different. Someone says something prior to a previous statement and -- you know, I take it all these have been documents produced by BlueWave? I mean, is that right?

10:51AM **MR. LEVENTIS:** Yes, Your Honor. The ones I have that I'm thinking of.

10:51AM **THE COURT:** You do not have to disclose documents -- someone gets on the stand, says something that a party believes is untrue, and you want to impeach him, you're not limited by the fact that you didn't disclose it previously.

10:51AM Okay. Let's bring in the jury.

10:53AM (Whereupon the jury entered the courtroom.)

10:53AM **THE COURT:** Please be seated. BlueWave, call your next witness.

10:53AM **MR. GRIFFITH:** Your Honor, BlueWave calls Burt Lively.

10:53AM **THE DEPUTY CLERK:** Please place your left hand on the Bible and raise your right. State your full name for the record.

10:53AM **THE WITNESS:** Robert Burton Lively IV.

10:53AM **THE DEPUTY CLERK:** Thank you.

10:53AM (Witness sworn.)

10:53AM **THE DEPUTY CLERK:** Thank you. You may be seated.

10:53AM **ROBERT BURTON LIVELY IV,**

10:53AM a witness called on behalf of the defendants, being first duly

11:03AM sworn, was examined and testified as follows:

10:53AM **DIRECT EXAMINATION**

10:54AM **BY MR. GRIFFITH:**

10:54AM **Q.** Good morning.

10:54AM **A.** Good morning.

10:54AM **Q.** I'm Joe Griffith. We met earlier. I represent Mr. Cal

10:54AM Dent, Mr. Brad Johnson, and BlueWave.

10:54AM **A.** Yes, sir.

10:54AM **Q.** Can you tell the jury your name for the record, please?

10:54AM **A.** I'm Robert Burton Lively IV. Everybody calls me Burt.

10:54AM **Q.** And I know you've been having some coughing spasms.

10:54AM **MR. GRIFFITH:** So, Your Honor, we would just warn

10:54AM everybody in advance.

10:54AM **THE COURT:** I think we have a ready supply of cough

drops. I think we've established that.
BY MR. GRIFFITH:
Q. Correct. So, Mr. Lively, tell me a little bit about your background. Are you married?
A. Yes, sir. Married. Been married for 20 -- 23 years. I have a 19-year-old son who's in college. He's on a baseball scholarship. I have a 17-year-old daughter who is still in high school. She's a softball scholarship and an academic scholarship. I have a 12-year-old daughter I hope is going to be the best of the bunch.
Q. All right. Good job. Where are you from?
A. I'm originally from Rome, Georgia. I live in Birmingham, Alabama, now.
Q. And how long have you lived in Birmingham?
A. I lived in Birmingham since the year 2000.
Q. And tell us a little bit about your education, starting in college.
A. Yes, sir. I -- I went to Auburn University, started in 1987. I graduated there in 1991. I played football down there for four years. I was Mr. Johnson's understudy.

And then when I graduated from college, I went to work back home in Rome, Georgia, for my grandmother and worked there for a couple of years, got some sales experience in cars and then in pharmaceuticals. I started in the pharmaceutical business in 1993.

10:56AM 1 And I worked for several pharmaceutical companies.
10:56AM 2 The big ones were Bristol-Myers Squibb, where I worked for, I
10:56AM 3 guess, roughly 11 years. And then I went to work for
10:56AM 4 Schering-Plough pharmaceuticals and worked there for a couple
10:56AM 5 of years. Those I worked in sales and sales management, was
10:56AM 6 involved in cardiovascular metabolic sales literally since
10:56AM 7 1993.
10:56AM 8 In 2007, I went to work for Berkeley HeartLab,
10:56AM 9 selling advanced cardiovascular diagnostic tests. And then in
10:56AM 10 2010, I went to work with BlueWave, representing HDL and
10:56AM 11 Singulex, and --
10:56AM 12 **Q.** Okay. Let me stop you there. So you said you worked
10:57AM 13 with -- in pharmaceutical sales with Bristol-Myers and
10:57AM 14 Schering?
10:57AM 15 **A.** Yes, sir.
10:57AM 16 **Q.** And what type of sales were you involved with in those two
10:57AM 17 organizations?
10:57AM 18 **A.** Well, I was originally a sales rep and then a specialty
10:57AM 19 rep in cardiovascular metabolic sales. Then I managed --
10:57AM 20 **Q.** And what is that? Metabolic --
10:57AM 21 **A.** Well, the main drugs that I was responsible for was
10:57AM 22 Pravachol, which was a cholesterol reducer, and then
10:57AM 23 Glucophage, and then the whole Glucophage family that came out
10:57AM 24 of it, spawned out of that, to treat type 2 diabetics and
10:57AM 25 metabolic disease.

10:57AM **Q.** And was that with both Bristol and Schering?
10:57AM **A.** With Schering, I actually had a product called Vytorin. It was a combination of Zocor, which was a lipid-lowering medicine, and Zetia, which was another lipid-lowering medicine in another category. And then various blood pressure, asthma, antibiotics along the way as well.
10:58AM **Q.** And so approximately when -- you said you worked at Berkeley HeartLab?
10:58AM **A.** Yes, sir.
10:58AM **Q.** Okay. Approximately when did you start at Berkeley HeartLab?
10:58AM **A.** I think that was in 2007, maybe towards the end of 2007.
10:58AM **Q.** And approximately how long were you at Berkeley HeartLab?
10:58AM **A.** Until December of 2009. So the first of 2010, that time frame.
10:58AM **Q.** And what was your role at Berkeley HeartLab?
10:58AM **A.** I was a sales representative to -- actually, I was sort of a helper for -- for Brad, Mr. Johnson. He had a large territory, had responsibility for a lot of docs, and so they asked me to come in and help him manage that. But I had the same responsibilities. I was selling advanced cardiovascular diagnostic tests.
10:59AM **Q.** Okay. And did you have a territory of your own at Berkeley?
10:59AM **A.** Well, we shared the same territory. It was the

10:59AM southeastern United States. It was Alabama, Mississippi, sort
10:59AM of the panhandle of Florida, and went a little bit into
10:59AM Louisiana, just sort of right around New Orleans.
10:59AM **Q.** Okay. So that was about two and a half states?
10:59AM **A.** The equivalent of about two and a half states, yes, sir.
10:59AM **Q.** Okay. And just kind of generally, what type of lab tests
10:59AM did BHL have while you were there? When I say BHL, I'm talking
10:59AM about Berkeley HeartLab.
10:59AM **A.** Berkeley HeartLab, yes, sir. So we sold a panel of
10:59AM advanced cardiovascular diagnostics that went above the
10:59AM standard lipid panel. And the reason we did is because, you
10:59AM know, people -- 50 percent of people drop dead of heart attacks
11:00AM with perfectly normal cholesterol. So what we wanted to do was
11:00AM we wanted to go above and beyond to try and see exactly what
11:00AM was causing, you know, that to happen.
11:00AM So Berkeley had a panel of tests that looked at
11:00AM different subfractions of LDL and HDL, which are bad and good
11:00AM cholesterol particles, distant inflammatory markers, distant
11:00AM genetic markers just to basically undercover the underlying
11:00AM risk of heart disease. Almost like cancer. Most people catch
11:00AM cancer, it's Stage 3 or Stage 4. And that's why people don't
11:00AM have a good survival rate because you catch it so late. Same
11:00AM thing with cardiovascular disease. Most people don't even find
11:00AM out they have cardiovascular disease until they have a heart
11:00AM attack or a stroke.

11:00AM And so what we're trying to do is just uncover heart
11:00AM disease at the early stages. And so that's what they did at
11:00AM Berkeley.
11:00AM **Q.** Okay. And what did you do to familiarize yourself with
11:00AM the Berkeley HeartLab testing?
11:01AM **A.** Well, there was pretty extensive training. There was like
11:01AM two weeks of training out in California where you are away from
11:01AM your family and, you know, you go through, you know, all --
11:01AM all-day classes of looking at what all these diagnostics are.
11:01AM But then over a period of the next -- well, in the
11:01AM past I'd been to a lot of medical education programs with the
11:01AM pharmaceutical companies, learned a lot about the
11:01AM cardiovascular system, so on and so forth.
11:01AM But with Berkeley, they had a lot of medical
11:01AM education programs that I would go to and I'd sort of listen
11:01AM and learn, and I say that I learned a lot through osmosis, just
11:01AM taking notes and going to these speaker programs and learning
11:01AM exactly what the heck all these tests were.
11:01AM And so, in addition to the formal training, there was
11:01AM a lot of ongoing training of going to -- going to the speaker
11:01AM programs and even, you know, the -- looking at things on the
11:01AM internet and reading and going to medical education programs
11:01AM that weren't even sponsored by Berkeley but included a lot of
11:01AM information on diagnostics.
11:02AM **Q.** Okay. Did you do any ride-alongs, what we've been --

heard of as ride-alongs with anybody?
A. Yes, sir. I spent some time -- when I first started with Berkeley, I spent three or four days in the field riding around with Brad just to show me, you know, what his -- his normal day looked like.

And then I went over to -- I can't remember if it was South or North Carolina, and I rode with Cal as well, sort of get an idea about how he did it, because they were -- they were the leaders in -- in Berkeley. So they -- I think Berkeley had a lot of new salespeople go ride with them to sort of see how -- you know, how you need to sell the product.
Q. Was Brad successful as a salesman at Berkeley?
A. As far as I know, I mean I -- you know, I couldn't -- you'd have to go look at the sales numbers, but, you know, he's -- he did well when I saw him, and our numbers -- you know, we shared the numbers, so, I mean, we were -- we were at or around the top, you know, sales performers at Berkeley.
Q. And what about Mr. Cal?
A. Mr. Dent was always a little bit behind us.
Q. Now, with -- without going into too much detail, because I want to focus on your time at BlueWave, but just generally what was your sales approach when you met with a doctor at Berkeley?
A. So I sort of started it the way that I said a while ago. You know, the first thing that we did was our -- I always sold completely off of our test report. And so I would show the

11:03AM standard lipid panel looking at LDL and HDL, and I would
11:03AM explain to whoever I was speaking with that 50 percent of
11:03AM people drop dead of heart attacks with perfectly normal
11:03AM cholesterols.
11:03AM I'll say the average LDL of cholesterol of a patient
11:03AM in coronary care right now, in CCU, post-heart attack in the
11:04AM United States of America right now, is 126 milligrams per
11:04AM deciliter. Well, the NCP guidelines say -- I know it's a lot
11:04AM of detail, but it's really important. The NCP guidelines say
11:04AM that if you have never had a heart attack before, the goal is,
11:04AM like, 150 or 160.
11:04AM So it's confounded clinicians through the years of
11:04AM why people are having heart attacks with perfectly normal
11:04AM cholesterols. So it's almost like the Titanic. It wasn't the
11:04AM tip of the iceberg sunk the Titanic; it was everything that was
11:04AM below the surface.
11:04AM And at that point I would have the test report
11:04AM covered at the top, just looking at the standard lipid panel;
11:04AM and then I'd flip it over, and, you know, the tests were easy
11:04AM to read. They were color-coded red, green, and yellow. You
11:04AM know, red is bad, green is good, and yellow is caution. So it
11:04AM was designed for the patients to -- and doctors to easily
11:04AM understand what were the dangers.
11:04AM So when you open that up, the problem is is a lot of
11:05AM people have underlying heart disease and they don't even know

it. Like I said, most people, the first symptom is heart attack.

Q. Okay.

A. So there were advanced markers, like I said, subfraction issues of good and bad cholesterol. There were advanced inflammatory markers. There were some -- some, you know, heart elasticity markers. There were some genetic markers. And all that was confounded at the bottom because it was all red below.

And so I would go line by line with the physicians. Normally my presentation took about an hour to review every diagnostic line by line. What -- what was the diagnostic? What did it mean? What did it tell you? What were the underlying causes of the abnormality? And then finally what were the treatment considerations? So what were your options when you did that?

Q. Okay. And that was all at Berkeley?

A. Yes, sir.

Q. Okay. Now, did Berkeley offer reimbursement to doctors in the form of process and handling fees?

A. Yes, sir, in lieu of a phlebotomist.

MR. GRIFFITH: Okay. And I want to bring up BlueWave 135, which is already admitted, Your Honor.

THE COURT: Okay.

BY MR. GRIFFITH:

Q. And we want -- and while you were at Berkeley, were you

11:06AM familiar with the process and handling fees compliance bulletin?
11:06AM **A.** I've seen this before, yes, sir.
11:06AM **Q.** Okay. And at the -- when you saw that, did that give you comfort at the time that what you were doing in terms of process and handling was lawful?
11:06AM **A.** Yes, sir.
11:06AM **MR. LEVENTIS:** Your Honor, if I could object to the leading nature of the questions.
11:06AM **THE COURT:** Rephrase the question not lead, Mr. Griffith. I know you're trying to move it along here, but rephrase.
11:06AM **BY MR. GRIFFITH:**
11:07AM **Q.** Did you experience any comfort from knowing that this corporate policy --
11:07AM **THE COURT:** No. In reviewing this --
11:07AM **BY MR. GRIFFITH:**
11:07AM **Q.** In reviewing this, how did it affect you?
11:07AM **A.** I mean, that would give me a lot of comfort knowing that -- I mean -- I mean --
11:07AM **THE COURT:** That's exactly why we don't allow leading questions.
11:07AM **THE WITNESS:** I don't know what you want me to say. I mean this tells me -- I mean, I'm not a lawyer. So, I mean, I'm a sales guy. So when I sit there and hear -- see from my

11:07AM corporate -- you know, the company that I work for telling me
11:07AM all this information about this -- these process and handling
11:07AM fees, you know, I don't even give a second thought to it. I'm
11:07AM like, well, everything is good.
11:07AM **BY MR. GRIFFITH:**
11:07AM **Q.** Okay. And did you rely on this policy?
11:07AM **A.** What do you mean by "rely on this policy"?
11:07AM **Q.** In terms of it. Just in terms of your --
11:07AM **A.** I'll -- you know, to be perfectly clear, I spent very
11:08AM little time talking about process and handling. It was always
11:08AM at the end of my discussion. And so, I mean, I didn't really
11:08AM give it a second thought, honestly.
11:08AM **Q.** Okay. And on the bottom of this is a -- is an individual
11:08AM named Jonathan Wolin. Do you see that?
11:08AM **A.** Yes, sir.
11:08AM **Q.** And who was that?
11:08AM **A.** That was the lawyer, the compliance lawyer for -- for
11:08AM Berkeley HeartLab.
11:08AM **Q.** Okay. Let's go to Mallory Exhibit 42, already admitted.
11:08AM Go to the second page. And while you were at Berkeley,
11:09AM Mr. Lively, did you have an opportunity to review this
11:09AM particular legal opinion?
11:09AM **A.** I couldn't say whether or not I actually read that, no.
11:09AM **Q.** Okay.
11:09AM **A.** No, sir.

11:09AM **Q.** So did you receive any -- what we call compliance training
11:09AM while you were at Berkeley?
11:09AM **A.** Yes, sir.
11:09AM **Q.** Okay. And what did that comprise of?
11:09AM **A.** It was typical of any company's compliance training. I
11:09AM mean, it was an online -- you know, you had online assessments
11:09AM from time to time. You reviewed, you know, all the different
11:09AM policies, and normally there was a graded test at the end.
11:09AM **Q.** Okay.
11:09AM **MR. LEVENTIS:** Your Honor, I'm sorry. Can we take
11:09AM the exhibit down?
11:10AM **THE COURT:** Yes. Please take it down.
11:10AM **BY MR. GRIFFITH:**
11:10AM **Q.** And the compliance training that you received, did it
11:10AM include Anti-Kickback Statute training?
11:10AM **A.** Yes, sir.
11:10AM **Q.** What about False Claims Act training?
11:10AM **A.** Yes, sir.
11:10AM **Q.** Okay. Stark training?
11:10AM **A.** Yes, sir.
11:10AM **Q.** And did -- had you received similar compliance training
11:10AM while you were at Bristol?
11:10AM **A.** Constantly.
11:10AM **Q.** What about Schering?
11:10AM **A.** Constantly.

11:10AM **Q.** Okay. So when you were at these two pharmaceuticals and Berkeley, how were you compensated?
11:10AM **A.** I was paid a salary plus a commission at all of them.
11:10AM **Q.** Okay. Now, you said that you left Berkeley in the end of 2009; is that correct?
11:10AM **A.** Yes, sir. We actually left at the first of 2010, but it was -- I think December 31st was our last day.
11:11AM **Q.** Okay. So how did that come about?
11:11AM **A.** Well, Berkeley had a policy in my territory of not -- of balance-billing patients, which basically meant that they extended Medicare courtesies to all patients, regardless of what insurance they had. So they accepted whatever assignment was, whatever the insurance paid as payment in full. So patients didn't get a bill.

In -- I'm thinking it was 2008, Celera purchased -- which is a large genomic company -- purchased Berkeley HeartLab. So Berkeley HeartLab -- at that time I guess Celera's accountants went in and said, "Hey, we're leaving so much money on the table by not billing patients these differentials, we need to go and try to recoup some of that money."

Now, some of that money, you got to understand, was where the insurance company had actually paid the patient directly. So what Berkeley did was Berkeley started sending bills to all our patients, regardless, for the past two or

three years. That destroyed my credibility in physician offices.

Q. How so?

A. Well, because when I walk into a doctor's office that I've been telling for, you know, two years that, "Hey, you can run these tests and patients are not going to have any out-of-pocket expenses," because they didn't have in-network arrangements with anybody, you know, they believed me.

I mean, I've been in this business for 25 years, so, I mean, a lot of these doctors I've known. And so I tell them that, and then all of a sudden patients start getting $3,000 bills from three years ago. That hurts. And I didn't have an answer for it.

And Berkeley never provided us with a clear answer. We gave them recommendations of what they could do to help minimize the circumstance, but I started losing business left and right. I was going to get laid off if -- if we didn't leave and do something different.

And so that's where we decided that we were -- you know, that we were going to go out and actually do something different.

Q. Okay. When you say "we," who is we?

A. Mr. Johnson and Mr. Dent, Mr. Yunger, Mr. Carnaggio, and myself.

Q. All of these folks were at --

11:13AM **A.** Berkeley HeartLab.
11:13AM **Q.** -- Berkeley at the time?
11:13AM **A.** Yes, sir.
11:13AM **Q.** Okay. So did you know -- well, how did your relationship with BlueWave start specifically, contractually?
11:13AM **A.** Well, contractually, Brad and Cal started BlueWave, and they just hired me as an independent contractor.
11:13AM **Q.** Okay.
11:13AM **A.** You know, they were going to take the financial -- and they were going to take the risk, and I was just going to be a contractor like anybody else that they would ever bring on. My company would be, I guess I should say.
11:14AM **Q.** Okay. And so when you joined in -- and approximately when did you join the BlueWave?
11:14AM **A.** We -- it was literally January 1st of 2010.
11:14AM **Q.** And you said that you were an independent contractor?
11:14AM **A.** Yes, sir. My company, RBLIV Consulting, was an independent contractor for BlueWave.
11:14AM **Q.** Okay. Now, when you started out in January of 2010, what other -- to your knowledge, who were the other sales representatives at BlueWave?
11:14AM **A.** The contractors, or the people that ran the companies, were myself, Richard Yunger, and Tony Carnaggio. And then Brad and Cal, like I said, owned BlueWave. They were salespeople too. I mean, they didn't just sit around and run the company.

I mean they went out in the field and sold like a -- like the rest of us did.

Q. Okay. And so did -- did you have a territory?

A. I guess you could call it that.

Q. Okay.

A. It was --

Q. Explain.

A. Well, keep in mind with Berkeley, I had basically two and a half states. With BlueWave/HDL, I had -- I had 48 states. Cal and Tony covered South Carolina and part of North Carolina, and pretty much I had the rest --

Q. Okay.

A. -- along with Mr. Johnson and Mr. Yunger.

Q. When you said you had 48 states, which two states did you not have?

A. South Carolina and North Carolina. We stayed out of Cal and Tony's way.

Q. Okay. So under the BlueWave independent contractor agreement, how were you compensated?

A. I was paid a percent of sales.

Q. And what -- when you first started at BlueWave, whose product were you marketing?

A. We were marketing HDL's product at the time starting out.

Q. Okay. And did there come a time when you began marketing another lab?

11:16AM **A.** We marketed Singulex's product. I can't recall the specific time frame, but it was after we had been selling HDL's testing for a while.
11:16AM **Q.** Okay. So did -- when you first got there with BlueWave, did you receive any sales training?
11:17AM **A.** Well, not -- not really because we -- you know, the whole situation was that we just took exactly what we were doing at Berkeley and just started doing it for HDL. It's like cars. I mean --
11:17AM **Q.** Did -- did BlueWave at some point start hiring other independent contractors?
11:17AM **A.** Yes, sir.
11:17AM **Q.** Okay. And did you undertake to provide those new sales reps with training?
11:17AM **A.** Yes, sir. I was one of the -- one of the trainers. What happened was when they would bring a new contractor on, they would require that contractor to get on a call with me. And, in essence, I would spend -- I would role-play with them. I would talk about, you know, these are -- you know, this is how you go about your day. This is how you present the test. This is line-by-line verbatim, you know, what to know about all the diagnostics.

And, you know, those went on with every contractor for around two hours, is how long each one of those calls took. But keep in mind a lot of these people we hired already had a

wealth of cardiovascular sales experience. A lot of them actually sold for other advanced cardiovascular labs too.

Q. Okay. Well, just in 2010, how many other advanced cardiovascular labs were you familiar with?

A. Well, there was Berkeley. There was Atherotech. There was Boston Heart lab. There was Cleveland HeartLab. There was, you know, several other smaller labs that did similar testing as well.

Q. Okay. To your knowledge, did these other labs pay P&H reimbursements?

A. Every one of them.

Q. Okay. Now, we talked about your sales approach at Berkeley. Tell us about your sales approach while you were at BlueWave.

A. Virtually identical. Like I said, I mean, we took a Chevrolet car and pulled the emblems off and put a Ford emblem on it and sold it as a Ford. I mean, it was basically the same test. There were a few differences, there were a few adds, a few subtracts.

So, you know, it was a few different diagnostic tests, but for the most part it was the same presentation. It was people are dropping dead of heart attacks. Perfectly normal cholesterols. Looking at the bottom and looking at all the other abnormalities and reviewing line-by-line verbatim.

Docs always ask me, "How long is this going to take?"

11:19AM 1 I said, "It depends how many questions you got."
11:19AM 2 I mean, it could take minimum of 45 minutes; it could
11:20AM 3 take two and a half hours. I mean, I spent whole afternoons
11:20AM 4 reviewing all the diagnostics associated with the test.
11:20AM 5 **Q.** Well, with specific respect to the HDL lab tests, what
11:20AM 6 kind of diagnostics did you or clinical aspects did you discuss
11:20AM 7 with the doctors?
11:20AM 8 **A.** Well, like I said, it was the same one, with the exception
11:20AM 9 that we -- you know, had a little bit -- a few more tools. We
11:20AM 10 had some more advanced inflammatory markers so that we could
11:20AM 11 talk about how your body is always inflamed and that's what
11:20AM 12 causes disease.
11:20AM 13 We had a few more heart risk markers and a few more
11:20AM 14 genetic markers that basically could target the exact treatment
11:20AM 15 for -- you know, for different medicines.
11:20AM 16 **Q.** Okay. Did you use clinical case studies in your clinical
11:20AM 17 discussions with the doctors?
11:20AM 18 **A.** Exclusively.
11:20AM 19 **Q.** Okay. Let's bring up Mallory 57, which is in evidence.
11:21AM 20 And do you see up on the top it says -- top left, it
11:21AM 21 says "Case Study Number 1"?
11:21AM 22 **A.** Yes, sir.
11:21AM 23 **Q.** Okay. Tell us how you would use this particular -- this
11:21AM 24 or similar case studies in your presentation to physicians.
11:21AM 25 **A.** So, I mean, this is a primary example. I mean, this is

a -- this is a very good lipid panel. As I have said before, 50 percent of people drop dead of heart attacks with this lipid panel.

If you go to a doctor that -- and most doctors, you got to remember, don't even do this type of testing. I mean, it's about 1 percent of the doctor population.

But if you look at this, most doctors aren't going to treat, they're not even going to say that there's anything wrong with this person right here because the total cholesterol is below 240 -- or excuse me -- below 200, LDL cholesterol is below 100, and the HDL cholesterol is basically double what, you know -- what the optimal range is. The triglycerides are normal, and the non-HDL cholesterol is normal.

So this is a patient that you would not think would have any risk of cardiovascular disease.

Q. Okay. And what would you point out to the physician regarding this case study that would give them assurance that what the lab tests that you were -- that HDL was providing was useful?

A. Well, what I would do is right there, as you see the rest of it, is I would open up the bottom and say, but it's not the tip of the iceberg that sunk the Titanic; it was everything below the surface.

And so then I would go down here, and I would review why this ApoB and LDL particle intermediate risk is actually

showing the early stages of cardiovascular disease. I'd also look down here at the Lp(a) mass, and tell physicians, say, "Look, Lp(a) is an endocrine risk factor for cardiovascular disease. This is the reason why people are dropping dead of heart attacks, because Lp(a) mass and Lp(a) cholesterol, you know, actually is an indicator that you have -- you have underlying cardiovascular risk. This is a clotting factor. This is what back, you know, years ago, they thought it was good to have high Lp(a) because your blood would clot and scar up, especially if you got cut. But this actually happens inside the vessels. So, you know, this Lp(a) mass is a big deal. And it needs to be treated in order to reduce this patient's risk.

Q. Were there any other aspects of -- of this particular case study that you focused on?

A. Well, the one I always focused on in particular -- and it's not even -- it's not elevated in this situation -- but it's this NT-proBNP. It's a $4 test that is a prognostic marker of abnormal stress on your heart. When that number gets elevated to above 125, which 39 percent of the general population have abnormal NP-proBNPs, and that is a death marker at one year.

So even though it's not elevated in this case, in the case that that was, then I always point to that NT-proBNP, whether it's elevated or not, and tell the doctor and say,

"Look, when you review these tests, keep in mind it's color-coded red, green, and yellow so that you can eyeball this from a distance and not -- and actually be able to make an assessment when it's going across your desk. If that NT-proBNP, and I'd train your eye to look down at this NT-proBNP." I said, "If that's elevated, all this stuff on this test is not going to kill you tomorrow except for that one right there, because if that one right there is elevated, you got a problem and you need to bring that patient back in."

So I always called attention to NT-proBNP.

Q. Did you find the case studies useful in your presentations?

A. Absolutely, because this is what the doctor is going to see when they start running the rests.

Q. Okay. So let's pull up Mallory 44.

This has already been admitted, Your Honor.

Mr. Lively, can you tell us in general terms what this is?

A. That's the new account form slash-- yeah, that's the new account form.

Q. Okay. For HDL?

A. For Health Diagnostic Laboratory, yes, sir.

Q. Now, did you -- when you made your presentation to the doctors, did you go over this form with them?

A. Well, first of all, you know, sales 101, I'm going to try

11:26AM to sell the doc on my product and service first. So when the
11:26AM doctor would agree that he would -- he or she would likely do
11:26AM that type of testing in their practice, then, you know, I would
11:26AM move -- you know, I would move on and start talking about how
11:26AM we're actually going to order that. And then if they agree
11:26AM that this is actually something they were going to do, then we
11:26AM would fill out this form.
11:26AM **Q.** Now, if you scroll down the form. And it has the
11:26AM assessment panel, custom assessment panel, and the follow-up
11:26AM panel.
11:26AM **A.** Yes, sir.
11:26AM **Q.** Do you see that?
11:26AM Was a doctor required in any way to order any
11:27AM particular number of tests?
11:27AM **A.** No, sir. Most times, what doctors would ask me, is they'd
11:27AM say, "Well what is an HDL panel?" And my answer has always
11:27AM been, "Whatever you want it to be. It could be as many tests
11:27AM or as few a tests as you want. It needs to be what you find
11:27AM valuable in your practice."
11:27AM So I had doctors that use the standard assessments.
11:27AM I had doctors that used custom assessments. I had doctors that
11:27AM used anywhere in between. So --
11:27AM **Q.** Now, did HDL offer reimbursement to physicians who
11:27AM actually drew the blood?
11:27AM **A.** Like a process and handling fee?

11:27AM **Q.** Correct.
11:27AM **A.** Yeah, in lieu of a phlebotomist, just like Berkeley.
11:27AM **Q.** Okay. Well, did you ever go to a doctor and just say, "We'll pay you $20 to order a lab test"?
11:28AM **A.** Not that I ever recall. That would be suicide.
11:28AM **Q.** Why is that?
11:28AM **A.** Like I said, I mean, it's sales 101. I mean, you never -- it doesn't matter if you're selling pencils or you're selling anything. I mean, you sell your product and you sell your service. You don't talk about how much something costs or how much you're going to get reimbursed or how much you're going to get paid. That's a loser. I mean, you have to sell people on yourself and your service and your -- and your product. If you don't, it's all built on sand.

11:28AM I mean, they'll do things for a while for -- for, you know, whatever the monetary purpose is. But, you know, after that, I mean, somebody else is going to come in with something bigger and better. So you got to sell yourself and your product and your service.

11:28AM **Q.** Now, you talked about the Singulex lab that you ultimately represented.
11:28AM **A.** Yes, sir.
11:29AM **Q.** Was it a similar approach to what we just talked about in terms of explaining to the potential physicians what the efficacy or reasons why they should order the Singulex test?

11:29AM **A.** It was similar, yes, sir.
11:29AM **Q.** Okay. And did you educate yourself on the efficacy of the Singulex test in order to make representations to the doctors?
11:29AM **A.** Yes, sir. It was a little more in-depth.
11:29AM **Q.** And how so?
11:29AM **A.** Well, it was -- the main test was cardiac troponin I, which is the same test that if you go into the ER right now with chest pain, they're going to -- they're going to run a cardiac troponin I. And that's going to tell a doctor whether or not you're having an actual heart attack or not.

The problem is is that's measured to a hundredth of a gram. And Singulex's test measured the same thing, but it measured it to a trillionth of a gram. So it's much more specific. But when you go to a doctor's office and you say, "Hey, look, this is this great test that can predict a heart attack 6 to 18 months out," they like that. They like to hear that. They're like, "Oh, that's great." But the problem is is when they saw that a troponin I was elevated, they couldn't tell the difference. It's just -- they were like, "Well, I've got to get them to the cath lab."

I'm like, "No, no, no, no. You got to remember, it's a lot more sensitive."

So, you know, I think that everybody that knows me in this courtroom said that I was a terrible Singulex salesman because it was just very in-depth and it was hard for people to

11:30AM understand how sensitive that test was -- for me. I mean, I
11:30AM just wasn't very good at it.
11:30AM **Q.** Okay. And did Singulex also offer reimbursement in the
11:30AM form of P&H fees?
11:30AM **A.** Yes, sir, in lieu of a phlebotomist once again.
11:31AM **Q.** So just kind of as a general understanding, what was your
11:31AM general understanding of the purpose of the processing and
11:31AM handling fee?
11:31AM **A.** The process and handling fee, as I understood it, was
11:31AM designed to reimburse for the time and effort that it takes to
11:31AM collect the blood, process the blood, fill out the paperwork,
11:31AM pack it up, and send it out to FedEx. It's -- I mean, it's --
11:31AM it's -- it's a complicated process. It takes a long time to do
11:31AM them. I mean, it takes -- you know, 45 minutes has been my --
11:31AM you know, my estimation of how long it actually takes to
11:31AM actually do all that stuff.
11:31AM **Q.** Well, in your mind, was any purpose of the P&H fee to
11:31AM induce a doctor to order a lab test?
11:31AM **A.** No, sir.
11:32AM **Q.** Were the doctors with -- who became your clients satisfied
11:32AM with the HDL and Singulex lab tests?
11:32AM **A.** Extraordinarily was the way that I took it. I mean,
11:32AM doctors told me all the time they're so thankful that I was
11:32AM able to bring this life-saving technology into their practice.
11:32AM **Q.** Okay. Did any of them -- did any doctors express their

opinion that it saved lives?
A. All the time, multiple examples.
Q. So there were -- did there come a time when you were asked to write up a pro -- what they call a pro forma for any practice?
A. Never asked -- oh, for a practice? I was never asked to create any kind of pro forma in terms of the actual document. It -- I had a document that I had with Berkeley that was a pro forma document that was approved and distributed to everybody.
Q. Okay.
A. And I edited that and -- you know, for use when people asked me how to run a lipid clinic.
Q. Well, let's go to USA Exhibit 1099. And can you see that the date is September 23rd of 2010?
A. Yes, sir.
Q. And it's from you to Brad Johnson and Sonja Stafford?
A. Yes, sir.
Q. Okay. And in the -- the paragraphs that start out to Lori Mallory. Who is that?
A. I've never met Lori Mallory. She's a CEO of -- he or she is the CEO of Kansas City Internal Medicine.
Q. Okay. The -- and let's go over this.

It says, "Dear Ms. Mallory: My name is Burt Lively. I'm a colleague of Brad Johnson. He asked me to provide you with a lipid clinic pro forma based on your discussion. This

pro forma is based on several assumptions. First, the average physician does 30 to 35 lipids per week. Based on your physician count of 25, that would be 750 to 875 lipid panels per week."

And it goes through various numbers throughout the paragraph; right?

A. Yes, sir.

MR. GRIFFITH: And so let's go to the next page. One more down.

BY MR. GRIFFITH:

Q. Okay. And so was this -- when you were making reference to the numbers, was this the chart -- or the pro forma that you were referencing?

A. Yes, sir. This is the one that I simplified from Berkeley's pro forma.

Q. Okay. So let me understand just kind of the general nature of what was going on. Had, to your knowledge, you or Brad presented this pro forma to this practice prior -- at the time of meeting or the presentation?

A. No, sir. I used this pro forma a couple of times. And it was only when a doctor said, "Hey, look, can you show me what the numbers are in running the lipid clinic?" And I wasn't at that meeting.

I remember -- I remember the call with Brad vividly, because I had to laugh out loud at the numbers that they were

wanting quoted.

Q. Okay. And so you said you had created two or three of these pro formas in your five years at BlueWave; correct?

A. Yes, sir.

Q. And so explain to us what a lipid clinic is.

A. Well, a lipid clinic is when a physician does any kind of cardiovascular testing, and then, as a follow-up -- you know, the thing with whenever you do advanced testing, y'all -- everybody has seen that test. You can't just call in the results back to the patient; you got to bring them back in.

And then, a lot of times, as I said, the diagnostics indicate that you have to change medicine. And it normally takes about 40 to 45 minutes when you go back and have this discussion with your physician. So you run the rest, and then you have the patient come back in in three or four weeks for follow-up. And it's an ongoing-type program. And that's called a lipid clinic. And, you know, people run these all over the country whether they really know that they're running it or not.

Q. Okay. Well, did you ever -- in the two or three times that you created such pro formas, was it always involving a potential lipid clinic?

A. Like I said, the only time that I would ever do this was when somebody asked, "How do I run a lipid clinic and what are the numbers?"

11:38AM **Q.** Okay. So you never went into an office and put a pro forma down on the table and said, "This is why you should start using HDL and Singulex lab tests"?

THE COURT: Is there objection?

MR. LEVENTIS: Objection, Your Honor.

THE COURT: Leading?

MR. LEVENTIS: Yes, Your Honor.

THE COURT: Sustained. Restate the question.

BY MR. GRIFFITH:

Q. Did you -- what did you do in terms of making presentations involving pro formas?

A. Like I said, it was only when a physician asked for it.

Q. Well, in this particular case, who provided the numbers which were inserted into the assumptions of this pro forma?

A. I think if you look back at the email, they gave me the numbers that they wanted me to figure it on. And the numbers were so ridiculous that I brought them down to even 200, which is -- like I said, I laughed about it because if this customer had ever done that, they would be the biggest customer in the history of advanced cardiovascular diagnostics.

Q. Okay. And so if you would go up to the first paragraph.

So all the numbers that are referenced in terms of the -- the underlying numbers that were used were -- who provided those?

A. The account provided the number of doctors and the

approximation of specimens to Mr. Johnson, and he relayed it to me and told me to put it in the lipid clinic format for their review.

Q. Okay. Well, was this pro forma effective?

A. No, sir.

Q. Why not?

A. It's too complicated. I mean, doctors -- doctors want to do things that are -- that fit into their practice and the way that they've been practicing medicine. This was -- even though, you know, they think that they want to do something different, when they see what they actually have to do, it's just too complicated. They just -- it was a complete failure. I don't even know if this account ever even sent a test in.

Q. To your knowledge, of the pro formas that you had drafted, did any of the doctors sign up with HDL or BlueWave or Singulex?

A. Never. It was a complete failure and I threw it away.

Q. Okay. Did you consider the pro forma as an inducement to the doctor or the doctor's practice?

A. No, sir.

Q. Now, you talked about no-balance billing previously. Do you recall that?

A. Yes, sir.

Q. And just in a nutshell, explain what no-balance billing is.

11:41AM **A.** So no-balance billing, when a provider -- doesn't necessarily have to be a laboratory. When any provider bills out to an insurance plan, they have a -- like, an MSRP, a retail price. And so let's say that that test, the retail price on that test, is $1,000. And when they submit that $1,000 and insurance comes back and they -- they pay $100, under a balance billing deal, you would actually pay -- have charged the patient for the difference between the retail price and the reimbursed price. So you'd get a bill -- a patient would get a bill for $900.

Now, likewise, under actual-balance billing, if you had another test on there that retailed out at another $1,000 and the insurance company just denied it altogether at zero, then the patient would actually get a bill for that retail amount of $1,000 as well as the difference between the retail bill and what insurance paid, which is another $900, so the patient would be stuck with a bill for $1900 under balance billing.

11:42AM **Q.** Okay. Well, let me ask you this: Did you know of any distinction between Medicaid, Medicare, and TRICARE with respect to balance billing and no-balance billing?

11:43AM **A.** It was my understanding that Medicare patients and government payers, it was illegal to balance bill patients. So if, you know, there was a test run and Medicare decided not to pay it, then it's illegal to bill Medicare patients for that

11:43AM 1 differential was my understanding.
11:43AM 2 **Q.** Okay. And so you did not understand that there was any
11:43AM 3 difference between Medicare, Medicaid, and TRICARE?
11:43AM 4 **A.** No, sir, not until the very -- I guess it was November of
11:43AM 5 2014 when HDL actually started billing TRICARE patients.
11:43AM 6 **Q.** Now, let's talk about your independent contractor
11:43AM 7 agreement. Did you ever believe that to be unlawful?
11:43AM 8 **A.** No, sir.
11:43AM 9 **Q.** Now, did you, Mr. Lively, ever try to tell a doctor which
11:44AM 10 lab tests to order for a particular patient?
11:44AM 11 **A.** No, sir.
11:44AM 12 **Q.** Okay. Did you ever recommend to a doctor which test to
11:44AM 13 order for a particular patient?
11:44AM 14 **A.** No, sir. Not for a particular patient, no, sir.
11:44AM 15 **Q.** Did you ever arrange for any doctor to order a specific
11:44AM 16 lab for a particular patient?
11:44AM 17 **A.** No, sir.
11:44AM 18 **Q.** Now, you were familiar back in June of 2014 that a special
11:44AM 19 fraud alert came out with respect to process and handling fees?
11:44AM 20 **A.** Yes, sir.
11:45AM 21 **Q.** Now -- and after that, did -- did you stay employed with
11:45AM 22 BlueWave?
11:45AM 23 **A.** Yes, sir.
11:45AM 24 **Q.** Okay. And for how long?
11:45AM 25 **A.** Until HDL tore up the contract.

11:45AM **Q.** Okay. And when did that occur?
11:45AM **A.** I believe that was in January of 2015.
11:45AM **Q.** And so what did you do when -- after the contract was terminated with HDL?
11:45AM **A.** I went to work with a lab called True Health Diagnostics.
11:45AM **Q.** And what is True Health?
11:45AM **A.** It's another advanced cardiovascular testing company. Just like I said about switching cars, it's just another model of car.
11:45AM **Q.** Did you -- is it your understanding that True Health bought the assets of HDL?
11:45AM **A.** Yes, sir.
11:45AM **Q.** Okay. And are the -- the tests that are offered by True Health similar to those that were offered by HDL?
11:46AM **A.** Almost identical.
11:46AM **Q.** Well, does True Health pay process and handling fees?
11:46AM **A.** No, sir.
11:46AM **Q.** In your experience, have you had success in marketing the True Health lab tests?
11:46AM **A.** It's been tough going growing. True Health bought HDL's assets. And when they bought HDL, HDL had about 10,000 specimens a week that were still running through HDL. And I think that True Health is around 8,000 a week right now.
11:46AM **Q.** And what about -- are any of your former clients --
11:46AM **A.** Almost all of those clients are former HDL clients.

11:47AM **Q.** Okay. And so they're still using the lab tests, the similar lab tests?
11:47AM **A.** Yes, sir.
11:47AM **Q.** Now, just briefly, in your experience, what -- what was the typical size of the office space that was required for physicians to perform specimen collection and process and handling --
11:47AM **THE COURT:** Is there objection?
11:47AM **MR. LEVENTIS:** Yes, Your Honor.
11:47AM **THE COURT:** Foundation, I take it?
11:47AM **MR. LEVENTIS:** Yes, Your Honor.
11:47AM **THE COURT:** Sustained.
11:47AM **BY MR. GRIFFITH:**
11:47AM **Q.** Did you have an occasion to visit all of your physician clients?
11:47AM **A.** Yes, sir.
11:47AM **Q.** Okay. Did you have an occasion to observe their office space?
11:47AM **A.** Yes, sir.
11:47AM **Q.** Were you knowledgeable about the office space required in these individual practices in order to perform collection and processing and handling?
11:48AM **A.** Yes, sir.
11:48AM **Q.** And, in your experience, what was the typical size that you saw in your various practices?

11:48AM **A.** It varied depending on, you know, if it was one doctor or if it was a group of doctors, but, you know, normally to do that, you got to have a space the size of an exam room, which is about the size of a bedroom in your house, 10 by 10, 12 by 12.

Q. And that would be for a small practice?

A. Yes, sir.

Q. What about the larger practices?

A. Well, then you could get as big as this courtroom, depending on the size of the practice. But, I mean, normally, two to three times that size if you had five or six doctors.

Q. And, in your experience, did the physician practices have waiting space for patients?

A. Well, everybody has a waiting room that they use. Some of them have other waiting rooms, two or three waiting rooms.

Q. Let me finish up with this, Mr. Lively.

Did you conspire with Cal Dent or Brad Johnson to knowingly and willfully violate the Anti-Kickback Statute?

A. No, sir.

Q. Did you conspire with Cal Dent and Brad Johnson to cause false claims to be filed with the federal government?

A. No, sir.

Q. Did you act in good faith while you were working at BlueWave?

A. Yes, sir.

11:49AM 1 **Q.** It was -- was it your perception that Brad Johnson and Cal
11:49AM 2 Dent acted in good faith while they were at BlueWave?
11:49AM 3 **A.** Yes, sir.
11:50AM 4 **Q.** Sorry. Just a few -- a few more questions.
11:50AM 5 For your physician clients who had signed up, did the
11:50AM 6 doctors order tests on every patient?
11:50AM 7 **A.** No, sir.
11:50AM 8 **Q.** What -- in your experience, what percentage of the
11:50AM 9 patients did the doctors --
11:50AM 10 **MR. LEVENTIS:** Your Honor, objection. I don't
11:50AM 11 believe there's a foundation he knows how many --
11:50AM 12 **THE COURT:** I think you would need to establish he
11:50AM 13 knew the total number of patients the doctor had.
11:50AM 14 **BY MR. GRIFFITH:**
11:50AM 15 **Q.** Were you familiar with the total number of patients that
11:50AM 16 your doctors saw on a weekly basis?
11:50AM 17 **A.** I mean, for the most part, yes.
11:51AM 18 **Q.** Okay.
11:51AM 19 **THE COURT:** I think he needs to establish how he
11:51AM 20 would know the total number of patients a doctor would have.
11:51AM 21 **THE WITNESS:** I'd ask them. I'd say, you know, "How
11:51AM 22 many patients do you see a day?" And they'd say, "Well, 30,
11:51AM 23 40, 20, depends."
11:51AM 24 **THE COURT:** Go ahead.
11:51AM 25 **BY MR. GRIFFITH:**

11:51AM 1 **Q.** So based on the fact that -- well, just generally, how --
11:51AM 2 in your experience, how many -- what percentage of patients did
11:51AM 3 a doctor usually order lab tests?
11:51AM 4 **A.** Lab tests, they typically order it on -- ordered lab tests
11:51AM 5 on most people. I mean, 80 to 90 percent --
11:51AM 6 **THE COURT:** I think you wanted to know about HDL.
11:51AM 7 **BY MR. GRIFFITH:**
11:51AM 8 **Q.** Yeah. What about HDL?
11:51AM 9 **A.** Probably 10 percent of the patients that they saw. They'd
11:51AM 10 pick and choose.
11:51AM 11 **Q.** And what about Singulex?
11:51AM 12 **A.** Less than that.
11:52AM 13 **Q.** In your experience -- we were talking about no-balance
11:52AM 14 billing. Did other companies offer no-balance billing?
11:52AM 15 **A.** I'm not familiar with all of the billing practices of
11:52AM 16 other companies. Some did; some didn't. Some offered flat
11:52AM 17 fees. It was -- it varied.
11:52AM 18 **Q.** Okay. And when I said "other companies," that would have
11:52AM 19 been lab companies?
11:52AM 20 **A.** Yes, sir.
11:52AM 21 **Q.** Okay. And with respect to the labs who were offering P&H
11:52AM 22 fee reimbursements, how many total do you believe did so in
11:52AM 23 your career?
11:52AM 24 **A.** Shoot. I mean, it would be -- that would be a tough
11:52AM 25 question because most of the smaller companies did because it

was -- you know, it was hard to hire all those phlebotomists all at once. So, you know, 10, 20 different labs were utilizing P&H to varying degrees.

MR. GRIFFITH: Thank you. That's all.

THE COURT: Thank you, Mr. Griffith.

Cross-examination by the government?

THE WITNESS: Your Honor, can I grab another --

THE COURT: Absolutely.

THE WITNESS: I'll try not to make too much noise.

CROSS-EXAMINATION

BY MS. STRAWN:

Q. Well, still good morning, Mr. Lively. How are you?

A. I'm very good. Thank you.

Q. My name is Elizabeth Strawn, and I'm one of the lawyers representing the United States in this case.

A. Yes, ma'am.

Q. Mr. Lively, you received quite a lot of money from BlueWave, didn't you, through this -- through this arrangement?

A. Well, it depends on what -- I mean, that's a relative thing. I mean, I got paid, I felt, fairly.

Q. So was that a lot of money?

A. To some people, it may; to other people, not. I mean, it was good money. I mean, I was happy.

MS. STRAWN: Mr. Phaneuf, would you display PDX10, please. 10, the demonstrative.

11:54AM **BY MS. STRAWN:**

11:54AM **Q.** And for the benefit of Mr. Lively, who hasn't seen this, about a dozen times already, Mr. Lively, this is a slide prepared by the government's expert forensic accountant depicting the total commissions that was -- that were received by each BlueWave sales representative. They're ranked there.

Can you see that okay?

11:54AM **A.** Yes, ma'am.

11:54AM **MS. STRAWN:** And if I could focus in on just sort of the top four maybe, please, Mr. Phaneuf, so we can see it. And then maybe highlight the line that indicates Burt Lively.

11:55AM **BY MS. STRAWN:**

11:55AM **Q.** Mr. Lively, you said the name of your company is RBLIV Consulting; is that right?

11:55AM **A.** Yes, ma'am. It was.

11:55AM **Q.** I beg your pardon?

11:55AM **A.** It was.

11:55AM **Q.** It was? Is that company no longer in existence?

11:55AM **A.** No, ma'am.

11:55AM **Q.** Excuse me. And if you look over to the right there, the amount listed is a little over $5.4 million. Do you see that there?

11:55AM **A.** Yes, ma'am.

11:55AM **Q.** Does that sound like it's in the ballpark?

11:55AM **A.** Ballpark, I would say.

11:55AM 1 **Q.** Excuse me. In exchange for those commissions, you met
11:55AM 2 with physicians?
11:55AM 3 **A.** Yes, ma'am.
11:55AM 4 **Q.** And sometimes you emailed them?
11:55AM 5 **A.** Excuse me?
11:55AM 6 **Q.** And sometimes you emailed them?
11:55AM 7 **A.** Yes, ma'am.
11:55AM 8 **Q.** Sorry. Losing my voice a little.
11:56AM 9 **A.** Of all people, I understand.
11:56AM 10 **Q.** And you recommended that they order HDL and Singulex
11:56AM 11 testing?
11:56AM 12 **A.** I recommended that they actually order the tests, yes.
11:56AM 13 **Q.** And your job was to persuade them to order HDL and
11:56AM 14 Singulex testing?
11:56AM 15 **A.** My job was to sell tests.
11:56AM 16 **Q.** And you got a cut of the revenue collected from that. Am
11:56AM 17 I right about that?
11:56AM 18 **A.** Yes, ma'am.
11:56AM 19 **Q.** So the more HDL and Singulex tests that you sold, the more
11:56AM 20 money you made?
11:56AM 21 **A.** Yes, ma'am.
11:56AM 22 **Q.** You pitched other things to your doctors as well, didn't
11:56AM 23 you?
11:56AM 24 **A.** At times.
11:56AM 25 **Q.** What else did you pitch?

11:56AM **A.** I recommended pharmacy services, you know, just -- you know, different imaging companies, various -- you know, different, you know, companies I worked with or had some type of relationship with just to -- when doctors asked, "Hey, do you got a contact that does this or does that?" I mean, I -- I, you know, referred doctors to other people.

11:57AM **Q.** And would you get commissions on those?

11:57AM **A.** At times.

11:57AM **Q.** And did you also sell for Cobalt, Royal Blue, and Eagle Pharmacy?

11:57AM **A.** Yes. I don't know about Royal Blue; but, yes, ma'am, Eagle Pharmacy and Cobalt, yes.

11:57AM **Q.** And what were they?

11:57AM **A.** Eagle Pharmacy is a sterile pharmacy that does, like, injections, injectable steroids and things like that. And Cobalt is a cancer genetic company.

11:57AM **Q.** Did -- did any of those also offer P&H fees?

11:57AM **A.** Cobalt did, yes, ma'am.

11:57AM **Q.** And did you offer those as well to your doctors?

11:57AM **A.** To the customers that signed up.

11:57AM **Q.** And did you get paid commissions on those sales as well?

11:57AM **A.** Yes, ma'am.

11:57AM **Q.** Now, you mentioned the -- on direct examination, Plaintiffs' 1099, the pro forma that you had sent to Brad Johnson. Do you remember testifying about that?

11:58AM **A.** Yes, ma'am.
11:58AM **Q.** And one of the sources of revenue you listed on there was the P&H fees that HDL would pay; is that right?
11:58AM **A.** Yes, ma'am.
11:58AM **Q.** And, to be clear, after you sent it to Brad, he approved of it; right?
11:58AM **A.** I have no idea what Mr. Johnson did after he received that.
11:58AM **Q.** Didn't you go ahead and send it to that practice after you sent it to Mr. Johnson?
11:58AM **A.** I'm -- I don't remember if I did or not. I mean, I'm assuming I did.
11:58AM **Q.** Would it help if you saw a document that --
11:58AM **A.** Absolutely.
11:58AM **MS. STRAWN:** Mr. Phaneuf, could you please go to Plaintiffs' Exhibit 1612.
11:58AM It has already been admitted, Your Honor.
11:58AM **THE COURT:** Okay.
11:59AM **MS. STRAWN:** If you could zoom in just on the email header.
11:59AM **THE COURT:** Can we move these arrows?
11:59AM **THE DEPUTY CLERK:** Just hit "clear."
11:59AM **THE COURT:** Thank you.
11:59AM **MS. STRAWN:** Oh, thank you.
11:59AM **BY MS. STRAWN:**

11:59AM **Q.** Mr. Lively, if you could have a look at that, please.
11:59AM **A.** Yes, ma'am.
11:59AM **Q.** Is that your email address at the top?
11:59AM **A.** Yes, ma'am.
11:59AM **Q.** And Thursday, September 23rd, wasn't that the date on the pro forma we looked at earlier?
11:59AM **A.** I don't --
11:59AM **Q.** You don't remember?
11:59AM **A.** I don't remember. I'm not going to say it is or it isn't. I mean --
11:59AM **Q.** Okay. And then the recipient there, could you read that email address?
11:59AM **A.** Yes, lmallory@kcim.com.
11:59AM **Q.** Looking at this, would you agree that you probably did send that pro forma to that practice?
11:59AM **A.** Yes, ma'am.
11:59AM **Q.** And you know, don't you, that it's -- it's not prudent to discuss specific earnings with physicians?
12:00PM **A.** I was not aware of that. I mean, when a doctor asks me something, I'll give them the information that I have.
12:00PM **Q.** But if it is about specific earnings, would you at least agree with me that it's probably not prudent to do that?
12:00PM **A.** These were all estimations, so, I mean, when a doc would ask me, "Hey, you got any idea?" I'm just going to answer their questions.

12:00PM **Q.** Did you think it was prudent or not?
12:00PM **A.** I didn't see any problem with it. I did this with Berkeley before. I mean, it's the same thing that I was doing, so I didn't think twice about it, honestly.
12:00PM **Q.** Did you think discussing the specific earnings may raise a legal risk?
12:00PM **A.** No, ma'am.
12:00PM **MS. STRAWN:** Your Honor, I'd like to move to an exhibit that's not been admitted.
12:01PM **THE COURT:** Yes.
12:01PM **MS. STRAWN:** May I approach?
12:01PM **THE COURT:** You may.
12:01PM **BY MS. STRAWN:**
12:01PM **Q.** If you could take a look at that, please, Mr. Lively.
12:01PM **A.** Yes, ma'am.
12:01PM **THE COURT:** What number is that, please?
12:01PM **MS. STRAWN:** Beg your pardon?
12:01PM **THE COURT:** What number is that?
12:01PM **MS. STRAWN:** It is Plaintiffs' 7017.
12:01PM **THE COURT:** Okay.
12:01PM **BY MS. STRAWN:**
12:01PM **Q.** Mr. Lively, if I could have you look, please, at the top right-hand corner of that document.
12:01PM **A.** Yes, ma'am.
12:01PM **Q.** Do you recognize this document?

12:01PM 1 **A.** Yes, ma'am.
12:02PM 2 **Q.** Is this a legal conference call test that you filled out?
12:02PM 3 **A.** Yes, ma'am.
12:02PM 4 **Q.** Does it appear to be the same one that you filled out?
12:02PM 5 **A.** Appears to be.
12:02PM 6 **Q.** Do you have any reason to believe it's not?
12:02PM 7 **A.** No, ma'am.
12:02PM 8 **MS. STRAWN:** I'd like to offer Plaintiffs' 7017 into
12:02PM 9 evidence.
12:02PM 10 **THE COURT:** Is there an objection?
12:02PM 11 **MR. GRIFFITH:** No objection.
12:02PM 12 **MR. ASHMORE:** No objection.
12:02PM 13 **THE COURT:** Plaintiffs' 7017 admitted without
12:02PM 14 objection.
12:02PM 15 **MS. STRAWN:** I'd like to use the ELMO. If I could
12:02PM 16 use the ELMO, please, Ms. Ravenel, please.
12:02PM 17 **BY MS. STRAWN:**
12:02PM 18 **Q.** Can you read that, Mr. Lively?
12:02PM 19 **A.** Yes, ma'am.
12:02PM 20 **Q.** I'm going to read along. If you could let me know if I
12:02PM 21 read it incorrectly, please.
12:03PM 22 "How much per year does a doctor earn from P&H fees
12:03PM 23 for performing 10 tests a week?"
12:03PM 24 "It is very difficult to specify a number based on
12:03PM 25 tests ordered and working days. Likewise, it would not be

prudent to discuss the specific earnings."

Did I read that correctly?

A. Yes, ma'am.

Q. Now, would you have wanted to know, Mr. Lively, if you've gotten any of the questions on that compliance test wrong?

A. Yes, ma'am.

Q. And would you want to know if your conduct raised any legal risks or red flags?

A. Yes, ma'am.

Q. And this was in 2013; right? The pro forma and this legal test, those were all happening in 2013?

A. The pro forma was in 2010.

Q. I stand corrected. Sorry. 2010.

A. Yes, ma'am.

Q. The legal test is in 2013?

A. Yes, ma'am.

Q. I stand corrected.

So you're -- at that time, you're still offering P&H fees to your physicians?

A. At that time, I believe so.

Q. And --

A. In lieu of a phlebotomist.

Q. And you were still involved in training any new sales reps that were coming on board?

A. Yes, ma'am.

12:04PM 1 **Q.** I'd like to now look at Question 17. Sorry -- actually,
12:04PM 2 I -- it's 18. Question 18.
12:04PM 3 So the question is, "How much is the P&H fee? Can
12:04PM 4 you pay any amount?"
12:04PM 5 And your response was "$17" and "No."
12:04PM 6 **A.** Yes, ma'am.
12:04PM 7 **Q.** Did that reflect your understanding at the time?
12:04PM 8 **A.** Yes, ma'am.
12:04PM 9 **Q.** If it turns out that that answer was not correct, is that
12:05PM 10 something you needed to know?
12:05PM 11 **A.** Yes, ma'am.
12:05PM 12 **Q.** Have you heard of a law firm by the name of Maynard
12:05PM 13 Cooper?
12:05PM 14 **A.** Yeah, I think they're the -- are they the bankruptcy
12:05PM 15 attorneys? I -- I mean --
12:05PM 16 **Q.** But you've heard of them?
12:05PM 17 **A.** I mean, I recognize the name. I don't --
12:05PM 18 **Q.** Would you want to know if an attorney at Maynard Cooper
12:05PM 19 said that your answer was wrong?
12:05PM 20 **A.** Yes.
12:05PM 21 **Q.** And did someone tell you that a lawyer at Maynard Cooper
12:05PM 22 opined that your answer was wrong?
12:05PM 23 **A.** Not specifically. They gave us an answer key to this.
12:05PM 24 They sent us a -- the answer key after the test, after you sent
12:06PM 25 it. And it was outlined exactly what the answers were.

12:06PM **Q.** And who did that? I'm sorry. Who's the "they"?
12:06PM **A.** I believe it came from somebody at BlueWave. I don't know who -- I can't remember specifically who it came from, but there was an answer key. I mean, there was -- they gave us the right answers after we took the test.
12:06PM **Q.** Do you know if it was Mr. Dent or Mr. Johnson?
12:06PM **A.** Could have been. I don't -- I mean, I can't remember. I get a thousand emails a day, so, I mean, I -- I mean, I don't --
12:06PM **Q.** I'm with you on that.
Did you rely on Mr. Dent or Mr. Johnson to provide you the answers after the answer key?
12:06PM **A.** Like I said, I mean, I just remember getting an answer key. I have no idea where it came from. It could have come from Brad or Cal, or it could have come from an attorney. I'm not -- don't specifically remember other than I remember we got an answer key.
12:07PM **Q.** And did you rely on that answer key?
12:07PM **A.** Yes, ma'am.
12:07PM **Q.** Now I want to just back up a bit to the period of time when you were still at Berkeley HeartLab.
12:07PM **A.** Yes, ma'am.
12:07PM **Q.** And doctors -- I think, if I understood your testimony on direct correctly, doctors were frustrated with you when Berkeley ended its zero-balance billing policy?

12:07PM **A.** Yes, ma'am.
12:07PM **Q.** And that hurt your sales?
12:07PM **A.** Yes, ma'am.
12:07PM **Q.** And that even factored into your decision to leave Berkeley and go with BlueWave; right?
12:07PM **A.** Well, the fact that they changed their billing policy was not an issue; it was the way that they were conducting the collection.

And we had multiple phone calls with sales management and saying, "Hey, look, if we could handle things this way, then why can't we call patients and proactively talk to them in that regard so that they're not surprised by a $3,000 on a bill from a test done three years ago?"

So, you know, our issue was not the billing policy; our issue was the way that the bills were being sent out so that we could actually just handle the customer service side. So, no, I mean, we didn't make the decision to leave based on the billing; we made the decision to leave based on the fact that management didn't listen to us.

12:08PM **Q.** So you heard about it from the doctors, that the patients got $3,000 bills?
12:08PM **A.** Yes, ma'am.
12:08PM **Q.** Did you ever hear complaints about HDL sending patients $3,000 bills?
12:08PM **A.** Yes, ma'am, eventually.

12:08PM **Q.** And that was in 2014?
12:08PM **A.** I, once again, can't recall the date exactly.
12:08PM **Q.** Before the special fraud alert was issued, did you get any complaints about patients getting $3,000 bills from HDL?
12:09PM **A.** Yes, ma'am. We started billing copays and deductibles for everyone in Florida, Colorado, Idaho, New York. And that may have been it. I don't know about all the rules, but I know that before -- it was around 2013, I believe, that we started sending out bills for copays and deductibles in those states. And I covered, like I said, pretty much the whole United States, so I touched on each one of those.
12:09PM **Q.** And, before that, there were none?
12:09PM **A.** No, ma'am.
12:09PM **MS. STRAWN:** No further questions.
12:09PM **THE COURT:** Thank you.
12:09PM Mr. Ashmore?
12:09PM **MR. ASHMORE:** No questions, Your Honor.
12:09PM **THE COURT:** Anything on redirect?
12:09PM **MR. GRIFFITH:** Just briefly, Your Honor.
12:09PM **REDIRECT EXAMINATION**
12:09PM **BY MR. GRIFFITH:**
12:09PM **Q.** Mr. Lively, Ms. Strawn put up the numbers that reflected your income over five years. Do you recall that?
12:10PM **A.** Yes, sir.
12:10PM **Q.** Okay. And as I recall -- and was it approximately

12:10PM 1 $5.4 million?
12:10PM 2 **A.** I believe that's what it showed.
12:10PM 3 **Q.** And was that over five years?
12:10PM 4 **A.** Yes, sir.
12:10PM 5 **Q.** So roughly about a million dollars a year?
12:10PM 6 **A.** On a gross basis.
12:10PM 7 **Q.** Yeah. Okay. Well, explain that to me. Let's compare
12:10PM 8 what you did at Berkeley in terms of your commissions and the
12:10PM 9 general environment in which you were working versus what you
12:10PM 10 were doing for BlueWave.
12:10PM 11 **A.** Well, it's apples and oranges.
12:10PM 12 **Q.** Why so?
12:10PM 13 **A.** Well, at Berkeley, as I said, I had 2 1/2 states. And
12:10PM 14 with HDL, I had 48 states. I had a lot of traveling. I mean,
12:10PM 15 I was gone on Monday, back on Friday. I put 80,000 miles on
12:11PM 16 the car and 100,000 miles in the air every year. I had
12:11PM 17 approximately 70 physicians that I had to take care of with
12:11PM 18 Berkeley; I had over 300 with HDL. You know, we had
12:11PM 19 approximately 700 specimens a week coming in with Berkeley; we
12:11PM 20 had 5,000 across -- you know, with all the states I had coming
12:11PM 21 in with HDL.
12:11PM 22 **MR. LEVENTIS:** Your Honor, could we approach?
12:11PM 23 **THE COURT:** Yes.
12:11PM 24 (Whereupon the following proceedings were held at the
12:11PM 25 bench out of the hearing of the jury:)

12:11PM **THE COURT:** Yes, sir?

12:11PM **MR. LEVENTIS:** I believe this is misleading to the jury, because they are making it sound like he's getting paid for the entire country. He did not get paid commissions on new sales in the entire country.

12:12PM **THE COURT:** Where did he get paid in?

12:12PM **MR. LEVENTIS:** Only in his area. He's making it sound like he was all over the United States. He's not. He's --

12:12PM **THE COURT:** That's reasonable. You need to go back and make that clear.

12:12PM **MR. GRIFFITH:** I'll clarify.

12:12PM **THE COURT:** Okay. Good.

12:12PM (Whereupon the following proceedings were held in open court in the presence and hearing of the jury:)

12:12PM **THE COURT:** Okay. Please proceed.

12:12PM **BY MR. GRIFFITH:**

12:12PM **Q.** And I don't mean to interrupt you, but we need one clarification. What specific states did you have clients with respect to BlueWave?

12:12PM **A.** That I actually had clients in?

12:12PM **Q.** Yeah.

12:12PM **A.** Alabama, Georgia, Florida, Mississippi, Louisiana, Colorado, Wisconsin, California, Washington, Wyoming -- or --

12:13PM **THE COURT:** How about ones in which you actually

earned commissions?

THE WITNESS: All of those.

THE COURT: Okay.

THE WITNESS: And then wherever -- see, you need to understand, is when anybody called in HDL and asked for -- you know, said that they were interested in the testing, that all fed through me. So when they called Richmond, they would send it to me, and then I would either call the account and try to set up the account myself or I'd hand it off to somebody if there was a sales rep that was close by. But I always had the option of taking that account, and I had them spread out all over the country.

BY MR. GRIFFITH:

Q. Okay. And I want to wrap up, but I just want to understand.

When you said it was apples and oranges between the compensation you got at BlueWave versus what you got at HDL, can you explain that?

A. Well, I explained the differences in what my sales territory and volume was; but, you know, with Berkeley, I had an expense account. Everything was paid for. I didn't have to pay for my taxes. I -- you know, I was responsible for all my travel. For any expense that I had, I had to pay it out of my pocket.

And so when you net it out, I still made a little bit

more money, but, you know, also the reason that I made that kind of money is because, in every organization, the peons at the bottom do all the work, and then you go up the food chain, and you have levels of management that are nonincome-producing.

What the whole premise behind BlueWave was to have the salespeople, the people that are actually doing the work and making the money, make the money and not have worthless levels of management that -- that, you know -- I mean, it's -- that's why we set the thing up in the first place the way it was. We didn't want a bunch of managers that were getting paid to basically approve expense reports.

Q. Thank you.

THE COURT: Thank you, sir. You may step down.

THE WITNESS: Thank you. Can I take my water with me?

THE COURT: You can take your water with you, a gift from the federal courts.

(Witness excused.)

THE COURT: Okay. I think it's time for our lunch break. We'll take about an hour. Please do not discuss the case.

(Whereupon the jury was excused from the courtroom.)

THE COURT: Please be seated. So give me a little forecast for the afternoon.

MR. COOKE: Thank you, Your Honor. I'm glad you

asked.

We have one more doctor, and then we have a -- the deposition. We have eliminated a witness that we were going to call, and then we'll have Mr. Johnson finishing us up. And I was sort of going to ask the Court when you thought we would do the charge conference, because --

THE COURT: We're going to -- let me just say, I've spent a fair amount of time out of court looking at the charge. And I realize I'm not going to get to it. I've got to go through the testimony and correlate it. Y'all have lots of objections, and I need to correlate it to the testimony. So I will not have it done.

We will not do that today. Okay? It's just -- that was my goal, but it's just -- looking over it last night, I realized I had more work to do. And I think it's an important issue. I need to do it right.

MR. COOKE: Well, then, that being the case, we would, you know, get as far through Mr. Johnson as we could. It's -- I guess we don't have any way of knowing whether we'll finish him today, but --

THE COURT: I think we just do the best we can.

MR. COOKE: Do the best we can.

THE COURT: And would he be your last witness?

MR. COOKE: Yes, we believe so.

THE COURT: Okay.

12:17PM Mr. Ashmore, again not committing you because you've got the weekend to think -- just like I'm going to be thinking about the charge, you get to think about your strategy, what's your present thinking?

MR. ASHMORE: I'll rest if they won't rebut, Your Honor. It's my general inclination -- I'm not sure, Your Honor. I'm just not sure. I may call Ms. Mallory.

THE COURT: Okay. That's certainly your prerogative.

Is the government planning to rebut?

MR. LEVENTIS: We don't know at this point, Your Honor.

THE COURT: Okay. Fair enough. That's everybody's options here. Everybody got their cards to their chest, I come in here, and that's exactly the way it's supposed to work. Okay. Let's take about an hour for lunch.

12:18PM (Recess.)

1:33PM **THE COURT:** Please be seated.

Any matters I need to address before we bring the jury back?

MR. LEVENTIS: Not from the government, Your Honor.

MR. COOKE: Nothing, Your Honor.

MR. ASHMORE: No, sir.

THE COURT: Every time you stand up, Mr. Cooke, I don't know what's coming.

MR. COOKE: It's Friday.

1:33PM **THE COURT:** Mr. Griffith is doing just as good as you are.

1:33PM **MR. COOKE:** Can I just go have the doctor sit in the back of the courtroom instead of us going out to --

1:33PM **THE COURT:** Absolutely. Go ahead and do that.

1:33PM All the fuss that I always do over having the next one waiting, I know every time there's a moment, you're like -- I can see you're, like, anxious. But it does make the trial move quicker, does it not? Just one after another.

1:34PM Let's go ahead and bring in the jury.

1:35PM (Whereupon the jury entered the courtroom.)

1:36PM **THE COURT:** Please be seated.

1:36PM BlueWave, call your next witness.

1:36PM **MR. COOKE:** Thank you, Your Honor. The defendants BlueWave and Johnson and Dent would call Dr. William Joseph Hollins, please.

1:36PM **THE DEPUTY CLERK:** Please place your left hand on the Bible, raise your right. State your full name for the record, please.

1:36PM **THE WITNESS:** William Joseph Hollins II.

1:36PM **THE DEPUTY CLERK:** Thank you.

1:36PM (Witness sworn.)

1:36PM **THE DEPUTY CLERK:** You may be seated.

1:36PM **THE WITNESS:** Thank you.

1:36PM **WILLIAM JOSEPH HOLLINS II, M.D.,**

a witness called on behalf of the defendants, being first duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. COOKE:

Q. Good afternoon, Dr. Hollins. I'm Dawes Cooke, and I represent three defendants in this case, BlueWave Healthcare Consultants and Mr. Johnson and Mr. Dent.

And you understand that; correct?

A. Yes, sir.

Q. Would you state your full name for the record, please.

A. William Joseph Hollins II.

Q. And before I forget, let me just remind you that you should not discuss any specific patients in response to any of my questions. I will ask about your practice and some other things, but don't give any particular case studies, if that's all right with you.

A. Yes, sir.

Q. Thank you. And I'll also tell you that the jury has heard a lot about advanced lipid. So we will talk some about it, but I don't think we need to go back to the ground zero on everything about each of these tests, if that's all right with you.

A. Yes, sir.

Q. All right. Good. That's probably confusing to you, but everybody else knows what I'm talking about.

Where do you -- where do you reside and work?

A. I reside in Columbia, South Carolina, and I've practiced there since 1986 as a cardiologist.

Q. Tell us about your practice.

A. I see adult patients with cardiovascular disease. Youngest patient would be probably around 18, the oldest maybe 101.

Q. And what's the name of your practice?

A. Columbia Heart Clinic.

Q. How many cardiologists are in that practice?

A. That number varies from time to time with different factors in the community, but right now I think the correct number is about 18, 16.

Q. Where did you get your education?

A. I went to University of South Carolina for my undergraduate degree in biology and also first two years in pharmacy school. And I did my medical school training at the Medical University of South Carolina in Charleston and my internal medicine residency and internship at Bowman Gray School of Medicine in Winston-Salem, North Carolina.

I came back to Charleston to do my cardiovascular medicine fellowship at Medical University of South Carolina in Charleston.

Q. Who did you study under at Medical University?

A. I was one of the last of the fellows under Dr. Peter

1:39PM Gazes. That's -- he was one of the main reasons I came back to
1:39PM Charleston. He's my hero and fantastic. He's the
1:39PM cardiologist's cardiologist.
1:39PM **Q.** What did you do after that?
1:39PM **A.** I went into practice in Columbia, July of '86.
1:39PM **Q.** Was that in interventional cardiology?
1:39PM **A.** Yes, sir. I'm an interventional cardiologist, have done
1:39PM interventional cardiology for 30 years, over 30 years.
1:39PM **Q.** And you still do it?
1:39PM **A.** I do.
1:39PM **Q.** Can you talk to us about your involvement in lipidology.
1:39PM **A.** So upon the invitation, actually, of my former chief of
1:40PM cardiology, Dr. Gazes, a physician, Robert Superko, came and
1:40PM gave a talk -- I believe it was either Keowee or Seabrook -- at
1:40PM a medical meeting. And turns out he was the medical director
1:40PM for a specialty laboratory in California called Berkeley
1:40PM HeartLab.
1:40PM And after that presentation, I felt like blinders had
1:40PM been taken off of me, if you will. I realized that we could
1:40PM assess each patient as individuals as to what put each
1:40PM individual at risk for a heart attack, not simply lump
1:40PM everybody into some pool based on their cholesterol value.
1:40PM And I remember coming back and telling my wife after
1:40PM that presentation that what he had done to remove those
1:40PM blinders, if you will, had changed the way that I would

practice medicine for the rest of my life.

Q. Who was the first person that you performed advanced lipid tests on?

A. It was actually myself.

Q. All right. Did it make a difference to you?

A. Yes, it did.

Q. How did it change the way that you practiced medicine?

A. So, from that point on, knowing that each patient can be assessed as an individual and that we can identify the specific inflammatory markers and lipoproteins that made that patient have a heart attack compared to the next patient and the next, it changed from the usual, "Okay. We've done your stent. We've gotten you out of hot water. Eat a low-fat diet, eat a heart-healthy diet, exercise, and here's your prescription for Lipitor or Crestor" or whatever the statin was -- that was the old way -- to a new way, which is, "After you leave the hospital, instead of not knowing the exact factors that apply for you, we're going to do some blood work, and we're going to assess for you what specific factors can be addressed that predict risk and that we can modify to reduce your risk."

And it made a big change.

Q. Let me dig out a little bit on that.

You have somebody who comes in, and you've told them stop smoking, lose weight, exercise, avoid stress, control your blood pressure, take a statin if they need a statin. What more

do you need to know? Are you at that point doing everything for that person that you could do with all this additional information?

A. We wish it was that easy. You know, most of the earlier studies were funded by large drug companies to get drugs like Lipitor and Crestor on the market. So there were so-called statin trials, the randomized control large studies for statins.

And we know from studies -- whether it was a primary prevention trial, meaning the patient never had a heart attack or event; secondary prevention trial, meaning we've already had one event, we don't want -- we're trying to prevent a second event; or whether the trials were so-called high risk, so people that have had multiple events or unstable angina or in hot trouble, doesn't matter -- the population -- primary prevention, secondary prevention, or just high-risk group -- we see the same monotonous 20 to 30 percent relative risk reduction, absolute risk reduction, sometimes single digit.

And that's disappointing that we can't reduce risk beyond 20 to 30 percent just by writing a prescription for a drug like Lipitor or Crestor or Zocor or whatever statin you choose.

What that means on the other side of the coin is that 60 to 70 percent of our patients continue to have events despite being on the statin. It's just unacceptable.

1:44PM 1 So just saying don't smoke, have a good blood
1:44PM 2 pressure, here's your statin, and then, you know, taking
1:44PM 3 aspirin -- you know, that's what we did. That's what we did in
1:44PM 4 the '80s and on into the '90s.
1:44PM 5 But with this ability to look below the surface at a
1:44PM 6 deeper look as to what specifically is at play for an
1:44PM 7 individual patient, we can make further changes to modify those
1:44PM 8 factors and get the inflammatory markers under control, get the
1:44PM 9 lipoprotein under control, not just the cholesterol, but the --
1:44PM 10 these things travel in your bloodstream as lipoproteins.
1:44PM 11 So we want to measure the lipoprotein, measure the
1:45PM 12 biomarkers that predict risks that are typically inflammatory
1:45PM 13 markers, and further our therapy, tailor it, customize it to
1:45PM 14 the patient to move those markers under an acceptable risk
1:45PM 15 level.
1:45PM 16 **Q.** Do you know of any important trials that were out there
1:45PM 17 that supported this kind of approach?
1:45PM 18 **A.** Well, years ago, there were trials using more than one
1:45PM 19 therapy. For example, combination therapy, drug therapy,
1:45PM 20 trials like the HATS trial, the FATS trial, the CLAS trial.
1:45PM 21 These trials used combination drug therapy as means to show
1:45PM 22 that we can get event rates down further than the typical
1:45PM 23 statin monotherapy trial. And they also looked at other things
1:46PM 24 like plaque regression in the cath lab where the plaques could
1:46PM 25 be regressed, et cetera, in the cath lab. So that was -- those

are some of the earlier trials.

Q. Dr. Hollins, we brought you here to ask you questions about process and handling fees.

Are you familiar with process and handling fees?

A. Just as a result of lots of questions about them, yes.

Q. Okay. Were you familiar with process and handling fees before HDL came into your life? And by HDL by the way, I don't mean the cholesterol; I mean the laboratory, Health Diagnostic Laboratories.

A. So here are my comments on processing and handling fees.

I always knew that, when we ordered a specialty lab, that we would get some sort of fee to offset the cost of processing and handling. I say "always." I was -- just make that word customary. It was customary and historical for our practice to get some sort of fee typically if we ordered lab outside of our practice, whether it be Berkeley or whether it be HDL or whether it be other labs.

Q. And what's the reason for that?

A. Well, the theory behind it is there's an excess in time and employee energy and focus to get that lab drawn, tubes in the right tubes, label the acquisition -- or requisition papers appropriately, package them up, and get them out the door.

Q. And I think you said that that's the theory. Do you get involved to a significant extent in that part of the practice in your office?

1:47PM **A.** No, sir, I don't. I'm not in the laboratory where the --
1:47PM typically when the blood is drawn and the patient's typically
1:48PM there on another floor or getting their lab work done, and I
1:48PM may not even be on that floor.
1:48PM **Q.** What role do -- does the receipt of process and handling
1:48PM fees have in your decision whether to order tests for patients?
1:48PM **A.** Whether we receive a processing or handling fee has no
1:48PM role in whether I decide to order a lab test.
1:48PM **Q.** You mean by no role, do you mean zero or do you mean not
1:48PM so much or --
1:48PM **A.** I mean zero.
1:48PM **Q.** All right. But it's money. Why wouldn't the payment of
1:48PM money have some influence --
1:48PM **A.** Well, we appreciate it if it's legal to have a cost
1:48PM offset, you know. When it became clear -- I believe the year
1:48PM was around 2014 -- that the government no longer considered it
1:48PM okay to receive a processing and handling fee, obviously, those
1:49PM fees stopped and we stopped receiving them.
1:49PM **Q.** And then did you stop ordering the tests?
1:49PM **A.** Absolutely not.
1:49PM **Q.** Did you slow down ordering the tests?
1:49PM **A.** Absolutely not.
1:49PM **Q.** At my request, have you looked at some statistics from
1:49PM your office showing the amount of tests that you ordered over a
1:49PM period of time?

1:49PM **A.** You showed me a bar graph, yes, sir.

1:49PM **MR. COOKE:** And, Your Honor, this would be another part of that same Exhibit 524.

1:49PM **THE COURT:** Yes.

1:49PM **MR. COOKE:** And I think --

1:49PM **MR. KASS:** No objection.

1:49PM **MR. COOKE:** -- without objection, I would mark that as -- what are we up to now, Mel?

1:49PM **MS. MASON:** 524-2.

1:49PM **THE COURT:** I'm sorry. What is it?

1:49PM **MR. COOKE:** 524-2.

1:49PM **THE COURT:** Thank you. 524-2.

1:49PM Any objection from the government?

1:49PM **MR. KASS:** No, sir.

1:49PM **THE COURT:** From Mr. Ashmore?

1:49PM **MR. ASHMORE:** No objection.

1:49PM **THE COURT:** Very good. BlueWave 524-2 admitted without objection.

1:50PM **MR. COOKE:** Did we number the graph before?

1:50PM **MS. MASON:** The other one was 1.

1:50PM **BY MR. COOKE:**

1:50PM **Q.** I'm going to put up on the screen a graphic that puts into graphic form this data.

1:50PM **MR. COOKE:** Do you object to that?

1:50PM **MR. KASS:** No objection.

1:50PM **BY MR. COOKE:**

1:50PM **Q.** Doctor, can you take a look at that, and without having you go back and compare each bar to the numbers, does that appear to represent the -- the trend, if any, following the stoppage of process and handling fees?

1:50PM **A.** I'm not sure I understand your question.

1:50PM **Q.** Well, does this appear to reflect essentially the same pattern after P&H was discontinued as before P&H was discontinued?

1:51PM **A.** Well, it appears to me that there's been no difference in the ordering of tests before and after processing and handling fees.

1:51PM **Q.** Is that consistent with your recollection?

1:51PM **A.** That is my practice.

1:51PM **Q.** Do you recognize either Mr. Dent or Mr. Johnson?

1:51PM **A.** I recognize Mr. Dent. I had met Mr. Johnson many years ago just on one occasion, I believe, and I would not have recognized him.

1:51PM **Q.** Who else did you work with at BlueWave?

1:51PM **A.** I knew Cal Dent, and I knew Tony Carnaggio.

1:51PM **Q.** Tony Carnaggio? Were they -- how often did they come and see you?

1:51PM **A.** I might see them once a month. I might see them every couple of months. I might see them more than once a month. But, typically, I'd just say around maybe once a month.

1:52PM 1 **Q.** Did you ever discuss the clinical aspects of these tests
1:52PM 2 with any of them?
1:52PM 3 **A.** Yes.
1:52PM 4 **Q.** Did you ever discuss process and handling fees with them?
1:52PM 5 **A.** No.
1:52PM 6 **Q.** Did they ever -- did they -- well, I'll just ask this as
1:52PM 7 neutrally as possible.
1:52PM 8 What, if anything, did they ever do to encourage you
1:52PM 9 to accept process and handling fees to order more tests?
1:52PM 10 **A.** Nothing.
1:52PM 11 **Q.** Nothing?
1:52PM 12 **A.** No.
1:52PM 13 **Q.** Did you become a member of the HDL medical advisory board?
1:52PM 14 **A.** Yes.
1:52PM 15 **Q.** What does that entail?
1:52PM 16 **A.** I was asked to become a member to give input about my
1:52PM 17 experience with what was happening in the clinical application
1:52PM 18 of these tests for patient care. We made trips to Richmond on
1:52PM 19 several occasions, weekend trips, and would spend the entire
1:52PM 20 Saturday going over cases, having lectures to go into details
1:53PM 21 as to how these tests are performed and how they could be
1:53PM 22 applied.
1:53PM 23 **Q.** Is there -- is there anybody who comes into your practice
1:53PM 24 who, in your opinion, would not benefit from these tests or
1:53PM 25 from some of these tests?

1:53PM **A.** Well, I hardly ever see anyone who's well. I'm the cardiologist. I do sleep medicine as well. And I would look -- I'm a clinical lipid -- I'm a board-certified in clinical lipidology, so I have a lot of patients. Almost all my patients have some kind of dyslipidemia and/or arthrosclerosis. So it would be a rare patient that I would see.

I do do sleep medicine because there's such an overlap between sleep issues and cardiovascular disease. There could be a patient that I'm seeing just for sleep that doesn't have lipid issues.

And, you know, I don't order the test on every single patient I see because it may not be medically indicated.

Q. Well, you've anticipated my next question. When you were a customer of HDL and Singulex, did you routinely order every test you could order on a patient?

A. I very rarely ordered Singulex testing. I ordered some just to see how clinically useful it might be. Those were very rare. And as far as HDL -- can you repeat that question again?

Q. Yeah. The question was did you routinely order every single test that they offered on every patient?

A. No, no.

Q. Did you -- did you find yourself influenced somehow by the way the requisition form would organize tests into panels?

A. The actual form? No.

1:55PM **Q.** Yeah. Did you create your own panels of tests?
1:55PM **A.** The initial assessment panel, we reviewed and created. And then I requested a follow-up panel, which was much more focused.
1:55PM **Q.** Did anybody ever suggest to you that you could get more processing and handling fees if you would just order Singulex tests along with HDL tests?
1:55PM **A.** No, sir.
1:55PM **Q.** Did you become a member of the medical advisory board for HDL before you started being a regular user of their tests or after?
1:55PM **A.** No. After.
1:55PM **Q.** Do you believe that you were invited in part because of the fact that you were such a heavy user of those tests?
1:55PM **A.** I was under the impression that I was invited because I had had a decade of experience using advanced lipid testing, or more, at that point in time.
1:56PM **Q.** All right. And what did you do as a member of the medical advisory board? How often did you speak?
1:56PM **A.** So, in my mind, the speaking is more like a -- I guess a member of the speakers bureau. I mean, and then the medical advisory board itself met several times in Richmond, and then whatever involvement from meeting with Cal or Tony to talk about specific tests or specific questions I might have for them.

I'm not sure I'm answering your question, but I have done speaking for HDL, including traveling to speak.

Q. Do you -- I know you've been asked this question plenty of times in this case, but do you remember a meeting in the spring of 2013 down at Hilton Head, at the Heritage Medical Practice?

A. When I was first asked that question, I did not remember that meeting. My -- you know, I was asked, "Do you remember that meeting?" and I had to say at first, "Hilton Head?" Because I did not remember speaking in Hilton Head.

Upon further discussion, I do remember that I was invited to go to Hilton Head and speak many years ago.

Q. Do you happen to remember anything that happened at that meeting or questions that were asked?

A. The main thing I remember is I had eaten at that restaurant before, and that's how I -- that's how I really remembered that I had been there.

Short of that, I remember Cal was there. I remember Cal introduced me as a speaker. And I addressed the scientific portion of the meeting, which is what I always do. And that's all I really remember.

Q. If somebody at a meeting were to raise their hand and ask a question of -- about process and handling fees, what would you do in response to that?

A. That would not be something I'm able to address. If it's a nonmedical question, I would -- whether it's about insurance

or processing and handling fee or whatever, if it's not related to the science or a medical question, I would refer that to whoever else might be present that could answer that.

Q. And do you remember at any meetings that you attended along with Mr. Dent or any representative of BlueWave of them in any way promoting process and handling fees as a reason to order tests?

A. No, sir.

Q. Kind of embarrassed to ask you this question because we don't know each other very well, but did you conspire with BlueWave to order unnecessary tests?

A. Absolutely not.

Q. Would you ever do that?

A. Absolutely not.

Q. Would you ever order tests for a processing and handling fee?

A. Absolutely not.

Q. Just a moment, if I may.

(Pause.)

MR. COOKE: That's all. Thank you.

THE COURT: Cross-examination?

MR. KASS: Thank you, sir.

CROSS-EXAMINATION

BY MR. KASS:

Q. Good afternoon, Dr. Hollins. My name is Michael Kass. I

represent the United States. And we met sort of during your telephone deposition last Friday. Went far later into the evening than I'd hoped to, and I appreciate your patience with us.

For the benefit of the record, that was me. You met Chris Kovach that evening, and there was a court reporter in the room with you. And your attorney, who may or may not be here, was on the phone as well; correct?

A. Correct.

Q. Great. Couple of questions for you, Dr. Hollins. Are you a partner in Columbia Heart?

A. Yes.

Q. Your medical --

A. Yes.

Q. You're a partner in Columbia Heart? Great.

And Mr. Cooke was asking you a bunch of questions sort of generally about advanced lipidology. I want to ask you just a few very narrow specific ones.

Peter, would you bring up Exhibit 3003, please, which is already in evidence.

I just want to ask you a little bit about Singulex. Now, this is not your requisition form; I'll tell you that straight off. But the test I want to ask you about --

Peter, if you wouldn't mind zooming in on panels. Right there. That's great.

2:00PM Yeah, we're just going to talk very briefly about these tests. So I believe you said, Dr. Hollins, that defendant Cal Dent would some to your office more or less once a month. Is that about right?

A. Something like that.

Q. Something like that. And, Dr. Hollins, you became aware of Singulex through defendant Cal Dent; is that right?

A. I believe that's correct.

Q. And defendant Cal Dent represented Singulex on sales calls to your office; correct?

A. Correct.

Q. Yep. And defendant Cal Dent made you aware of Singulex troponin tests; is that right?

Let me rephrase that. He made you aware of the troponin test offered by Singulex; correct?

A. Correct.

Q. I'm sorry?

A. Correct.

Q. And is that -- if you look here at your screen, is that the troponin test listed there?

A. So that is the troponin I, the high-sensitivity troponin that you have marked there in yellow.

Q. And if you look underneath and sort of to the left of there, you'll see there's also a reference to an interleukin-6 and an interleukin 17A test that Singulex offered.

2:01PM 1 Cal Dent also made you aware of those two tests from
2:01PM 2 Singulex; correct?
2:01PM 3 **A.** Correct.
2:01PM 4 **Q.** And after defendant Cal Dent introduced you to Singulex's
2:02PM 5 troponin test and Singulex's interleukin tests, you ordered
2:02PM 6 those tests; right?
2:02PM 7 **A.** Very rarely.
2:02PM 8 **Q.** Yeah. Could you tell us a little bit about your
2:02PM 9 experience with those tests, please?
2:02PM 10 **A.** I don't remember the specific patient or the question that
2:02PM 11 came up, but something would have come up clinically that would
2:02PM 12 have made me interested in looking deeper at particular markers
2:02PM 13 of inflammation for a particular patient, and that would have
2:02PM 14 triggered me to order it.
2:02PM 15 **Q.** Right. And when we talked about it in your deposition by
2:02PM 16 telephone last Friday, you said, and I quote, "On the few
2:02PM 17 occasions that I ordered it, you know, I just did not find it
2:02PM 18 that useful."
2:02PM 19 Is that a fair statement?
2:02PM 20 **A.** I think that's a fair statement.
2:02PM 21 **Q.** And that was true of Singulex's troponin test; correct?
2:02PM 22 **A.** Yes. I may not have given it enough of a chance --
2:02PM 23 **Q.** That's kind of you to say.
2:02PM 24 **A.** -- to make a judgment entirely on it. But just based on
2:02PM 25 my limited use, very limited use, the few times that I used it,

I didn't see that it was coming back to be helpful. So I didn't continue to use it.

Q. And the same was true of Singulex's interleukin-6 and interleukin-17a tests?

A. These are very rarely done by me. I don't know how many times, but it was -- we're talking very rare.

Q. And not really useful; right?

A. Just based on my very rare, limited experience with this.

Q. And you mentioned earlier, when Mr. Cooke was asking you questions, that you always knew -- I think I've got this right -- you always knew that, when you ordered from specialty labs, there'd be some sort of process and handling fee or something like that; right?

A. It was customary and historical that we would receive some offsetting fee of processing and handling from the specialty lab.

Q. Sure. You knew the fee was coming in?

A. It was -- it was customary.

MR. KASS: Peter, can you bring up demonstrative PDX -- I think it's 14 or 15. And I think if I remember correctly -- again, I apologize. We've had some computer issues.

BY MR. KASS:

Q. If you look here, this is broken down into two boxes. The second row from the bottom of the first box, do you see

reference to Columbia Heart Clinic and W. Joseph Hollins II?
A. Yes.
Q. Is that you, sir?
A. Yes, it is.
Q. And if you look across to the right from there, this is -- we hired a forensic accountant to do some math on the process and handling payments. And it looks like, if I'm not mistaken, you received $70 in processing and handling fees from Singulex between 2012 and 2013. Does that seem about right to you?
A. That does.
Q. And that's, of course, what you said. You only ordered the tests a few times; right?
A. Correct.
Q. And then if you look down to the second box, you'll see -- the second from the bottom, again "Columbia Heart Clinic, W. Joseph Hollins II."

And it looks like between 2012 and 2014, you received -- or excuse me -- your practice received $54,146 in processing and handling fees from Health Diagnostic Laboratories. Does that seem about right to you?
A. Yes.
Q. And when -- when we talked during your deposition by telephone last Friday, I asked you what happens with those processing and handling fees. And you told me -- correct me if I'm wrong -- the money went to the general fund of the

2:05PM practice; correct?
2:05PM **A.** Correct.
2:05PM **Q.** And I asked you during your deposition, "How is that
2:05PM general fund used by your practice?"
2:05PM And you answered -- and I quote -- "I mean my best
2:05PM answer there is that money to the practice would be spent on
2:05PM paying bills, and then if there's money at the end of the day,
2:05PM there might be a bonus to the partners. There might not be.
2:05PM It depends on, you know, how the quarter was."
2:06PM Does that sound about right?
2:06PM **A.** So we're a private practice, and we pay our bills. And at
2:06PM the end of a quarter, we assess whether there's any money to
2:06PM bonus to any partners. There are plenty of quarters where
2:06PM there is no money to bonus or some quarters that are negative,
2:06PM and sometimes there are quarters, depending on pay periods and
2:06PM whatnot for employees, where there is money left over, and that
2:06PM will be bonused to the partners.
2:06PM **Q.** And you're one of those partners?
2:06PM **A.** Correct.
2:06PM **Q.** I'd like to talk about some of your other monetary
2:06PM dealings with Health Diagnostic Laboratory. Mr. Cooke made a
2:06PM reference to the medical advisory board for Health Diagnostic
2:06PM Laboratory that you served on. And Health Diagnostic
2:06PM Laboratory paid you $3,000 each month to serve on that board;
2:06PM correct?

2:06PM **A.** Correct.
2:06PM **Q.** And you, in addition to that, gave a number of paid speeches on behalf of Health Diagnostic Laboratory between 2012 and 2014; correct?
2:06PM **A.** Correct.
2:06PM **Q.** And in those speeches, you would tell other providers about Health Diagnostic Laboratory's lab tests; correct?
2:07PM **A.** Those speeches were CME talks to talk about the lab tests.
2:07PM **Q.** Lab tests offered by Health Diagnostic Laboratory?
2:07PM **A.** Correct.
2:07PM **Q.** And Health Diagnostic Laboratory wrote you a check for each of those speeches; correct?
2:07PM **A.** Correct.
2:07PM **Q.** And Health Diagnostic Laboratory wrote you a check for somewhere between $2,000 and $2,500 for each of those speeches; correct?
2:07PM **A.** Those were -- that was per hour.
2:07PM **Q.** Per hour. Okay. So if the talk was more than an hour, it might be more than $2,500.
2:07PM **A.** Exactly.
2:07PM **Q.** Thank you, sir. No more questions. Appreciate your time today.
2:07PM **THE COURT:** Mr. Ashmore?
2:07PM **MR. ASHMORE:** No questions, Your Honor.
2:07PM **THE COURT:** Mr. Cooke?

2:07PM 1 **MR. COOKE:** A couple of follow-up.
2:07PM 2 **REDIRECT EXAMINATION**
2:07PM 3 **BY MR. COOKE:**
2:07PM 4 **Q.** When you answered the question about what happens to the
2:07PM 5 money that comes into the practice, were you referring
2:07PM 6 specifically to P&H fees or to all the money that comes into
2:07PM 7 your practice?
2:07PM 8 **A.** Well, all of the money that comes into the practice -- I
2:08PM 9 want to make sure I'm correct when I say this.
2:08PM 10 I believe all the money that comes into the practice
2:08PM 11 just -- it does. It doesn't go to any individual doctor. All
2:08PM 12 the money that comes to the practice comes to Columbia Heart
2:08PM 13 Clinic, PA, and then it's processed from that point. But no --
2:08PM 14 no specific doctor gets paid directly from anybody.
2:08PM 15 **Q.** And then on these CMEs, that means continuing medical
2:08PM 16 education?
2:08PM 17 **A.** Correct.
2:08PM 18 **Q.** Do you -- in order to qualify for CME credit, do you have
2:08PM 19 to have your presentation approved and set in advance?
2:08PM 20 **A.** Yes, sir, I do.
2:08PM 21 **Q.** Who approves it?
2:08PM 22 **A.** There was a department at HDL laboratory for CME, and
2:08PM 23 those slides had to be submitted and approved in advance. And
2:08PM 24 I wasn't able to add or subtract from them. I had to give the
2:08PM 25 presentation after their approval.

2:08PM 1 **Q.** Now, in order for these to qualify for CME credits, are
2:09PM 2 they allowed to be infomercials for the specific laboratory?
2:09PM 3 **A.** So my understanding is, in order to be approved, they had
2:09PM 4 to be purely educational, nonprofessional, if you will.
2:09PM 5 **Q.** And were you allowed to provide promotional materials in
2:09PM 6 the CME?
2:09PM 7 **A.** No.
2:09PM 8 **Q.** Thank you.
2:09PM 9 **THE COURT:** Let me ask you a question.
2:09PM 10 On the -- how long were you on the advisory
2:09PM 11 committee on which you were earning the $3,000 a month?
2:09PM 12 **THE WITNESS:** I think that was about a year and a
2:09PM 13 half perhaps.
2:09PM 14 **THE COURT:** And how often did the medical advisory
2:09PM 15 committee meet?
2:09PM 16 **THE WITNESS:** To my memory, we met two or three times
2:09PM 17 in Richmond.
2:09PM 18 **THE COURT:** And that would require you to travel
2:09PM 19 there on a weekend?
2:09PM 20 **THE WITNESS:** Go down on a weekend.
2:09PM 21 **THE COURT:** And did that money go directly to you or
2:09PM 22 to your practice?
2:09PM 23 **THE WITNESS:** That was money that would go directly
2:09PM 24 to me.
2:09PM 25 **THE COURT:** And how frequently did you give speeches?

2:10PM **THE WITNESS:** I give a lot of talks.
2:10PM **THE COURT:** I'm thinking specifically regarding HDL.
2:10PM **THE WITNESS:** I submitted invoices for those talks, so they're on -- they're somewhere documented, but I would guess six or eight, at the tops, maybe 10 talks. But I -- somewhere in there. I would say six or eight.
2:10PM **THE COURT:** When you travel -- I know you mentioned you went to Hilton Head -- how did you bill for that? How would that have been billed?
2:10PM **THE WITNESS:** So those out-of-town talks were flights. You know, I went to Ohio; I went to Portland, Oregon; I went to Austin, Texas; I went to somewhere in Idaho. I flew around and spent weekends doing that.
2:10PM And I was asked to turn in the actual number of
2:11PM hours that the talk took, and I was asked to turn in the number
2:11PM of hours of travel time as part of an invoice and to turn in
2:11PM expenses as part of that. So all of that was turned in to HDL.
2:11PM **THE COURT:** So when you -- how much were you making per hour?
2:11PM **THE WITNESS:** The talks, if I'm correct, I believe, were, like, $2,000 for one hour. And, typically, these talks were at least about three hours. It would take an entire half of a Saturday morning.
2:11PM **THE COURT:** So you would make $7500 -- so 6,000 --
2:11PM **THE WITNESS:** 6,000 would be typical for a three-hour

talk on a Saturday.

THE COURT: And if you had to go out of town, how would you bill for that? How much per hour?

THE WITNESS: Well, it's about the same thing.

THE COURT: About $2,000 an hour?

THE WITNESS: Somewhere in there -- 2500, somewhere in there, that I would get reimbursed for an out-of-town talk.

THE COURT: So how many hours would you spend -- you mentioned you went to Idaho and these other states --

THE WITNESS: Well, the travel time was extensive. And they asked me to fill out the invoice.

THE COURT: I understand. I'm trying to figure out how much you billed.

THE WITNESS: So I did that. I mean, I kept track of the actual travel time and submitted that.

THE COURT: On your out-of-town trips, what would you estimate for that weekend, the number of hours?

THE WITNESS: It could be quite extensive. I know -- I think probably the most extensive was the one to Ohio because it was snowing. And after I arrived at the airport, I was in a car in the snow on the interstate for hours and hours. So that one was a -- probably the biggest one.

THE COURT: And how much would that be?

THE WITNESS: It was -- the fee was -- or the scale they gave me to turn in was $300 per hour for travel time.

2:12PM **THE COURT:** Okay. So that differed. You didn't get the 2500 per hour.

2:12PM **THE WITNESS:** Oh, no, not for travel.

2:12PM **THE COURT:** What would you estimate Ohio's trip for total compensation?

2:12PM **THE WITNESS:** I think that one was the biggest one and -- but with all the time spent plus giving the talk, I believe that total was around $18,000.

2:13PM **THE COURT:** Okay.

Any questions occasioned by the Court's questions.

From the government?

2:13PM **MR. KASS:** No, sir.

2:13PM **THE COURT:** From the defense?

2:13PM **MR. COOKE:** Yes, I do have a couple of questions.

REDIRECT EXAMINATION

BY MR. COOKE:

2:13PM **Q.** Was that a common practice in the medical field, for physicians to be retained to give continuing medical education courses around the country?

2:13PM **A.** I would just say that, from my experience, most of the speaking I do is promotional rather than CME. But it's common to be invited to speak at CME presentations and CME courses. Those are commonly held -- seminars are commonly held.

2:13PM **Q.** What about promotional? Is that also common within the --

2:13PM within the medical field?
2:13PM **A.** It's very common, yes.
2:13PM **Q.** And that would be not just laboratories, but pharmaceutical companies and --
2:13PM **A.** Most of it is pharmaceutical companies.
2:14PM **Q.** And medical device --
2:14PM **A.** For me, at least.
2:14PM **Q.** Medical device companies, those types of things as well?
2:14PM **A.** I can't remember that I've ever spoken for a medical device company. I can't recall that. But I have -- I do lots of presentations for pharmaceutical companies to -- that's the way people get education about new drugs and new applications of drugs.
2:14PM **MR. COOKE:** All right. Thank you. That's all.
2:14PM **THE COURT:** Thank you.
2:14PM Mr. Ashmore?
2:14PM **MR. ASHMORE:** No, sir.
2:14PM **THE COURT:** You may step down, Doctor. Thank you very much.
2:14PM **THE WITNESS:** Thank you.
2:14PM (Witness excused.)
2:14PM **THE COURT:** Mr. Cooke, next?
2:14PM **MR. GRIFFITH:** Your Honor, this is going to be a 30(b)(6) deposition.
2:14PM **THE COURT:** Very good.

2:14PM 1 Ladies and gentlemen, you may recall earlier we
2:15PM 2 played some depositions. And this is depositions of a party.
2:15PM 3 It's just --
2:15PM 4 You're actually going to read it?
2:15PM 5 **MS. SHORT:** Yes.
2:15PM 6 **THE COURT:** Okay. We have a live witness -- a live
2:15PM 7 person here. And the -- it is as if this is a party witness.
2:15PM 8 It is as if it was a person testifying under oath as if that
2:15PM 9 person was here.
2:15PM 10 Mr. Griffith, please continue.
2:15PM 11 **MR. GRIFFITH:** Yes, Your Honor. And I would say in
2:15PM 12 advance that if I make a mistake, I would ask, you know, that
2:15PM 13 everybody point it out to me to correct.
2:15PM 14 **THE COURT:** I don't think those folks from the
2:15PM 15 government will neglect you at all.
2:15PM 16 **MR. GRIFFITH:** I'm sure they will.
2:15PM 17 **THE COURT:** I don't think you have to worry about
2:15PM 18 that.
2:15PM 19 **MR. GRIFFITH:** Your Honor, can I -- can I state who
2:15PM 20 the witness is?
2:15PM 21 **THE COURT:** Yes.
2:15PM 22 **MR. GRIFFITH:** Okay. It's Jennifer Williams, who was
2:15PM 23 the OIG representative.
2:15PM 24 **THE COURT:** And just remind the jury who OIG is.
2:16PM 25 **MR. GRIFFITH:** The OIG is the Office of Inspector

General of the Department of Health and Human Services.

THE COURT: Thank you.

Please.

MS. SHORT: I was just going to -- Your Honor, just to clarify for the jury, this is not Jennifer Williams.

THE COURT: Right. They know this is the lady they've seen going back and forth getting the witnesses. So we know that's not -- but thank you, Ms. Short, for bringing that up.

MR. GRIFFITH: Okay. Starting at -- Your Honor, do you want me to read -- enunciate the page number when I start?

THE COURT: I think, as I understand it, you and the government have made your designations. I've approved those, so I think you just read on. And if there's a break, you might just say "break" or something to clear to the jury that that -- you know, that that particular question and answer has ended and there's another one. Okay?

MR. GRIFFITH: Very good.

(Whereupon the following deposition was read into the record:)

JENNIFER WILLIAMS,

a witness called on behalf of the defendants, being first duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. GRIFFITH:

2:16PM **Q.** And are we here for your 30(b)(6) deposition of the United States? Is that your understanding?
2:16PM **A.** Yes.
2:16PM **Q.** Okay. Did you receive a copy of Exhibit Number 1?
2:17PM **A.** Yes.
2:17PM **Q.** Okay. And it's my understanding that you're going to be testifying as to Topics 1 through 6, 12, 13, and 17. Is that your understanding?
2:17PM **A.** That's my understanding, yes.
2:17PM **MR. GRIFFITH:** Break.
2:17PM **BY MR. GRIFFITH:**
2:17PM **Q.** What have you done to prepare for your deposition?
2:17PM **A.** I reviewed documents, including those listed in the topics. I spoke with Jennifer and Steve. I did some independent searches on using the HHS OIG website for some of the terms used in the topics. I spoke with people who are knowledgeable about facts that I did not have knowledge of. And I think that's it.
2:17PM **Q.** And who were the people besides Jennifer that you spoke to?
2:17PM **A.** I spoke with Lauren Marziani, who is within the office of counsel at the OIG. And I also spoke with an agent I previously had been -- it was my understanding, when this was originally scheduled in May, that I would be speaking on a topic that ends up I'm not testifying on regarding recording,

so I spoke with an agent about that.
Q. And who was that?
A. Eric Rubenstein, I believe his name is. I can't say for sure because I haven't -- it's been a while.
Q. Okay. You said you reviewed documents. Do you recall which documents you reviewed?
A. I reviewed all the documents referenced in the topics on which I have been designated to testify. And I also reviewed other advisory opinions that referenced some of the terms included in those topics. I looked at some safe harbors and preamble to the safe harbors that included some of the terms designated in the topics.
Q. Okay. And where -- where are you employed?
A. I'm employed at HHS-OIG, which is the Office of Inspector General, and I am in the industry guidance branch within the office of counsel to the inspector general.
MR. GRIFFITH: Break.
BY MR. GRIFFITH:
Q. And so what is your particular position at the OIG's industry guidance branch?
A. I'm the deputy branch chief.
Q. And what do your duties entail?
A. As deputy branch chief, I manage six people within the industry guidance branch. I'm responsible for reviewing advisory opinions that the staff attorneys draft. I used to be

a staff attorney, but now I'm in the management.

In general, the industry guidance branch, we issue advisory opinions and respond to advisory opinion requests, which doesn't always necessarily result in the issuance of an advisory opinion. We provide technical assistance to other branches, other agencies. We issue guidance documents, including special fraud alerts, special advisory bulletins, compliance program guidance.

We review regulations promulgated, both proposed and final, by other agencies. And we also are involved in analyzing the fraud and abuse risks associated with alternative payment models that come out of CMMI, which is the Centers for Medicare and Medicaid Innovation Center. CMMI, I think that acronym is correct from my understanding of what the acronym means is correct. And then we will draft waivers in connection with those models, if necessary.

Q. And what would a waiver typically be for?

A. So it's in conjunction with alternative payment models that come out of CMMI. So, you know, like, the OCR which is -- so comprehensive joint model, bundled payment models. So the innovative types of alternative payment models that are being used to test new ways of reimbursement.

Sometimes they involve payment streams that implicate the Stark and Anti-Kickback Statute, also, potentially, the prohibition of Federal Beneficiary Inducement Statute. So we

2:20PM have to analyze in conjunction with CMS and their attorneys.
2:20PM They do the Stark analysis. Our group does the anti-kickback
2:21PM and bene inducement analysis, and, if necessary, we'll craft a
2:21PM waiver that is applicable to certain payment streams that are
2:21PM necessary to test the model.
2:21PM **Q.** Quite busy.
2:21PM **A.** Oh, yeah.
2:21PM **Q.** So -- and how long have you been with OIG?
2:21PM **A.** I started in January 2011.
2:21PM **Q.** What did you do before that?
2:21PM **A.** I worked at Mintz Levin for eight years before that.
2:21PM **Q.** Did you have a specialty at Mintz Levin?
2:21PM **A.** I did. I was a health care attorney.
2:21PM **Q.** And so, generally, can you just give me an overview of
2:21PM what the OIG does.
2:21PM **A.** Sure. OIG is an independent agency within the Department
2:21PM of Health and Human Services. Our mission is to protect the
2:21PM integrity of the federal health care program and the health and
2:21PM welfare of federal health care program beneficiaries.
2:21PM We do this by trying to combat fraud, waste, and
2:21PM abuse through nationwide audits, investigations, and
2:21PM evaluations, and also through the issuance of guidance to help
2:22PM people understand and comply with fraud and abuse laws.
2:22PM **Q.** And so does OIG ultimately report to the secretary of the
2:22PM Department of Health and Human Services?

2:22PM **A.** I don't believe we report to the secretary because we are an independent agency. Many of the authorities that have been delegated to us, initially, by statute, are delegated to the secretary. For example, our authority to promulgate safe harbor regulations, I believe, was delegated to the secretary of HHS, and then it's been delegated to OIG.

2:22PM **Q.** But the OIG is a part of the U.S. Department of Health and Human Services?

2:22PM **A.** So we're within the Department of Health and Human Services. We are unique among inspector general offices in the sense that our jurisdiction extends beyond the agency to every individual and entity that receives federal health care program dollars. So most IGs are focused on fraud, waste, and abuse within their own agency; ours extends well beyond the agency.

2:23PM **Q.** And so you can -- you had mentioned previously that CMS, the Centers for Medicare & Medicaid Services -- and I just understood you to say that CMS performed Stark analysis and your particular branch performed anti-kickback analysis. Did I --

2:23PM **A.** Correct.

2:23PM **Q.** -- sort of get that correct?

2:23PM **A.** Correct. Stark is -- CMS promulgated the Stark regulations, and so they have the jurisdiction to interpret those regulations; we do not.

2:23PM **Q.** So if a -- can you give me an example of how that would

work in terms of a -- if there was a health care provider who had a questionable practice that might implicate both the Stark and Anti-Kickback Statute, does OIG and CMS conduct, typically, a joint investigation of such practice?

A. So we have the authority to enforce the Stark statute and regs.

Q. Okay.

A. And, yes, we typically will consult with CMS.

MR. GRIFFITH: Break.

BY MR. GRIFFITH:

Q. Okay. Do any Anti-Kickback Statute-related federal regulations have a definition of fair market value?

A. The term itself is not defined in any regulations, no. It is used in context in at least three safe harbors which are regulations. When it describes one -- the safe harbors have a number of required elements to receive protection under them. And, for example, the space rental safe harbor, one of the required elements is that the remuneration be fair market value and an arm's length transaction and not determined in a manner that takes into account the volume or value of referrals.

Q. And what were the other two safe harbors that you referenced?

A. The second one is equipment rental. And that can be found at 42CFR1001.952(c). Space rental is (b), and personal services safe harbor, which is (d), 1001.952(d).

2:25PM **Q.** And the -- just to be clear, both the equipment rental and the personal services safe harbor also have an element that remuneration must be paid at fair market value, arm's length, not taking any account the volume or value of referrals?

2:25PM **A.** Correct.

2:25PM **Q.** Has the OIG issued any guidance defining fair market value?

2:25PM **A.** I'm not sure if "definition" is the appropriate characterization. It's used in context in a number of places. There is -- on our website, under the "compliance" tab, if you choose "advisory opinions," there's a frequently asked questions section. And within there, we give a list of preliminary questions for people to review when they are submitting an advisory opinion request that will help us to analyze the arrangement.

2:25PM And included in there, we describe the -- that fair market value, again, means must be determined in an arm's length transaction without taking into account any referrals that one party can give to another. It's a little bit more in plain English, but it's got all the same components that we've discussed. It's also used many times in the advisory opinions.

2:26PM So in preparation for the deposition, I ran some searches again on our website. I searched the exact term "fair market value" in advisory opinions only and came up with 374 results. Some of those were duplicates, so I think the true

number is probably closer to 175 or so. But that gives you an idea of how often it's used in advisory opinions.

So I will add that in the advisory opinion context, we are statutorily precluded from opining on whether an arrangement is fair market value, but we will evaluate the methodology that the parties used to determine fair market value. And there are a couple of opinions that speak to that, specifically Advisory Opinion 10-16 and 11-17.

Q. And Advisory Opinion 10-16 and 11-17 specifically address the methodology for determining fair market value?

A. It specifically addresses the fact that we will evaluate the methodology to see if it's reasonable. So we can't opine on whether something is fair market value, but we can say that the methodology you used to determine fair market value is suspect.

Q. Does OIG have any guidance on what methodologies would be approved or looked upon favorably by OIG?

A. No.

Q. With respect to fair market value analysis --

A. So it's -- we don't tell people how to structure their arrangements. What we will say is there are certain types of ways that we find suspect. So we will say, you know, per-click, per-order, per-patient types of methodologies are disfavored under the Anti-Kickback Statute and will receive much greater scrutiny.

2:28PM 1 And you can also look to advisory opinions to see
2:28PM 2 arrangements. There was one in particular involving -- I don't
2:28PM 3 remember the number -- fundus photograph, I think, for eyes,
2:28PM 4 where one of the parties to the transaction was subleasing
2:28PM 5 equipment. And the methodology they used to sublease it, we
2:28PM 6 said, seemed reasonable because it was based on a fixed amount.
2:28PM 7 **Q.** You said that OIG has -- looks upon certain types of
2:28PM 8 methodologies with disfavor, including per-click, per-order,
2:28PM 9 and/or per-service; is that right?
2:28PM 10 **A.** Yes.
2:28PM 11 **Q.** Are there any other types of methodologies upon which OIG
2:28PM 12 looks with disfavor that you can recall?
2:28PM 13 **A.** Any methodology that takes into account the volume or
2:28PM 14 value of referrals would be suspect in our eyes.
2:28PM 15 **MR. GRIFFITH:** Break.
2:28PM 16 **BY MR. GRIFFITH:**
2:28PM 17 **Q.** Yeah. Has OIG issued any guidance with respect to
2:28PM 18 standards by which fair market value should be determined with
2:28PM 19 respect to physician compensation?
2:29PM 20 **A.** Again, we -- it's not our practice to issue guidance to
2:29PM 21 tell people how to structure their transactions. What we do is
2:29PM 22 we tell them -- is we inform people of methodologies that we
2:29PM 23 find suspect. So, again, anything that takes into account the
2:29PM 24 volume or value of referrals, which would be per-click,
2:29PM 25 per-order, per-patient, percentage-based arrangements is

2:29PM another example we've given.
2:29PM **MR. GRIFFITH:** Break.
2:29PM **BY MR. GRIFFITH:**
2:29PM **Q.** Well, I understand that you give guidance on what it is
2:29PM that you find disfavorable.
2:29PM **A.** Uh-huh.
2:29PM **Q.** My question is, do you have any -- are there any standards
2:29PM provided in guidance regarding how to perform a fair market
2:29PM value analysis?
2:29PM **A.** We don't see that as our role. Its not our role to
2:29PM determine -- to tell people how to determine fair market value
2:29PM aside from avoiding methodologies that we find suspect.
2:29PM **Q.** Has OIG issued any guidance on the qualifications that an
2:30PM appraiser must have in order to perform a fair market value
2:30PM analysis in the Anti-Kickback Statute context?
2:30PM **A.** The qualifications?
2:30PM **Q.** Right.
2:30PM **A.** Not to my knowledge.
2:30PM **Q.** Okay. So if a health care provider's compensation
2:30PM arrangement with a physician is not in compliance with an AKS
2:30PM exception or safe harbor, what is OIG's guidance on the
2:30PM applicable definition of fair market value?
2:30PM **A.** Well, when we do an analysis of an arrangement under the
2:30PM Anti-Kickback Statute, first we look to see, is the statute
2:30PM implicated? Which means are the objective elements satisfied?

Is there remuneration being offered, paid, solicited, or received in return for or to induce referrals or the arranging for referrals or in return for the purchase, lease, or ordering or arranging for recommending the purchase, lease, or ordering of federally reimbursable items or services.

If the statute is implicated, then we'll look to see if it satisfies the requirement of a safe harbor. If it does not, then we move on to a case-by-case analysis. And, again, I'm speaking in the advisory opinion context. We will look to see, does it present more than a minimal risk of fraud and abuse under the Anti-Kickback Statute? If it presents a minimal risk of fraud and abuse, then we could issue a favorable opinion, but if it presents more than a minimal risk of fraud and abuse, then we would go towards an unfavorable opinion.

Q. Okay. So when you were talking about how you analyze a particular arrangement, I understood you to say that the first analysis is whether or not the Anti-Kickback Statute is implicated.

A. Correct.

Q. And so -- and I've seen the word implicated used throughout numerous OIG opinions, and I just want to make sure I understand the meaning of that word.

Are you saying that "implicated" means that it meets all the objective elements of the Anti-Kickback Statute?

2:31PM **A.** Yes. Because the Anti-Kickback Statute is an intent-based
2:32PM criminal statute. We are -- we do not opine on intent.
2:32PM **Q.** Okay.
2:32PM **A.** So when I say "implicated," I mean the other elements of
2:32PM the statute as we just went through.
2:32PM **Q.** Okay. Okay. So in the -- what we're discussing -- if an
2:32PM arrangement is implicated, implicates the Anti-Kickback Statute
2:32PM and does not meet a safe harbor, I understand that you do a
2:32PM case-by-case analysis.
2:32PM **A.** Correct.
2:32PM **Q.** Okay. And as part of that case-by-case analysis, is there
2:32PM a definition of fair market value that is applied to a
2:32PM particular arrangement?
2:32PM **A.** So, again, we don't define the term except to say that
2:32PM certainly methodologies are suspect. We are not experts on
2:32PM fair market value, and we are not -- and we are precluded,
2:32PM statutorily precluded, from opining on whether an arrangement
2:32PM is fair market value in the advisory opinion context.
2:32PM So aside from saying this methodology is suspect or
2:32PM questionable and, therefore, we can't approve it, no, we do not
2:33PM offer affirmative guidance on how to establish or the
2:33PM methodology one should use to establish fair market value.
2:33PM **Q.** Does the Anti-Kickback Statute authorize the application
2:33PM of Stark definitions of fair market value to OIG Anti-Kickback
2:33PM Statute analysis?

2:33PM **A.** No. They are two separate and independent statutes.
2:33PM **Q.** Now, we spoke about -- you just spoke about the Anti-Kickback Statute. Is there any OIG guidance on the application of Stark definitions of fair market value to Anti-Kickback Statute analysis by OIG?
2:33PM **A.** No. Again, the Stark regs are CMS regs, and so they interpret the Stark regs. OIG interprets and enforces the kickback statute.
2:33PM **Q.** Is there any OIG guidance to health care providers on situations where there's a difference of opinion regarding the fair market value of services or remuneration in the Anti-Kickback Statute context?
2:33PM **A.** Not to my knowledge, no. Again, our requirements, our guidance, says that an arrangement must be fair market value. We set forth certain methodologies that are suspect, but we don't get -- in the advisory opinion context, we don't get into disputes.

If an arrangement -- so in the advisory opinion context, a requestor has to certify that the facts they're giving to us are true, and one of the facts typically is that the arrangement is commensurate with fair market value.

So we accept that certification as true. We will look to the methodology used to determine it, but because we are statutorily precluded from opining on fair market value, we just accept that certification. If it's not true, the advisory

2:34PM opinion has no force and effect. It does not protect the conduct.
Q. Okay. When OIG is analyzing an arrangement under AKS and a safe harbor is not met, does the OIG apply elements of safe harbors to an arrangement to determine whether or not to -- whether or not the risk is minimal or not?
A. We evaluate the overall risk posed by an arrangement. So to receive protection under a safe harbor, every single element requirement must be satisfied. There is no close enough. So if a safe harbor is not satisfied, then we move on to the next step. We don't look to the safe harbor to inform our analysis necessarily of an opinion or of an arrangement. Excuse me.
Q. And I'm not trying to misquote you; I'm just trying to understand.

So are you saying if a safe harbor is not met and you're doing a case-by-case or circumstances analysis, you do not apply the elements of the safe harbor to the arrangement?
A. We may look to it to inform our analysis, but it is a separate and independent analysis because if every single element is not satisfied, then the safe harbor offers no protection.
Q. Does the Anti-Kickback Statute have a definition of commercial reasonableness?
A. A definition? No. It's not present in the statute nor does that term appear in the statutory text.

2:36PM **Q.** Do any AKS-related federal regulations have a definition of commercial reasonableness?
2:36PM **A.** There is no definition in the regulations. It is used in context. Commercial reasonableness typically appears in connection with fair market value and in an arm's-length transaction, not taking into account volume and value of referrals. Those concepts are related and typically, if not always, appear together.
2:36PM **Q.** So I understand commercial reasonableness is not defined in the Anti-Kickback Statute or the regulations. Is there a definition of commercial reasonableness in any OIG guidance?
2:36PM **A.** There's not a definition per se, and it's not quite a term of art as fair market value is. You will see it maybe "commercially reasonable business purpose," might be "legitimate business purpose," might be "actual and necessary services." So there are --
2:37PM **THE COURT:** Analogous.
2:37PM **MS. MASON:** I can't talk.
2:37PM **THE WITNESS:** -- analogous terms used, but we consider those terms to be self-evident, self-explanatory.
2:37PM **MR. GRIFFITH:** Break.
2:37PM **BY MR. GRIFFITH:**
2:37PM **Q.** Okay. Well, I understand the commercial reasonableness concept as discussed in CPG's and advisory opinions; is that right?

2:37PM **A.** Correct.

2:37PM **MR. GRIFFITH:** Break.

2:37PM **BY MR. GRIFFITH:**

2:37PM **Q.** Okay. So it's not the OIG's role to tell health care providers or instruct health care providers how to determine whether an arrangement is commercially reasonable or not, but the OIG will tell them the disfavorable methodologies with respect to commercial reasonableness?

2:37PM **A.** So we interpret and enforce the Anti-Kickback Statute, which is a prohibiting statute. It says, you know, you can't knowingly and willfully pay remuneration in return for referrals or arranging for referrals.

2:37PM So our guidance interprets that. So we tell them what -- you know, what that would encompass. We don't tell them how you can structure a business arrangement. We just tell you what types of arrangements might implicate the statute and potentially violate the statute.

2:38PM **Q.** Is there any OIG guidance on what qualifications a person must possess in order to perform a commercial reasonableness analysis?

2:38PM **A.** No.

2:38PM **MR. GRIFFITH:** Break.

2:38PM **BY MR. GRIFFITH:**

2:38PM **Q.** But does OIG routinely perform a commercial reasonableness analysis with respect to its analysis of the Anti-Kickback

2:38PM Statute as applied to an arrangement?
2:38PM **A.** So in the advisory opinion context, we will look to see if
2:38PM an arrangement appears on its face not to be commercially
2:38PM reasonable. If it does, we will note that in the opinion;
2:38PM otherwise, we will accept the requestor's certification as
2:38PM correct.
2:38PM **Q.** So a requestor can certify that his arrangement is
2:38PM commercially reasonable?
2:38PM **A.** Yes. And we will look at the other facts provided in
2:39PM connection to determine if there are factors that would lead us
2:39PM to conclude it is not.
2:39PM **Q.** Well, in the advisory opinion context, when OIG is
2:39PM analyzing arrangement, is commercial reasonableness always
2:39PM applied to the arrangement from OIG's perspective?
2:39PM **A.** Again, we look at the overall level of risk posed by an
2:39PM arrangement. So if an arrangement as presented to us would not
2:39PM be commercially reasonable in the absence of referrals, then we
2:39PM would conclude likely that the arrangement poses more than a
2:39PM minimum level of fraud and abuse risk.
2:39PM **MR. GRIFFITH:** Break.
2:39PM **BY MR. GRIFFITH:**
2:39PM **Q.** So the Anti-Kickback Statute regulations set forth --
2:39PM excuse me. So do the Anti-Kickback Statute regulations set
2:39PM forth any standards or protocols for the OIG in doing and
2:39PM performing an advisory opinion where the arrangement does not

2:39PM 1 meet a safe harbor?
2:39PM 2 **A.** So we have a number of regulations. We have the safe
2:39PM 3 harbors. We have regulation that govern how we treat advisory
2:40PM 4 opinion requests which are found at 42 CFR 1008. But those
2:40PM 5 regulations do not dictate how we perform an analysis of the
2:40PM 6 Anti-Kickback Statute.
2:40PM 7 **Q.** Does the Anti-Kickback Statute authorize the application
2:40PM 8 of Stark definitions of commercial reasonableness to an
2:40PM 9 Anti-Kickback Statute analysis by OIG?
2:40PM 10 **A.** The statute does not.
2:40PM 11 **Q.** What about the regulations?
2:40PM 12 **A.** They do not. They are separate and independent statutes
2:40PM 13 and regulations.
2:40PM 14 **Q.** What about OIG guidance? Is there any guidance on
2:40PM 15 applying Stark definitions of commercial reasonableness to an
2:40PM 16 Anti-Kickback Statute analysis by OIG?
2:40PM 17 **A.** We don't have the authority to interpret the Stark
2:40PM 18 provisions. That's -- again, that's all under CMS's
2:40PM 19 jurisdiction. Our regulations do not. Our regulations
2:40PM 20 promulgated interpreting the Anti-Kickback Statute do not
2:40PM 21 reference Stark.
2:41PM 22 **Q.** Okay. And I understand about the Anti-Kickback Statute
2:41PM 23 and the anti-kickback regulations, but I specifically am just
2:41PM 24 talking about OIG guidance.
2:41PM 25 Is there any guidance which says that OIG will apply

2:41PM Stark definitions of commercial reasonableness to an Anti-Kickback Statute analysis?
A. Not that I'm aware of.
Q. Is there any OIG guidance to health care providers on situations where there is a difference of opinion as to the commercial reasonableness of a particular arrangement?
A. No, unless that difference of opinion relates to a methodology that we have described as suspect.
Q. Does the Anti-Kickback Statute have a definition of the term "arranging"?
A. The statute does not.
Q. Do any AKS-related regulations have a definition of "arranging"?
A. Not to my knowledge. We consider that term self-explanatory.
Q. So there's no OIG guidance on the definition of "arranging" in the Anti-Kickback Statute context?
A. There is no definition of "arranging" in the Anti-Kickback Statute.
Q. Well, I understand in the statute. I'm asking specifically in OIG guidance. Has OIG provided any definition of "arranging" in any of its guidance?
A. There is not a per se definition. Again, when we evaluate arrangements in the advisory opinion context, we will describe our analysis, including whether the conduct constitutes

arranging for or recommending.

For example, there's an advisory opinion that discusses promotional activities -- I don't remember the number; it's a 98-something or a 99-something -- where we say promotional activities fall directly within the purview of the statute because they constitute arranging for or recommending.

Q. Has the OIG issued any guidance regarding standards by which conduct can be determined to be arranging or not?

A. We have not issued stand-alone guidance on that topic. Generally it comes up when we are in the context of evaluating or describing types of arrangements or relationships.

MR. GRIFFITH: Break.

BY MR. GRIFFITH:

Q. Does the OIG take the position or has it issued any guidance on whether the arranging in an Anti-Kickback Statute context means generally arranging the order of a service or item versus having to order a specific item or service for a specific patient?

MR. GRIFFITH: "Objection. Vague."

BY MR. GRIFFITH:

Q. Do you understand my question?

A. We haven't issued guidance specifically on that topic. When we evaluate an arrangement, we look to see what remuneration is being paid or solicited between the parties and what the relationship of those parties is.

2:43PM If there is a direct referral arrangement or if there's an indirect referral arrangement which would potentially constitute arranging for referrals or arranging for the -- or recommending the purchase of federally reimbursable items or services. So it's a very context-specific analysis.

2:44PM **Q.** So if a salesman provides passion --

MR. GRIFFITH: Break.

BY MR. GRIFFITH:

Q. In terms of our discussion on arranging, same series of questions with respect to recommending. Okay?

A. Okay.

Q. Does the AKS statute have a definition of "recommending"?

A. It does not.

Q. Do any AKS related regulations have a definition of "recommending"?

A. There is no per se definition. Again, it's typically used contextually.

Q. And does the OIG have any guidance on the definition of "recommending"?

A. Well, we have lots of guidance out there and much of it incorporates the use of the term "recommending." Again, we consider the term itself to be self-explanatory. We use it when analyzing or describing relationships or arrangements between parties. So, again, it's very contextual, so there is no per se definition of the term.

2:44PM **Q.** Is there any OIG guidance or standards by which conduct is
2:45PM determined to be recommending or not?
2:45PM **MR. GRIFFITH:** "Objection. Vague."
2:45PM **BY MR. GRIFFITH:**
2:45PM **Q.** You can answer.
2:45PM **A.** We don't set forth standards for determining whether
2:45PM conduct is recommending. We will look at a particular
2:45PM arrangement and state whether it's our conclusion that it
2:45PM involves recommending in context so there is guidance in that
2:45PM sense.
2:45PM **MR. GRIFFITH:** Break.
2:45PM **BY MR. GRIFFITH:**
2:45PM **Q.** Has OIG given any guidance with respect to recommending as
2:45PM to -- as to conduct by a salesman needing to be with respect to
2:45PM a specific patient regarding a specific -- specific order in
2:45PM order to be considered recommending?
2:45PM **MR. GRIFFITH:** "Objection. Vague."
2:45PM **BY MR. GRIFFITH:**
2:45PM **Q.** You can answer.
2:45PM **A.** So we haven't offered stand-alone general guidance in that
2:45PM sense. You know, in the advisory opinion context, we are
2:45PM required to analyze the facts and arrangements as they are --
2:45PM as they are presented to us. So to the extent that those facts
2:45PM had been presented to us and resulted in an issued advisory
2:46PM opinion, then you would -- then there would be guidance on that

2:46PM point. I'm not familiar with the specific advisory opinion
2:46PM that dealt with that exact issue.
2:46PM **MR. GRIFFITH:** Break.
2:46PM **BY MR. GRIFFITH:**
2:46PM **Q.** Does the Anti-Kickback Statute define or explain the
2:46PM phrase "takes into account the value or volume of referrals"?
2:46PM **A.** The statute does not, nor is that term used in the
2:46PM statute.
2:46PM **Q.** What about the anti-kickback-related regulations?
2:46PM **A.** The safe harbors do. Some of the safe harbors do include
2:46PM those terms, including the ones we discussed earlier, space
2:46PM rental 952(b), equipment rental, 952(c), and personal services,
2:46PM 952(d).
2:46PM Again the terms "fair market value," "commercially
2:46PM reasonable," "arm's length," and "takes into account the value
2:46PM or volume of referrals," all of those terms are used in those
2:46PM three safe harbors because they are closely related concepts.
2:46PM **Q.** Does the phrase "takes" -- "take into account" mean the
2:47PM same thing as "varies with" in terms of the value and volume of
2:47PM referrals?
2:47PM **A.** Not necessarily. Something can vary directly with the
2:47PM value or volume of referrals -- or I should restate that.
2:47PM Something can take into account the volume or value of
2:47PM referrals but not vary directly with the volume or value of the
2:47PM referrals.

2:47PM **MR. GRIFFITH:** Break.
2:47PM **BY MR. GRIFFITH:**
2:47PM **Q.** Who at OIG makes a determination as to whether or not a
2:47PM claim is tainted or disqualified as a result of an
2:47PM Anti-Kickback Statute violation?
2:47PM **THE COURT:** Mr. Griffith, you do not need to read
2:47PM objections. Just go right over.
2:47PM **MR. GRIFFITH:** Okay. Thank you, Your Honor.
2:47PM **BY MR. GRIFFITH:**
2:47PM **Q.** Do you know?
2:47PM **A.** There's not, like, one person who decides whether a claim
2:47PM is tainted. There's typically an agent assigned to our
2:47PM investigations. They often work in conjunction with someone
2:47PM from the office of counsel to assist them with questions they
2:47PM might have analyzing claims, but there's no way to look at an
2:48PM individual claim and determine whether it's been tainted by a
2:48PM kickback violation. You have to look at the conduct between
2:48PM parties.
2:48PM **Q.** Are you familiar with Exhibit Number 2?
2:48PM **A.** Yes.
2:48PM **Q.** Is this one of the documents that you reviewed?
2:48PM **A.** Yes.
2:48PM **Q.** Okay. Okay. So I'm not going to go through this thing
2:48PM sentence by sentence, but I'm going to just point out some
2:48PM particular areas and ask questions on it. Okay?

2:48PM **A.** Okay.
2:48PM **Q.** So on the first page, on the last sentence of the first paragraph, it says, "This special fraud alert supplements these prior guidance documents and advisory opinions and describes two specific trends OIG has identified involving transfers of value from laboratories to physicians that we believe present a substantial risk of fraud and abuse under the Anti-Kickback Statute."

Do you see that?

2:48PM **A.** Yes.
2:48PM **Q.** Okay. And so the OIG identified trends which later on in the document include on page 3 blood specimen collection, processing, and packaging arrangements, and then on page 5, registry payments.

Do you see that?

2:49PM **A.** Yes.
2:49PM **Q.** With respect to the process, blood specimen collection, processing, and packaging arrangements, I'm just going to call those process and handling for short.

What did OIG -- in terms of the trend that was observed, what labs were in the trend which was observed or identified by OIG?

2:49PM **A.** I'm not familiar with the specific laboratories. The way we became aware of it was through initially a response to our annual solicitations for new and modified safe harbors and

special fraud alerts.

We issued that in December 2010, and we received a response requesting a special fraud alert on this conduct in February 2011. Then one or more ACRB attorneys were working on cases where they saw the same conduct, and so we determined a special fraud alert was appropriate.

MR. GRIFFITH: Break.

BY MR. GRIFFITH:

Q. And I thought you said -- and you correct me if I'm wrong -- that in February of 2011, OIG received a request for a special fraud alert.

A. That's correct.

Q. Regarding process and handling?

A. Yes.

Q. Who was that request from?

A. I believe it was from Hope Foster with Mintz Levin. I will note that was within the time that I was -- ethically, I was not able to work on that specific request because I had come from Mintz Levin within the prior year. So I did not review it at that time.

Q. Okay. So noted.

And was Hope Foster requesting a special fraud alert on her own accord or on behalf of a client?

A. I don't recall. It is a publicly available document.

Q. Okay. And so on the bottom of the page, the last

2:50PM sentence, it says, "OIG may also initiate administrative
2:50PM proceedings to exclude persons from the federal health care
2:50PM program to impose civil monetary penalties for fraud,
2:51PM kickbacks, and other prohibited activities under Section
2:51PM 1128(b)(7) -- B as in boy, 7 -- 1128(a)(7) of the act.
2:51PM And so it says, "OIG may initiate administrative
2:51PM proceedings."
2:51PM What are the administrative remedies or actions that
2:51PM were available to OIG to stop the P&H trend of labs that were
2:51PM discovered by OIG?
2:51PM **A.** Our administrative remedies are set forth in the regs. I
2:51PM believe it's at 42 CFR 1003. We have mandatory exclusion and
2:51PM permissible exclusion among our remedies, and it specifies when
2:51PM each those are available. Conviction of a violation of the
2:51PM kickback statute results in mandatory exclusion, so clearly
2:51PM that was not available at the time.
2:51PM **MR. GRIFFITH:** Break.
2:51PM **BY MR. GRIFFITH:**
2:51PM **Q.** Okay. Okay. So on the second page, in the first
2:51PM paragraph, second sentence, it says, "In that special fraud
2:51PM alert we stated that whenever a laboratory offers a -- or gives
2:52PM to a source of referrals anything of value not paid for at fair
2:52PM market value, the inference may be made that the thing of value
2:52PM is offered to induce the referral of business."
2:52PM Do you see that?

2:52PM **A.** I do.
2:52PM **Q.** Okay. Does this mean that, as long as anything of value is paid at fair market value, that no inference is available that the payment was for an inducement of referrals?
2:52PM **A.** Not necessarily. And, in fact, I think later in this special fraud alert, we specifically say that payments at fair market value can implicate and potentially violate the statute.
2:52PM **Q.** Okay. In the second paragraph, the first and second sentences say -- says -- I'm not going to read them, but it basically says that if the laboratory pays more than fair market value, that the Anti-Kickback Statute is implicated.
Do you see that?
2:52PM **A.** Yes.
2:52PM **Q.** And then it further says, "If payments are suspect under Anti-Kickback Statute" -- and my question is what is the -- how does the OIG define the word "suspect"?
2:53PM **A.** Well, we don't have a stand-alone definition of it.
2:53PM **Q.** Okay.
2:53PM **A.** But it means we would give it a higher level of scrutiny.
2:53PM **Q.** And then on the last sentence in that paragraph, it says, "OIG also historically has been concerned with arrangements in which the amounts paid to a referral source take into account the volume or value of business generated by the referral source."
2:53PM So is the -- is such an arrangement as described

there, is that just a concern of OIG or is it a prohibition of the OIG?

A. Well, it states here it's a concern.

Q. Okay.

A. The kickback statute sets forth the prohibited conduct.

MR. GRIFFITH: Break.

BY MR. GRIFFITH:

Q. Has the OIG issued any guidance as to what legal structure is to be used to be --

MS. MASON: Oh, wait.

MR. GRIFFITH: Excuse me. Page 73.

MS. MASON: Excuse me. I had duplicate pages. It threw me off. Okay.

BY MR. GRIFFITH:

Q. Has the OIG issued any guidance as to what legal structure is to be used to be compliant with the Anti-Kickback Statute?

A. With -- specifically with respect to the legal structure, I don't believe we have issued guidance. Again, our guidance typically focuses on things that we find to be problematic. We don't tell people how to structure their business arrangements.

Q. And the same question with respect to operational safeguards.

A. Yeah. We've offered guidance in our compliance program guidance documents that I've mentioned earlier. They kind of outline best practices for a compliance program as well as

identify risk areas, but we do not set forth specific operational safeguards, because they can vary greatly between types of providers.

MR. GRIFFITH: Break.

BY MR. GRIFFITH:

Q. Does OIG take the position that, if a doctor chooses not to bill Medicare for a specimen collection fee, that the doctor can receive a payment from the lab for the same?

A. Right. That's correct. We should have to analyze the arrangement to determine whether the physician typically bills for that service, look to see who is paying the physician, and analyze it, again, on a case-by-case basis.

MR. GRIFFITH: Break.

BY MR. GRIFFITH:

Q. Has OIG taken the position that a lab's fair market value payment to a physician who refers to the lab can ever not be considered an inducement for referrals?

A. Okay. So we haven't analyzed that in a vacuum. We analyzed the arrangement in its entirety. So, you know, I can't say that we've taken a specific position on that. Typically, if a laboratory is making a payment to a physician, the statute is implicated.

Q. And if the statute is implicated, then the analysis ultimately depends on the intent of the parties?

A. Well, whether or not a violation occurs ultimately depends

2:55PM on the intent of the parties.
2:56PM **Q.** Okay.
2:56PM **A.** The analysis -- so, again speaking from the advisory opinion context -- looks at the risk of fraud and abuse presented by an arrangement.
2:56PM **MR. GRIFFITH:** Break.
2:56PM **BY MR. GRIFFITH:**
2:56PM **Q.** Okay. Has OIG issued any guidance regarding standards for determining the intent of the parties with respect to an AKS arrangement?
2:56PM **A.** To my knowledge, we have not issued standards. We will describe certain conduct that we believe evidences unlawful intent.
2:56PM **Q.** Okay. Then on the bottom of page 4 and top of page 5, it says, "Characteristics of a specimen-processing arrangement that may be evidence of an unlawful purpose include, but are not limited to, the following," and there are six bullet points there:
2:56PM Payment exceeds fair market value for services rendered.
2:56PM Payment also made by a third party.
2:56PM Payment is made directly to the physician ordering rather than his practice.
2:56PM Payment made on a per-specimen basis.
2:57PM Payment offered on the condition of either a

specified volume or type of test.

Payment made to a physician's group practice despite the fact that a specimen is actually performed by a phlebotomist in the physician's office.

And my question to you is the OIG just deems these as possible unlawful practices; is that correct?

A. Well, we state that these are characteristics that may be evidence.

Q. Okay. And I just want to clarify. These six bullet points, they are not necessarily evidence of an unlawful purpose; is that true?

A. Well, we say they may be.

Q. Okay.

A. We certainly would consider them suspect.

Q. Does OIG consider the fair market value, the payment at fair market value, evidence of a lawful purpose?

A. I certainly would expect that to be asserted as a defense were we to investigate this type of arrangement. But, as we said elsewhere in this document, fair market value payments can still implicate the statute, the Anti-Kickback Statute.

Q. And you agree that the special fraud alert, Exhibit Number 2, did not specifically state that P&H fee arrangements are automatically unlawful?

A. We do not conclusively -- in this type of guidance, we cannot say that a described arrangement violates the statute,

because it is an intent-based criminal statute which requires an examination of the party's intent.

MR. GRIFFITH: Break.

BY MR. GRIFFITH:

Q. Let's go to Exhibit Number 3. And is that a document that you reviewed to prepare for this deposition?

A. Yes.

Q. Okay. And so is this Advisory Opinion Number 99-3?

A. Yes.

MR. GRIFFITH: Break.

THE WITNESS: Do we agree that it's a fixed-percentage-based arrangement?

BY MR. GRIFFITH:

Q. Yes.

A. That's what it states here, so yes.

MR. GRIFFITH: Break.

BY MR. GRIFFITH:

Q. And also if you would go to the -- on page 7, the same paragraph, I'll just point it out, in the first paragraph, if you can just read that first sentence.

A. "So in this case" --

Q. You can read it to yourself.

A. Oh.

Q. Yeah?

A. Okay.

2:59PM **Q.** And so it appears from this paragraph that the sales agent was in a position to make contact with persons that were ordering the service.
2:59PM **A.** It says "may involve contact between the sales agent and persons in a position to order the services."
2:59PM **Q.** All right.
2:59PM **A.** So, yes, "may involve."
2:59PM **Q.** Okay. So it -- and so we -- did I say something that was inaccurate when I said he was in a position to order the services?
2:59PM **A.** Well, it says "may involve," so I don't know if, in every instance, whether that's correct.
2:59PM **Q.** Okay. And then if you go to -- to the page before, which is page 6, and just look down here (indicating). And if you can just read that last sentence to yourself.
2:59PM **A.** Okay.
2:59PM **MR. GRIFFITH:** Break.
3:00PM **THE WITNESS:** That's correct. Oh, sorry.
3:00PM **BY MR. GRIFFITH:**
3:00PM **Q.** Yeah, is that -- am I -- is that your understanding as well?
3:00PM **A.** That's correct. I will tell you it's our practice -- it's our current practice -- and I imagine it's our practice back then too -- that when an arrangement doesn't qualify for a safe harbor, we don't list every reason why because even not

satisfying one requirement is disqualifying.
Q. Right.
A. So it may be the case there were other reasons it didn't qualify that are not reflected here.
Q. Okay. But you agree that one of the -- one of the disqualifying reasons in this particular instance was because an exact specification of the schedule for performance of services was not available?
A. An exact schedule meaning that -- so the total compensation in the aggregate couldn't be set in advance, yes.
MR. GRIFFITH: Break.
THE WITNESS: So those two things fall within the same required element, so they're numbered typically. They fall within the same number. And so I think these are typically analyzed in conjunction -- so I just wanted to make sure we had a complete reading on the record.
BY MR. GRIFFITH:
Q. Okay. Right. Okay. So, first of all, while we're on this section regarding the specification, has OIG issued any standards or guidelines to assist health care providers in the identification of exact specifications of the schedule for performance of services?
A. So when we promulgate safe harbors, we go through notice and comment, rulemaking. So we start off with a proposed rule, and then we solicit comments. And in the final rule, we have

what we call preamble, and we address comments that we received in response to our proposed rule. So there may be -- I don't know. I would have to look at the preamble. There may be language in the preamble that speaks to this element, but I don't know for sure.

Q. Okay.

A. I would imagine if there were -- if there had been confusion as to the requirements, I imagine comments would have come in asking for clarification.

Q. Okay. And this is a percentage sale commission arrangement. And I think you testified earlier that -- maybe you didn't, so I would just ask the question.

Can aggregate compensation from a percentage sales commission arrangement ever meet a safe harbor under the Anti-Kickback Statute?

A. This safe harbor, no, because if it's a percentage-based compensation arrangement, it's not possible for the aggregate compensation to be set in advance unless the total was somehow specified. Again, this is why we don't speak in absolutes because facts can change the underlying analysis.

Q. And so --

A. But, typically, it is a disfavored methodology under the Anti-Kickback Statute.

Q. And while we're on that page, if you -- if you start right there (indicating) it's talking about "the suspect

3:02PM characteristics include but are not limited to."
3:02PM **A.** Okay.
3:02PM **Q.** And it has on the bottom of this page and on the top of this page 6 items which I'll just try to briefly summarize them.
3:03PM Compensation based on a percentage of sales, direct billing of federal health care program by a seller, sold by the agent, direct contact between the agent and the physician, direct contact between the sales agent and the federal health care program beneficiary, use of health care professionals as sales agents, and the marketing services for items covered by or reimbursable by the federal program.
3:03PM Is that a --
3:03PM **A.** That are separately reimbursable.
3:03PM **Q.** Okay. Separately. And so these, while they have been deemed suspect, they're not necessarily prohibited; is that correct?
3:03PM **A.** Well, I believe this is a favorable opinion. So we found under the facts and circumstances of this arrangement, we would not subject it to sanctions. So, in this circumstance, we approved it.
3:03PM **Q.** Okay. But my question was, while these six items that are called suspect characteristics for sales arrangements, they're not necessarily prohibited by the OIG; is that correct?
3:04PM **A.** If they are offset by appropriate safeguards, then they

would not be prohibited.
Q. Okay. And when you say -- I think you said that OIG ruled favorably on this request previously; is that correct?
A. Yes. We refer to these as favorable opinions when we say we would not subject it to sanctions.
Q. Okay. And so when the OIG says it agrees not to impose any AKS sanctions in connection with this particular sales arrangement, what particular sanctions are possible against a health care provider such as reflected in 99-3?
A. It would be that -- I don't have them memorized. It would be the sanctions listed in the sections noted here, which is 1128B(7) or 1128A(7) of the Social Security Act.
MR. GRIFFITH: Okay. I think we -- you skipped --
THE READER: Thought those were objections.
MR. GRIFFITH: Your Honor, I'm going to start -- we skipped over line 11 on 97.
MS. SHORT: You're free to keep going.
THE COURT: That looks like objections.
MR. GRIFFITH: Okay. This is -- I'm on 97 at 11.
BY MR. GRIFFITH:
Q. Okay. You've just marked your objections. You know, you said that.
It says OIG will not subject companies to sanctions in connection with the proposed arrangement. And my question to you is, what sanctions are available to OIG in this

3:05PM circumstance?
3:05PM **A.** It would be that -- I don't have them memorized. It would be the sanctions listed in the sections noted here, which is 1128B(7) or 1128A(7) of the Social Security Act.
3:05PM **Q.** Okay. Okay. So do you agree that, in this particular instance, in Advisory Opinion 99-3, the OIG issued a favorable opinion on the sales commission arrangement even though the aggregate compensation took into account the value or volume of referrals?
3:06PM **A.** We apparently felt that there were enough safeguards under the facts as presented to us to issue a favorable, yes.
3:06PM **Q.** Okay. And, likewise, the OIG issued a favorable opinion on this percentage sales commission arrangement even though the salesman could not give an exact specification of the schedule for performance of the sales services; is that correct?
3:06PM **A.** So it states that the services to be provided precludes an exact specification. So if I'm understanding your question correctly, there was not an exact specification of the sales -- of sales agent's schedule, that's correct.
3:06PM **Q.** And the OIG nevertheless found favorably on this arrangement?
3:06PM **A.** It did.
3:06PM **Q.** Okay. And the OIG found favorably on this sales commission arrangement even though the salesman may have had direct contact with those ordering the services; is that

correct?
A. That is correct.
Q. Okay. Thank you.
And just on the first page, real quick, right above the factual background, it says, "This opinion may not be relied on by any person other than the addressee and it's further qualified as set forth in part 3 below and 42CFR part 1008."
Do you see that?
A. Yes.
Q. Is that standard language for advisory opinions?
A. Yes. Advisory opinions only -- or apply only to their requestors.
Q. Okay. If you can take a look at Number 4. And did you read Exhibit Number 4 before you came to the deposition?
MR. GRIFFITH: Break.
BY MR. GRIFFITH:
Q. Okay. It appears on the bottom of the first page that "based on the facts certified, that we concluded the proposed arrangement could potentially generate prohibited remuneration under the Anti-Kickback Statute."
A. Uh-huh.
Q. Do you see that?
A. Yes.
Q. And so this appears to be different from the prior

advisory opinion in terms of its conclusion. Is this -- this is not considered -- this Exhibit Number 4 is not considered a favorable opinion, is it?

A. No. This is what we refer to as an unfavorable opinion.

MR. GRIFFITH: Break.

BY MR. GRIFFITH:

Q. Then it goes on to say, however, "the absence of safe harbor protection is not fatal."

Do you see that?

A. Yes. It's very dramatic.

Q. Huh?

A. It's very dramatic. We've changed that language.

Q. Well, you consider that dramatic language?

A. It's not -- it means the arrangement does not necessarily violate the kickback statute.

Q. Okay. And so -- and I think we discussed this, but I just want to make sure. So when you're at this point when an arrangement does not meet a safe harbor, the next sentence says, "The arrangement must be subject to a case-by-case evaluation"?

A. Correct.

Q. Okay. And so, at that point, it's my understanding that the OIG takes all the facts and circumstances of a particular arrangement in trying to determine whether or not substantial risk or whether a minimal risk of fraud and abuse exists for

3:09PM 1 the particular arrangement; is that correct?
3:09PM 2 **A.** That's correct.
3:09PM 3 **Q.** Okay. And in doing that facts and circumstances analysis,
3:09PM 4 does the OIG consider or apply specific elements of a safe
3:09PM 5 harbor to the arrangement?
3:09PM 6 **A.** So we go through the safe harbor analysis. And then if
3:09PM 7 it's not satisfied, we evaluate the arrangement in its
3:09PM 8 totality. Safe harbor could potentially inform our analysis,
3:09PM 9 but we're not tethered to it in any way after it's been
3:09PM 10 disqualified from applicability.
3:09PM 11 **Q.** So if you go to page 4. And I'm looking at the second
3:09PM 12 paragraph. And, specifically, it says, "Under the proposed
3:09PM 13 arrangement, the physician could receive up to twice the $3
3:09PM 14 amount that Medicare pays for blood specimen collections plus
3:10PM 15 any necessary blood-drawing supplies free of charge."
3:10PM 16 Do you see that?
3:10PM 17 **A.** Yes.
3:10PM 18 **Q.** And then later on in the paragraph, it says, "Where a
3:10PM 19 laboratory pays a referring physician to perform blood draws,
3:10PM 20 particularly where the amount paid is more than the laboratory
3:10PM 21 receives in Medicare reimbursement, an inference arises that
3:10PM 22 the compensation is paid as an inducement to the physician to
3:10PM 23 refer patients to the laboratory, particularly in the
3:10PM 24 circumstances presented here."
3:10PM 25 Did I read that correctly?

3:10PM **A.** Yes.
3:10PM **Q.** So does this -- does this sentence that I just read mean that a lab can pay a doctor a $3 blood collection fee and not create an inference that the compensation was paid as an inducement for the referrals?
3:10PM **A.** Not necessarily.
3:10PM **Q.** And why is that?
3:10PM **A.** So what this is saying is that anything in addition to the $3 amount is definitely not okay. It's not saying whether $3 or anything less than $3 is or is not okay.
3:11PM **Q.** Okay. Well, is it your understanding that this advisory opinion would preclude or prohibit a lab from paying a physician a $3 specimen collection fee?
3:11PM **A.** Advisory opinions apply only to the requesting person or entity, so it doesn't preclude anyone from doing anything other than to let the requestor know that the arrangement as described would present more than a minimal risk of fraud and abuse and they may be subject to sanctions.
3:11PM **Q.** Okay. But the OIG publishes these advisory opinions; right?
3:11PM **A.** We are statutorily required to publish them.
3:11PM **MR. GRIFFITH:** Break.
3:11PM **BY MR. GRIFFITH:**
3:11PM **Q.** Okay. And do you agree that this advisory opinion, 05-08, does not address payments to physicians for process and

handling fees?
A. So it said the facts as described to us that the payment would be a per-patient amount for the physician's services in collecting the blood specimens. So it's not clear to me what that would encompass.
Q. Well, do you see anything in the document that references process and handling by physicians? Do you?
A. Not in the facts. I can look through the analysis if you'd like, but as presented to us, the term "process and handling" does not appear.
MR. GRIFFITH: Break.
BY MR. GRIFFITH:
Q. Okay. Show you Exhibit Number 5. And did you review Exhibit Number 5 in preparation for your deposition?
A. I believe I did.
Q. Okay. And is this considered a favorable opinion?
A. Yes, this is what we would characterize as a favorable opinion.
Q. Okay. And just to try to summarize, the arrangement in question in this Advisory Opinion 98-10 appears to be the payment of a sales commission to an independent manufacturer rep?
A. Yes.
Q. And if you look on page 2, it says that the sales agent A would receive a monthly commission of between 1 and 1.25

3:12PM 1 percent of invoiced amounts, the specific percentage being set
3:13PM 2 in advance for each purchaser.
3:13PM 3 Do you see that?
3:13PM 4 **A.** Yes.
3:13PM 5 **Q.** And then if you go to page 3, I'm looking at the first
3:13PM 6 full paragraph, right about here (indicating). And it says in
3:13PM 7 part, "Moreover, because such agents are independent
3:13PM 8 contractors, they are less accountable to the seller than an
3:13PM 9 employee."
3:13PM 10 Do you see that?
3:13PM 11 **A.** Yes.
3:13PM 12 **Q.** Do you know what the OIG's basis is for that assertion?
3:13PM 13 **A.** So in our safe harbor preamble, there is a safe harbor
3:13PM 14 that applies to compensation or remuneration provided to
3:13PM 15 employees. It's a statutory exception that is interpreted by a
3:13PM 16 regulatory safe harbor. Our understanding of the reason for
3:13PM 17 the employee exception which we declined to extend to
3:13PM 18 independent contractors is that employees are more accountable
3:13PM 19 to their employers than an independent contractor would be.
3:13PM 20 **MR. GRIFFITH:** Break.
3:13PM 21 **BY MR. GRIFFITH:**
3:13PM 22 **Q.** Okay. If you look on the next paragraph, on the last
3:14PM 23 sentence of that paragraph, it appears to be saying that this
3:14PM 24 particular sales commission arrangement would not qualify under
3:14PM 25 this personal services safe harbor because the nature of the

3:14PM services provided in the contract precluded an exact specification of the schedule of performance and a determination of the sales agent's total aggregate compensation in advance.

Do you see that?

A. Yes.

Q. Okay. So that is similar to the situation in the prior commission agreement advisory opinion that we looked at; correct?

A. Correct. Neither satisfied that particular requirement of the safe harbor.

MR. GRIFFITH: Break.

BY MR. GRIFFITH:

Q. Okay. But in any event, in this particular case, this Advisory Opinion 98-10, the OIG made a favorable decision on this percentage sales commission arrangement; agreed?

A. We found that the safeguards within the arrangement did allow us to reach a favorable conclusion, yes.

MR. GRIFFITH: Your Honor, that's the end.

THE COURT: Okay.

(Witness excused.)

THE COURT: Folks, let's take our afternoon break. Ten minutes.

(Whereupon the jury was excused from the courtroom.)

THE COURT: You may be seated. Do I -- I take it

3:15PM 1 from here we've -- we've -- basically, you're going to call
3:16PM 2 your client now. Is that your plan?
3:16PM 3 **MR. COOKE:** Yes, Your Honor.
3:16PM 4 **THE COURT:** Very good. We'll go to approximately
3:16PM 5 5:00. Okay? And so when you're doing it, if you're kind of
3:16PM 6 getting close to it, you might signal me it would be a good
3:16PM 7 time for a break. I'm sure you'll know that better than I
3:16PM 8 will. Okay?
3:16PM 9 **MR. COOKE:** I was going to comment, I can't see why
3:16PM 10 you didn't want us to try this whole case with depositions.
3:16PM 11 **THE COURT:** Yeah, I think somewhere y'all are saying,
3:16PM 12 you know, I think the judge had a point there about that. You
3:16PM 13 know? Not only did he obey -- follow the rules -- that was
3:16PM 14 kind of the point -- it was tough going. And at least I had
3:16PM 15 the benefit of the transcript. You know, we all probably ought
3:16PM 16 to think in the future, if we're going to do this, we might
3:16PM 17 have a scrolling transcript or something just to help the jury
3:16PM 18 follow it. You know?
3:16PM 19 **MR. COOKE:** We had a technical glitch, Your Honor.
3:16PM 20 **THE COURT:** Y'all had a technical glitch? Y'all were
3:16PM 21 planning to do that? It's tough going, but I actually didn't
3:16PM 22 have any problem following it. But I could see not -- I
3:16PM 23 watched my jurors. Some of them were just having trouble
3:17PM 24 figuring it out, I could tell. Because it's awfully technical
3:17PM 25 stuff, and they didn't have the document.

Okay. Let's take about a 10-minute break.

(Recess.)

THE COURT: Any matters we need to address before we bring in the jury?

MR. LEVENTIS: Nothing, Your Honor.

MR. COOKE: Nothing, Your Honor.

THE COURT: Very good. You can bring in the jury, please.

(Whereupon the jury entered the courtroom.)

THE COURT: Please be seated.

BlueWave, call your next witness.

MR. COOKE: Thank you, Your Honor. The defendants BlueWave, Johnson, and Dent call Robert Bradford Johnson.

THE DEPUTY CLERK: Please place your left hand on the Bible, raise your right. State your full name for the record, please.

THE WITNESS: Robert Bradford Johnson.

THE DEPUTY CLERK: Thank you.

(Witness sworn.)

THE DEPUTY CLERK: Thank you.

ROBERT BRADFORD JOHNSON,

one of the defendants herein, called as a witness on his own behalf, being first duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

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BY MR. COOKE:

Q. Even though I just did it, would you state your full name for the record, please?

A. Yes, sir. Robert Bradford Johnson.

Q. And you're a defendant in this lawsuit?

A. I am.

Q. Where do you live?

A. I live in Vinemont, Alabama.

Q. Okay. Looked like it took you a minute to --

A. We say Cullman, Alabama, but I live out in the country.

Q. What family do you have?

A. I actually am married. I have five daughters. Four of them are adopted. Three are adopted through the foster care system, and two of them have special needs.

Q. I understand your latest adoption was in December?

A. Yes, sir, it was. We --

Q. And has Stacy, your wife, been here?

A. Yes, she is.

Q. Where did you grow up?

A. I grew up in a real, real small town, a one-track viaduct. It's Centre, Alabama. It's spelled C-e-n-t-r-e. So I grew up there.

Q. How old are you?

A. 49.

Q. Can you tell us your educational background.

3:40PM **A.** Yes, sir. I graduated from Cherokee County High School, Centre, Alabama. From there, I accepted a football scholarship to Auburn University and graduated with a marketing degree and a biology minor.

And, from there, I ended up getting a MBA -- well, after working for Merck, they paid for me to have an MBA, got a master's. And I have done other educational things since then too.

Q. You played football at Alabama?

A. No, sir. Completely opposite, no, sir. We don't even --

Q. Auburn?

A. That's a no-no. That's a very bad thing.

Q. I'm glad we got that one over with.

A. I have to clarify that. When I'm here in South Carolina, I get asked, "Are you from Alabama? Are you for Alabama?"

"No. I played in Alabama, but at Auburn."

Q. All four years?

A. I did.

Q. I'm glad we got that out of the way early.

THE COURT: Hoping that'd be your last mistake.

THE WITNESS: I want to tell you, woo.

BY MR. COOKE:

Q. Did you have any jobs growing up?

A. Yes, sir, I -- obviously, I had jobs of mowing yards and things like that like normal people do. But probably the

biggest job I had in -- was probably my junior year of high school. My dad says, "I'm going to teach you a life lesson."

And he sent me to work for a company called Ellis Brothers. They're the world's largest cottonseed producers. And so he said, "Son, this will make you appreciate an education."

So I ended up carrying cement blocks for most of the day. And when you see these big trucks going down the road with 50-pound bags of cotton seed, I was the one that picked them up and threw them on the truck.

Q. Did that teach you the value of an education?

A. At that time, I have to say, I think it was the hardest thing I have ever done. And all I could think was, "Dad, you don't have to worry. I'll get a degree."

Q. Where did you go to work? You mentioned the pharmaceutical company. So where did you go to work right out of college?

A. After I graduated from Auburn, I actually went ahead and stayed in school and got a biology minor, to give you an idea. And so -- because I knew going into the pharmaceutical sales arena, which I knew a lot of people in the industry, so I wanted to venture into that market. So I actually took a job with Merck Sharp & Dohme at the time, and it's now called Merck Pharmaceuticals.

Q. How long did you work there?

3:43PM **A.** How long did I work there? '91, maybe '97, '98, somewhere
3:43PM in there. The years kind of blend together nowadays.
3:43PM **Q.** How did you wind up in pharmaceuticals?
3:43PM **A.** I actually knew -- I actually knew some athletes that, at
3:43PM the time, the pharmaceutical industry liked to hire athletes
3:43PM because we could actually get in faster with physician offices.
3:43PM And that was the biggest thing right there. So that's how I
3:43PM actually got in the door.
3:43PM **Q.** And that actually works, that they'll let you in because
3:44PM you played football at Auburn?
3:44PM **A.** Actually, it really does. It helped my dad played
3:44PM football at Alabama under Coach Bryant, but -- so those two
3:44PM combined, people want to talk to you, so they always wanted to
3:44PM ask questions. And you got to realize the average
3:44PM pharmaceutical rep has a time talking to a physician of three
3:44PM minutes and about 20 seconds, to give you a ballpark idea. So
3:44PM this opened massive numbers of doors.
3:44PM **Q.** What did you do after Merck?
3:44PM **A.** Well, through Merck. I mean if you'd like, I'd like to
3:44PM tell you about what I did through Merck before I jumped,
3:44PM because it's a train -- it's the foundation, I guess.
3:44PM When I was at Merck, I actually was hired to work in
3:44PM Alabama, but they had moved me to Daytona, Florida. I worked
3:44PM in Daytona, Florida, as a sales rep down there. And I was
3:44PM moved from there to Tuscaloosa, Alabama, from there to Decatur,

3:44PM 1 Alabama, from there to Gadsden, Alabama, from there to north
3:44PM 2 Georgia. I moved, when I was with Merck, 13 times, to give you
3:45PM 3 an idea. So I have moved a lot.
3:45PM 4 And so while at Merck, I sold pretty much every
3:45PM 5 product that they have. And Merck has lots of products. So
3:45PM 6 from Merck they had asked me to go in and take a promotion to
3:45PM 7 move into Pennsylvania, to the home office.
3:45PM 8 I'm a -- you can tell my accent is pretty strong.
3:45PM 9 And if I start speaking too fast, I apologize here now. So I
3:45PM 10 moved from the South all the way up to -- actually, Savannah,
3:45PM 11 Georgia, where I was working at the time, and I moved to
3:45PM 12 Pennsylvania.
3:45PM 13 There, I actually was in the national service center,
3:45PM 14 which means -- and I'll make it real quick. A physician calls
3:45PM 15 and says, "Hey, Brad, I've got a patient here, a kid who's got
3:45PM 16 bitten by a black widow spider. I've actually given him three
3:45PM 17 doses of the medicine. What do I do?" So I had to address
3:46PM 18 that.
3:46PM 19 From there, I took another promotion within Merck
3:46PM 20 where I actually ended up training all of Merck's specialty
3:46PM 21 cardiovascular sales representatives. There was about 400,
3:46PM 22 maybe 450 at the time. So I actually trained all of them
3:46PM 23 across the country.
3:46PM 24 So -- and from there -- do you want me to go on?
3:46PM 25 **Q.** Were these the sales reps that you were training?

3:46PM **A.** They were sales representatives. They were. So Merck was trying to make them not sales representatives, but at the time somebody had drawn a linear curve, saying every time you had a sales rep, sales go like this. And so they were sales reps.

3:46PM **Q.** Yeah. So what did you do after Merck?

3:46PM **A.** After Merck -- well, at Merck I'd been told that "Hey, your experience is worth something." And long story short, I put my résumé out and got a hit pretty quick.

3:46PM So a company called Takeda Pharmaceuticals, big Japanese pharmaceutical company had just really opened up in the States, and they had offered me a district manager position in the state of Alabama. So I ended up hiring 12 people, building a team, training a team, and working there.

3:47PM **Q.** Were you successful in pharmaceutical sales?

3:47PM **A.** Yes, sir. And not to be arrogant or bragging, I guess the word to say, at Merck I did have the highest share in the nation for aquatic -- cholesterol medicine called Zocor. At Takeda we had the number two team in the country for Actos, which is a TZD. I'm going to make the analogy easy. If I say it out loud, most people won't know. And so we did real good there as well.

3:47PM **Q.** Did you develop -- what was it that you would say accounted for your ability to sell these drugs?

3:47PM **A.** Woo. I think salespeople are something that's -- I think you have some personality to do it, but I think you also are

learned. You have to learn it. It's just like in any good thing or any job, you have to acquire skills as you go along.

I'm a firm believer in a book called "Soar with Your Strengths." And the book basically states, hey, you do what you're best at. I believe God gives us all innate abilities to do certain things, whether it be a doctor, whatever it may be. I've always felt sales has sort of been my ability that was given to me.

So while at Merck, I learned something called sales tapes, sales books. And I have pretty much listened to and read pretty much every book just about written when it comes to that kind of stuff, to give you an idea.

Q. You told me once that you're a pretty heavy reader?

A. I read around 50 to 65 to 70 books a year, to give you an idea. So I am -- and I read everything too. So I read probably three or four hours a day, and I listen to audio books when I drive, which enables you to learn a lot more, because people consider that, in success stories, wasted time if you don't listen to them.

Q. And you spend a lot of time in the car.

A. Woo. I would say that's probably the understatement and -- in my business.

Q. When did you leave Merck -- Takeda? I'm sorry.

A. I was there for, I think, right at four years, I believe is correct. And when I left Takeda, I ended up forming -- I

3:49PM think it was my second company at the time called Forse
3:49PM Medical. And my brother had called me and says, "Hey, there's
3:49PM a niche in the market here." And it was sterile medicines.
3:49PM So I ended up getting the sales rights to a
3:49PM compounded pharmacy out of southeast Alabama. So I started
3:49PM building that and, lo and behold, I had people calling me
3:49PM asking could they work with me. And that started building.
3:49PM And I was already -- had a real estate company where I was
3:50PM acquiring real estate, doing things of that magnitude. Then I
3:50PM was teaching real estate classes.
3:50PM So from that, then, lo and behold, Berkeley come
3:50PM along and sort of made me an offer I couldn't refuse.
3:50PM **Q.** When did that happen?
3:50PM **A.** I believe 2002, 2001, somewhere right in those dates. As
3:50PM I said, the dates nowadays, I have to hold my résumé and look
3:50PM to see if I'm on the right track.
3:50PM **Q.** You've been here the last couple of weeks, so you know
3:50PM that the jury has heard something about Berkeley HeartLab. But
3:50PM I'd like them to hear about it from your perspective. What was
3:50PM it about Berkeley that attracted you?
3:50PM **A.** Good question. Berkeley, at the time when I got called, a
3:50PM headhunter had called me and talked to me. I ended up
3:50PM having -- my regional director had called. And what ended up
3:50PM turned out to be my regional director. Better statement. He
3:50PM called and says, "We'd like to talk to you about coming to work

for us. Would you be interested?"

So being who I am, I reached out to the two smartest people I knew in the state of Alabama as far as physicians. I reached out to Bruce Trippe in Montgomery, Alabama, an endocrinologist; and I reached out to Dr. Teague in Birmingham, Alabama, another endocrinologist. I knew these guys from my interactions in the business. And I said, "What do you think about that test?"

Their exact words were "It is the best test in the entire country."

And I says, "Do you do it?"

And they said, "Brad, it costs a thousand dollars to do it on patients."

I said, "Okay." So I said, "Would you do it if you wasn't killed with the cost issue?"

And they said yes. They said right now we currently pick and choose who we want to do this on. You either have to have a substantial sum of money or they did it on Medicare patients, because Medicare, as I'm sure y'all have learned from this business, is -- there is no cost. You cannot balance-bill a Medicare patient for lab services.

So -- so that is what actually drew me more into it, to listen to them. And Dr. Trippe said the exact same statements, which confirmed that I was going to talk to them.

Q. And you did go talk to them?

3:52PM **A.** I did. And I ended up taking a job there. And I'm one of these people that always asks questions. And what I mean by that is this: If you're Bill Gates or Warren Buffet and you go to the doctor, does the doctor do the same thing on him as he would you?

So I asked myself those questions. I learned real quick-like when I went to Berkeley labs. There was pictures of famous governors, congressmen, senators, actors, all these people all over the walls there. You learn real quick-like, a lot of people don't get the best of the best. And that's just the way it was. And, you know, the Berkeley test was the most cutting-edge test in the world at that time. You only had really three advanced cardiovascular testing companies in the country, to give you an idea, so --

Q. So how did that translate into then selling tests for Berkeley?

A. Woo. When I started with Berkeley, obviously, I was in training there for about two weeks, I had a real strong science foundation, knowledge. I had sold so many hypertensive, so many diabetes medicines, so many cholesterol medicines. So I kind of knew the market.

So lab tests was a whole different arena for me. So there was about 17 sales reps, I believe, at Berkeley at the time, and obviously we was there. The CEO did lot of the training. We had -- Rob Lewis was one of the compliance

officers at this time. I had -- my regional director was brand-new in the industry, so he was involved in the training with me. A COO, who came from another lab as well, was actually in the training, because Berkeley was not a new company -- it had been in existence about seven years -- but they were -- they were struggling, to give y'all a ballpark idea, so at that time.

Q. And, again, what year was this?

A. 2002, I believe.

Q. And then did you become successful there at Berkeley?

A. I feel like I did pretty good at Berkeley, to give you an idea. At Berkeley, to give you an idea, I was paid a salary, and the majority of my money was paid commissions. Just go ahead and tell you how it was.

And so I started off -- the company was doing about 35, 40 tests a week. And within seven months, I was doing about 145 tests a week, to give you a ballpark idea. And I'm not saying that to be arrogant, but it's going to lead to a foundation here.

I ended up having the VP of sales riding with me every month. I ended up having the -- my regional director riding with me almost every month, to give an idea. And business started booming. It started going at a fast pace. They couldn't understand how I was finding accounts, things like that. But you got to realize I've covered huge

3:55PM 1 geographies while at Berkeley now. You know, you've heard
3:55PM 2 people here today talk, "Where did you work?" You know.
3:55PM 3 Well, I worked Alabama, Mississippi, Georgia,
3:55PM 4 Tennessee, and I could come into South Carolina if I so
3:55PM 5 desired. They basically said, "Brad, we don't care where you
3:55PM 6 go. Get business."
3:55PM 7 So I drove probably 130, 140,000 miles a year, to
3:55PM 8 give you an idea. I went wherever I could go to find some
3:55PM 9 business and worked with tons of pharmaceutical reps and
3:55PM 10 anybody in the medical field.
3:55PM 11 **Q.** Let's talk about compliance training.
3:55PM 12 **A.** Okay.
3:55PM 13 **Q.** Did you receive compliance training at Merck or at Takeda?
3:55PM 14 **A.** Actually, I did receive compliance training at Merck and
3:56PM 15 at Takeda Pharmaceuticals, correct.
3:56PM 16 **Q.** So what was your understanding -- when you got to
3:56PM 17 Berkeley, what was your understanding about the purpose of
3:56PM 18 compliance -- compliance training?
3:56PM 19 **A.** Well, I mean, compliance training in pharmaceutical is a
3:56PM 20 different standard of training. And it's basically, in a
3:56PM 21 nutshell, to make it in layman's terms, you can't go in and
3:56PM 22 offer a doctor a TV. You can't go in and bribe a person. You
3:56PM 23 cannot do those things. I mean, that's the easiest way to
3:56PM 24 describe it to make it simple, so --
3:56PM 25 Because in the pharmaceutical industry, when I was

3:56PM going in, in the '80s, it was rife with fraud. What I mean by
3:56PM that is it was very common for people to send somebody on a
3:56PM cruise. It was very common to pay somebody a thousand dollars
3:56PM for five scripts or something like that. Or it was very common
3:56PM for some pharmaceutical reps to sell their medicines to
3:56PM physician practices.
3:56PM So things like that were kind of rife.
3:56PM **Q.** And did the Anti-Kickback Statute come to your attention?
3:57PM **A.** Yes, sir. We was trained on that as well.
3:57PM **Q.** So you would not try to tell this jury that you didn't
3:57PM know about the Anti-Kickback Statute?
3:57PM **A.** I think anybody in the medical field has heard of the
3:57PM Anti-Kickback Statute. I mean, that's just -- I don't know if
3:57PM you can actually be in it and not be told about it, especially
3:57PM in the United States. Now, foreign countries, I might not be
3:57PM able to answer that question.
3:57PM **Q.** When you got to Berkeley HeartLab, were you introduced to
3:57PM the idea of process and handling fees?
3:57PM **A.** Yes, sir, I was. I actually -- I think it was the end of
3:57PM the second week of training. Myself, Mike Gottfried was in a
3:57PM room. Michael Mercer, the new COO that came in, I believe he
3:57PM was there at the time. Grace, the sales rep out of Tampa,
3:57PM Florida, was being trained with us. Frank Ruderman, the CEO,
3:57PM who was involved from all aspects of the training. Rob Lewis
3:57PM did a wonderful compliance training and talked about the

process and handling fee. And that's where I first learned about the process and handling fee.

So I kept asking, "Tell me about this draw fee." And he stopped me in the middle of the meeting and says, "You cannot say the word 'draw fee.'" He said it is a $3 draw fee, a $17 process and handling fee. He said one word makes a difference. The other word makes it legal. And that's where that came about.

Q. Again, we've heard it previously. What's the difference between a draw fee and a process and handling fee?

A. The government here defines a draw fee as stuck you with a needle here and draw. That's 3. Process and handling fee, you're pulling the tubes up, whether it be two tubes, four tubes, whatnot. You're inverting them. You're putting them in centrifuges. You're putting them in fridges. You're packing them in boxes. You're labeling them. You're going to the front desk and photocopying insurance cards, putting them with them, getting extra billing sheets as well with them, and putting them all together, to give you an idea.

Q. Why is that the laboratory's business?

A. Well, I learned real quick-like the hardest aspect I thought of selling the test. The science to me was a no-brainer. It was piece of cake. You could see it.

Robert Superko was the leading guy in the world at the time. You had really about three or four. Tom Dayspring

was coming into the picture, but Robert Superko was probably the top 40. You've heard actually Dr. Hollins, I think, spoke before. I think their expert mentioned his name. You also heard -- I think Burt mentioned his name. Fishberg mentioned his name. He was a cutting-edge guy, and, you know, he was out there.

But you learned real quick-like. How do you get blood? You go into an account and LabCorp is there, are they going to look at you as a competitor? Or are they going to say "Oh, no problem. We'll do the work for you even though you're going to take some of our tests"? It don't work that away. They fight you tooth and nail across the board.

Now, at Berkeley we also had the option to put a phlebotomist in the practice as well. We had lab-to-lab contracts. And our lab-to-lab contracts was $35, to give you an idea. So you have those options.

But getting the blood is the critical aspect of this, so -- to give you an idea. So, I mean, it's -- it's very, very difficult, my situation.

Q. And you had compliance training specifically on process and handling fees?

A. Yes, sir, we did. Actually, the biggest thing about the process and handling fee, you noticed even at the end of training, it was done at the end of training. It was not done at the beginning of training. And the reason being is you've

4:00PM got to sell the science to the physician out of the gait. If
4:00PM you don't, you can kiss it goodbye. It just don't work. I'm
4:00PM sorry.
4:00PM And I know you've heard people say that. That's how
4:00PM I was trained. That's how I trained people. Period. If you
4:01PM can't convince a physician this is going to be beneficial to
4:01PM you and your patients, then there's something wrong.
4:01PM You see, the huge advantages about this stuff was
4:01PM everybody already knew. The majority of people have normal
4:01PM lipids drop dead of heart attack. A lipid panel has been
4:01PM around since 1957 or '58. So I used to ask -- I always like to
4:01PM ask the staff questions more so than physicians. "What piece
4:01PM of technology do you have in your house that's been around
4:01PM since 1957?"
4:01PM That's a question. And a lot of people look around
4:01PM and go, hmm. Some of them usually make a joke, but still.
4:01PM Long story short, that was how it went.
4:01PM **Q.** Let me focus a little bit on the specific advice and
4:01PM training you got about process and handling fees. I'd like to
4:01PM show you some language.
4:01PM **MR. COOKE:** Your Honor, may I approach?
4:01PM **THE COURT:** You may.
4:01PM **BY MR. COOKE:**
4:01PM **Q.** And I'm going to show you what's been marked as BW493, and
4:01PM a lot of it's blacked out, but I want you to look at the page 3

4:02PM under "Process and Handling." Don't read it out loud, but --
4:02PM **THE COURT:** That's in?
4:02PM **MR. COOKE:** It's not in.
4:02PM **THE COURT:** Okay.
4:02PM **BY MR. COOKE:**
4:02PM **Q.** Don't read it out loud for that reason, but look at it for a moment and read it to yourself. And I'm going to ask you the question, do you recognize that language?
4:02PM **A.** Yes, sir. This is actually one of the legal opinions we had while at Berkeley. We actually had -- we had -- ended up when I was at Berkeley, I had three compliance officers -- not one, not even two, but three -- go over process and handling fee. Not only that, but we had two legal opinions that I knew of. I've been told there might be more, but I knew there was two out there. And so this was the exact verbiage.
4:02PM See, here's another thing. It wasn't new to the industry at that time.
4:02PM **Q.** Let me stop you. I'm going to ask you about that.
4:02PM **MR. COOKE:** But we'd like to offer that as an exhibit.
4:02PM **MR. LEVENTIS:** Can I take a look at it, Your Honor?
4:02PM **THE COURT:** Absolutely. Please show it to Mr. Leventis.
4:03PM **MR. LEVENTIS:** No objection, Your Honor.
4:03PM **THE COURT:** Very good. Mr. Ashmore?

4:03PM **MR. ASHMORE:** No objection, Your Honor.

4:03PM **THE COURT:** Very good. BlueWave 493 admitted without objection.

4:03PM **BY MR. COOKE:**

4:03PM **Q.** I'm going to ask you about this.

4:04PM **A.** Yes, sir.

4:04PM **Q.** At the top do you recognize the name of the law firm there?

4:04PM **A.** Ropes & Gray. A 1200-man law firm, one of the biggest in the entire country. Yes, I do know who they are.

4:04PM **Q.** And the date of that was July 28th, 2005?

4:04PM **A.** That is correct.

4:04PM **Q.** It's from Stephen Warnke. Do you know who that was?

4:04PM **A.** I don't actually remember the name. I just -- I knew about everything that was going on out there.

4:04PM **Q.** Who is Andy Ambrose?

4:04PM **A.** Andy Ambrose was the CFO.

4:04PM **Q.** And who was Frank Ruderman?

4:04PM **A.** Frank Ruderman, you've already heard his name mentioned. He was the CEO at Berkeley HeartLabs, to give you an idea.

4:04PM **Q.** Now, the way this was produced, a lot has been blacked out, but can we scroll forward? There's a section on page 3 called "Processing and Handling Fees." If we could bring that up.

4:04PM Could you read that to the jury, please?

4:04PM 1 **A.** Sure. "In settings where BHL has not instituted lipid
4:05PM 2 clinics, it commonly agrees to pay a specimen 'processing and
4:05PM 3 handling fees' to ordering physicians to compensate them for
4:05PM 4 the unique personnel and overhead expense associated with the
4:05PM 5 collection, processing, and spinning of Berkeley HeartLab's
4:05PM 6 blood specimen. Fair market payment for services that are
4:05PM 7 directly related to lab functions and are not separately
4:05PM 8 reimbursed by third-party payers is consistent with the federal
4:05PM 9 anti-kickback and Stark laws, provided, of course, that the
4:05PM 10 payment arrangement is consistent with fair market, is not an
4:05PM 11 inducement for test referrals, and meets the other technical
4:05PM 12 criteria of Stark II. Following our discussions at the
4:05PM 13 May 25th meeting and a recent advisory opinion by the HHS
4:05PM 14 Office of Inspector General (OIG), we have revised the BHL
4:05PM 15 processing and handling template to provide a uniform
4:05PM 16 nationwide schedule of payments for use with referring
4:05PM 17 physicians, to specify in detail the unique BHL-related tasks
4:06PM 18 expected of them, and to fulfill the Stark II requirements of a
4:06PM 19 'signed' written agreement. Moreover, while we are not in a
4:06PM 20 position to opine on fair market value, we understand that the
4:06PM 21 new P&H rates payable to doctors will be based on time and
4:06PM 22 motion studies undertaken by BHL as well as on amounts
4:06PM 23 currently charged by commercial testing laboratories to BHL
4:06PM 24 when they draw, package, and ship Berkeley specimens. BHL
4:06PM 25 should roll out this revised agreement and schedule quickly and

should also ensure that payments to New York physicians are consistent with the specific requirements of the New York Laboratory Business Practices Act."

Q. Is that what you were taught?

A. Yes, sir. Actually, yes. No questions asked, because my first compliance officer at Berkeley was Rob Lewis. Rob had been in the business long time. Michael McNulty actually was the second compliance officer, and he's the one actually who stated to me that P&H has been around forever and a brother. And, actually, I was involved in a lot of the training of the new people, to give you an idea. So this was kind of common practice across the board. And I'd already heard about it in the industry. So this was standard.

And then our new compliance officer, when he came in, which was Jonathan Wolin. And I think they actually end up being compliance officers at HunterLabs in 2010 and 2012. This is how we were trained.

Q. When he says that they considered the fees charged by -- let me read the whole sentence.

A. Uh-huh.

Q. He says, "Moreover, while we are not in a position to opine on fair market value, we understand that the new P&H rates payable to doctors will be based on time and motion studies undertaken by BHL as well as on amounts currently charged by commercial testing laboratories to BHL when they

draw, package, and ship BHL specimens."

What did that mean to you?

A. Actually, a lab-to-lab agreement at that time was 35 bucks. I mean, that's the only way you get the business. Period. And that's actually what we paid. So Frank had -- Frank Ruderman was the one who approved that at the time.

Q. What -- how much P&H did Berkeley pay?

A. That actually depends on which time you want to know. Actually, when I started, it was 20. They changed the process and handling fee 2007, 2006, somewhere in there. They dropped it down. But what they don't tell you is there was a floating scale in there as well. And they show you a 2008 -- or 2005 they show one at 8, which is totally averse to 11.50. But I know I had accounts at 14, $15. And then in February 2010, even after we left, we come to find out they was paying $21. So just to give you an idea.

Q. Did you get a copy of their P&H agreement to --

A. Yes.

Q. -- figure that out?

A. Yes.

Q. I think I cut you off earlier.

A. Yes, sir.

Q. You were getting ready to talk about what you knew was going on in the industry --

A. Yes, sir.

4:09PM 1 **Q.** -- by other laboratories. Would you explain that, please.
4:09PM 2 **A.** Yes, sir. Actually, in the industry, you got to
4:09PM 3 realize -- let me explain it. At this time in the industry
4:09PM 4 there's only about a 120 people nationwide. Okay? By 2014,
4:09PM 5 you have about 450, maybe 500 people nationwide. And when I
4:09PM 6 say people nationwide, I'm talking about sales reps, people in
4:09PM 7 accounts, things like that. I'm not talking lab techs and
4:09PM 8 stuff. I'm talking about salespeople.
4:09PM 9 And, as I say, since it's a close-knit industry, you
4:09PM 10 know everybody. Atherotech, one of our business competitors,
4:09PM 11 was out of Birmingham, Alabama. Obviously, I would know them.
4:09PM 12 They actually offered me a job over there in my third year with
4:09PM 13 Berkeley, I believe. I also knew the number one sales rep in
4:10PM 14 the country with Atherotech. And so I knew exactly the
4:10PM 15 processing and handling fees that were offered. We knew their
4:10PM 16 billings programs across the board as well. Billing programs
4:10PM 17 as far as competitors, just at this small time at Berkeley, was
4:10PM 18 all over the table.
4:10PM 19 When I started with Berkeley, the test was $715 minus
4:10PM 20 for that. You may go, "What does that mean?" If your
4:10PM 21 insurance pays $715, you owe zero. If your insurance pays a
4:10PM 22 dollar, you owe 714, to give you an idea. Atherotech had a
4:10PM 23 direct bill payment to physician's offices where physicians
4:10PM 24 could buy the test and retail bill it. LipoScience did the
4:10PM 25 same. They also had the inverse where they would bill the

patient so much dollars as well. And this is just at my time with Berkeley, to give you an idea.

And then in 2009 at Berkeley, Boston Heart Diagnostics came into the picture. And they kind of changed the game a little bit. Boston hired two friends of mine that I actually trained at Berkeley. They offered no-balance billing across the board. They offered an $18 process and handling fee as well. We actually, Cal and myself -- I know I got a call as well about working for them as well. That company was owned by Bain Capital, which was Mitt Romney's company, to give you an idea, and they took off like a shot. And so end of 2009, to give you an idea.

Q. Did -- at the time that you were at Berkeley, did they get any other legal opinions that you became aware of?

A. Actually, we did. They was pretty much -- Berkeley was very compliant. Let me make sure I emphasize this to you all. They were very compliant. And I'll tell you why.

When you got a company, the number one goal -- you got angel investors. Angel investors are people that fund your idea. They want to get their money back. Only two ways to get your money back is to go public or sell. Okay? So they were always looking at legal compliance issues.

We also -- Jonathan Wolin brought in Greg Root legal opinion, to give you an idea as well. And that became a major player. So they was always focusing on compliance.

4:12PM **Q.** Let me show you Mallory's Exhibit Number 42 and scroll down until we get to the opinion.

Is this the Greg Root opinion?

4:12PM **A.** Yes, sir, it is. This was given out -- anytime someone asked or had a question about the process and handling fee, we distributed this.

4:12PM **Q.** Okay. So you actually had a copy of this opinion?

4:12PM **A.** We did. We did have a copy.

4:12PM **Q.** Can we scroll down a little bit?

And do you see a reference to OIG advisory opinions?

4:12PM **A.** I do.

4:12PM **Q.** And which opinion does it refer to there?

4:12PM **A.** 05-08.

4:13PM **Q.** Did you understand back then what that was all about? Did you know what an OIG opinion was?

4:13PM **A.** I wouldn't have probably looked at it. I would have probably looked at the attorneys, asked them what we needed to know.

4:13PM **Q.** Can we go to the next page, please.

Do you see there BHL's response to the advisory opinion was to do what? Could you read that out loud, that first paragraph?

4:13PM **A.** "In response to the advisory opinion, BHL revised its practice of compensating physicians for the collection, processing, and handling of specimens. First, BHL conducted a

4:13PM time and motion study, along with a fair market value
4:13PM compensation analysis, to determine the cost of performing the
4:13PM unique and labor intensive specimen processing and handling
4:13PM associated with BHL's testing."
4:13PM **Q.** Okay. And go to the last paragraph in that section.
4:14PM **A.** You want me to read it?
4:14PM **Q.** Yes.
4:14PM **A.** "BHL should continue to structure specimen collection,
4:14PM processing, and handling agreements so that they comply with
4:14PM the personal services and management of safe harbor to federal
4:14PM anti-kickback provisions. The safeguards implemented by BHL
4:14PM should allow it to easily comply with this safe harbor. The
4:14PM most crucial requirement of the safe harbor is that
4:14PM compensation is consistent with fair market value. In 2005,
4:14PM BHL conducted thorough analysis to determine the fair market
4:14PM value compensation for performing of processing and handling
4:14PM services required by BHL testing. In '05, I reviewed the
4:14PM documentation of BHL's time and motion study as well as the
4:14PM accompanying compensation analysis and agreed with Berkeley's
4:14PM conclusion that $7 represented fair market value compensation
4:14PM for the involved process described earlier in this letter. As
4:14PM for specimen collection, by not paying more than Medicare
4:15PM reimbursement ($3), BHL should avoid the risks contemplated by
4:15PM the OIG advisory opinion."
4:15PM **Q.** I'm going to go back up to that paragraph right there

4:15PM 1 where my finger is. And see if it -- I think it's important to
4:15PM 2 talk about what -- what revisions were made to the P&H
4:15PM 3 agreement. Could you read that out loud, please.
4:15PM 4 **A.** Yeah. "BHL then revised its arrangements with ordering
4:15PM 5 physicians for the collection, processing, and handling of
4:15PM 6 specimens. Instead of paying one sum for these services, BHL
4:15PM 7 began compensating the physicians 3 for the venipuncture or
4:15PM 8 collection and 7 for the process and handling of the specimen
4:15PM 9 described above. In addition, Berkeley began requiring the
4:15PM 10 physician practice to agree that it will not submit claims to
4:15PM 11 Medicare for any specimen collections paid for by Berkeley."
4:15PM 12 **Q.** It says, "In addition, BHL began requiring the physician's
4:15PM 13 practice to agree that it will not submit claims to Medicare
4:15PM 14 for any specimen collected and paid for by BHL"?
4:16PM 15 **A.** Correct.
4:16PM 16 **Q.** Go down to the bottom of the letter so we can see the
4:16PM 17 signature. And so you were actually given copies of that
4:16PM 18 opinion --
4:16PM 19 **A.** Yes, sir, we did. We had that.
4:16PM 20 **Q.** -- to distribute?
4:16PM 21 And did Berkeley also come out with a compliance
4:16PM 22 bulletin on process and handling fees?
4:16PM 23 **A.** Yes, sir, they did.
4:16PM 24 **Q.** That would be 135. And while this doesn't appear to be
4:16PM 25 dated, it refers to February 1, 2008, saying there that the fee

was $10 and then it was going to be 11.50.

Can you tell the jury why that happened -- and, first of all, how did it get to $10 from $20?

A. Tom Weider, the VP of sales, said -- we was talking and socializing. He said, "Berkeley is doing everything they can to sell." Okay? So when you're trying to sell a company, you want to do everything you can to make it look, one, squeaky clean. And, two, want to make the ROI as high as you can make it.

Q. ROI is return on investment?

A. That is correct.

And so what they were trying to do is get the payments lower so they had more income coming in.

Q. Did you ever hear them say that they had reevaluated what the fair market value of process and handling was?

A. They -- the words we got told was "this is kind of what happened." And I don't -- I was never -- came in and somebody said, "Hey, listen, we did another analysis and it's saying, hey, you got to do this. This is it."

Because it says 11.50 here. I know one of my physician accounts in Dover, Alabama, had a $15 process and handling fee even at this time. And the reason I know that is because he called and says, "I am losing money hand over freaking fist on this." And he says, "You want me to do your testing? I love your testing. It's the best in the world.

But I cannot afford to lose any more money."

Q. Were you taught, as part of your training, that you can never talk about finances with doctors?

A. No. Actually, that's a misnomer. A lot of people were hung up, one, on process and handling. Two, you can't talk about money.

Okay. The lipid clinic pro forma that y'all have seen was actually created by Jennifer Mason at Berkeley HeartLabs. Okay?

Q. Who is Jennifer Mason?

A. She was a -- she wasn't a compliance officer. Frank loved titles, and he gave everybody a big title. And she was in charge of all the RDs at one time, and then he promoted her up to, like, clinical operations lab manager or manager or something like that.

Q. RDs is registered dieticians?

A. That is correct. Registered dietician is an RD, yes.

So this is a big thing. You heard Cal talk about it a little bit. I was there before him as well, because it was the first time I saw the lipid clinic pro forma. And Frank was trying to push what's called -- form heart centers, is what they was trying to transition to.

But the first time I saw it done and rolled out was by David Kaufman. David Kaufman was the vice president of sales at Berkeley HeartLabs. And he presented it to

Simon-Williamson Clinic in Alabaster, Alabama, Dr. Michael Collins, who loved their tests and was doing great. And that's where it came out originally.

What's interesting about this, talking about this lipid clinic pro forma stuff, it was definitely distributed. And, actually, I watched it trained in front of 40 or -- Berkeley had around 50 salespeople, I think, at the end. So watched it distributed over and over again. No one had ever said, "Hey, this is illegal as crap." And I'll tell you why.

I got a call from the COO. His name was Michael Mercer. He calls me and says, "Brad, I got some bad news for you."

I said, "Okay. What's up?"

He says -- you know, immediately when you think -- when somebody calls you with bad news, at Berkeley, at the time, was "we're going to have to cut your commissions," stuff like that. But I digress.

Let me talk about what he said. He says, "Frank Ruderman is coming down and working with you in your territory."

And I told him, I says, "What have I done wrong?"

You didn't want Frank with you. Frank was -- he could come in and destroy an account faster than he could get one. And he came down and said, "I'm not riding with you in the car." At the time, I was driving a -- a Polish Crown Vic

or something like that. I always drove crappy cars.

And he says, "I'm not riding in something like this." So he rented a big, old fancy Cadillac and came down. And him and his girlfriend at the time went to all my big, big lipid clinics and rolled out lipid clinics pro formas. He walked in with big binders and showed all the numbers and all the financials and says, "This is what we want to do."

And in those, they wanted to do $600,000 bill-outs in space. Now, it may look cool. You know, possibly put a dietician in there, possibly put somebody in there doing cooking, an exercise person in there. We actually had an exercise physiologist, dieticians in some. And I actually ended up having even cooking classes in a lot of clients.

But some of them offered phlebotomists. If it was in a good geography where there was sources of physicians around that was ordering blood tests, they sent them there as well in lieu of the process and handling fee.

Q. So that's what a lipid clinic is?

A. That is exactly the definition. And let me explain why.

Why would you want what's called a lipid clinic or a disease management for my heart risk reduction center? It involves one thing and one thing only. Remember, I had already said that they wanted to sell the company. They wasn't going to go public. The angel investors wanted their money.

So what was happening was a typical lab company has a

4:22PM two-time valuation. What that means is, if you do 100 million
4:22PM in sales, you're worth 200 million, maybe 2.5. Some of you,
4:22PM 250 million. All right?
4:22PM A disease management company has a 10 times
4:22PM valuation. And so now you've got 100 -- 100 million in sales,
4:22PM now it's worth a billion unilaterally. So -- and that was one
4:22PM of the --
4:22PM **Q.** But what was the idea of a pro forma? You're describing
4:22PM to a physician what?
4:22PM **A.** Well, the lipid clinic pro forma is -- it's basically --
4:22PM the physician already does it. Okay? It's pretty simple math
4:23PM when you look at it, because they're talking about Level 3,
4:23PM Level 4 visits. They're really focused on nurse practitioners
4:23PM and PAs in the practice, to give you an idea.
4:23PM And you may go, well, why -- well, one, nurse
4:23PM practicers and PAs see a lot of patients.
4:23PM Two, they're a lot less expensive than physicians.
4:23PM Three, they're open. They want to learn. They want
4:23PM to hear new stuff. They're always eager.
4:23PM So the lipid clinic pro forma was a model designed
4:23PM basically -- it already showed the physician what they were
4:23PM kind of doing. But Frank had this grandiose idea that, hey,
4:23PM this is cutting edge. People are going to jump on this with
4:23PM both feet, and everything else. But if you really started
4:23PM looking at it, most physicians just sort of looked at it.

Does that make sense?

Q. Yes, it does.

Did anybody ever tell you that you weren't allowed to talk about money to doctors?

A. No, never. I mean, never.

Now, obviously, they -- nobody wanted us to go in, "Hey, I'm going to pay you quid pro quo," whatever, that kind of crap. That didn't happen. For the processing and handling fee, the dollars here was not wrong. And so the thing is, you got to realize, it was clinical sale first. The process and handling fee was on the back end of everything, if you even mentioned it. So --

Q. Let me show you Plaintiffs' 1296. This is a document titled "Physician Criteria." Do you remember that one?

A. I do. I do. Actually, this is -- I actually -- and I'm going to take claim for it. I actually drafted it. I drafted it in 2002, my first six months with Berkeley HeartLabs. And you may go why?

I mentioned I was doing about 140, 150 tests a week. The rest of the company was doing 30, 35. I had been asked, why are you so successful? How are you finding your accounts? What I did when I started with them, I sat down and I looked at any physician that did the testing already, even if I didn't know them. And I tried to look at commonalities amongst them all. Okay?

4:25PM So, you know, if you -- it's just like if you're going fishing today. You know, if you know where the best spots are, you can sort of plot it. Same situation in this. And so I drafted this on behalf of David Kaufman as well as Mike Gottfried. And this was actually given out and used. And I actually -- if I didn't know better, I'd swear every advanced testing company out there has this. So I'll walk through it.

"Early adopter (individuals that utilize latest and greatest extremely fast)." Okay. Pharmaceutical reps have this data called -- it's called IMS data. What that tells you is -- it's data that will tell you quickly what doctor is going to write a new test -- not a new test, but write a new medicine out of the gate. It's people that go out and buy the brand-new Apple iPhone that day. That's the kind of mentality of that. Okay?

"They have their own lab or the ability to draw their own blood. This means that the employee in the lab works for the practice and not LabCorp or Quest."

The reason this is so important is there's a few ways to get the blood. Okay? One, you can walk into the account and they can say, "Hey, we'll draw it. No problem." Two, process and handling fee. Three, lab-to-lab agreements.

Okay. Let me walk you through a lab-to-lab agreement. I go over and I'm a competitor of yours. Whether you like it or not, I'm a competitor. It's just the way the

cookie crumbles. So what happens is I go in and talk to the LabCorp rep. Her first words is, "Let me call my boss."

Now, if they're receptive at all, they're going to call their boss and they're going to say, "We need a lab-to-lab agreement." So what happens is you're working it up the chain to try to get somebody to make a decision. And in most situations when you're trying to do this, you're looking at anywhere from three months to five months to actually get the blood drawn. So I've already sold that physician. He loves the test. He wants it.

And the reason this is so important and stuff -- and, I mean, this is very important. And this is why I believe in this test with all my heart. It's because my mom and dad's personal physician, Dr. Brian Perry, he actually had a Quest phlebotomist in his practice. I couldn't get a test ordered. Dr. Perry said, "But I have no problem with" -- Quest had a rule, "We will not draw for anybody outside of Quest." That's just their philosophy in this geography.

So I ended up saying, "Dr. Perry, my mom is a diabetic." I said, "She's 107 pounds." I said, "She walks three miles a day. She looks like the epitome of health, but her brother is a train wreck beyond train wrecks."

Q. Can I stop you for just a second on that.

A. Sure.

Q. I want you to tell that story in -- kind of in a condensed

4:28PM 1 way, but did you also use this story from time to time to try
4:28PM 2 to convince doctors to buy these tests?
4:28PM 3 **A.** Yes. When you're talking to doctors about ordering the
4:28PM 4 tests and stuff, every doctor -- or every person has had a
4:28PM 5 family member, a friend, or someone that all of a sudden
4:28PM 6 something happened to them one day and they were gone. I mean,
4:28PM 7 everybody's heard that story now with social media the way it
4:28PM 8 is.
4:28PM 9 **Q.** So go ahead and finish that. And we're doing it both so
4:28PM 10 that they can hear part of your sales presentation and so that
4:28PM 11 you can explain what this provision in your --
4:28PM 12 **A.** Oh, lord. My sales presentation? All right.
4:28PM 13 So --
4:28PM 14 **THE COURT:** You can abbreviate it more.
4:28PM 15 **THE WITNESS:** Yeah, I was fixin' to say.
4:28PM 16 Listen, I'll give you what I talked to the staff
4:28PM 17 about. Let's make it easy for everybody today.
4:28PM 18 So this means that the employee of the lab
4:28PM 19 works -- okay. So my folks, I got a kit sent to them. They
4:28PM 20 drove 45 minutes to Gaston, Alabama.
4:28PM 21 **BY MR. COOKE:**
4:29PM 22 **Q.** This is your parents?
4:29PM 23 **A.** My parents, my mom and dad.
4:29PM 24 And I had a friend, actually, from high school that
4:29PM 25 worked in a -- was a phlebotomist in there for, I think,

4:29PM 1 LabCorp. She said, "Brad, I got no problem. I'll draw the
4:29PM 2 blood for you, send it off for you."
4:29PM 3 The results come back. Dr. Perry says, "Come down
4:29PM 4 here. Let's look over this stuff and you can tell me your
4:29PM 5 thoughts as well."
4:29PM 6 Went down, met with him. And my mom's was beyond
4:29PM 7 miserable. And if you saw my mom, you look at her and go
4:29PM 8 there's no way.
4:29PM 9 **Q.** This is the Berkeley test?
4:29PM 10 **A.** This is Berkeley. And this is what even sold me even
4:29PM 11 more. I mean, that's why this stuff is so powerful when you
4:29PM 12 start looking at it. And so, long story short, he said, "I'm
4:29PM 13 going to do a nuclear stress test on them."
4:29PM 14 And I said, "Whatever you want to do."
4:29PM 15 He said, "I" -- he had a nuclear stress test machine
4:29PM 16 at the time, so he did it. They both failed. Sent them to
4:29PM 17 Princeton cardiology in Birmingham who I had a relationship
4:30PM 18 with. They cathed -- they did another nuclear stress test at
4:30PM 19 Princeton cardiology on them. And my mom failed and my dad
4:30PM 20 passed with flying colors. If you saw my mom and my dad, you'd
4:30PM 21 be like there's no way.
4:30PM 22 Well, I was in the cath lab with my dad in the room
4:30PM 23 in there with the cameras and stuff. Long story short, I'll
4:30PM 24 make it quick, they took a picture. I saw her artery, and I
4:30PM 25 was like, "That's not good."

4:30PM 1 My dad goes, "What? What? What? What? What?"
4:30PM 2 I said, "Dad, I don't want to say anything to you."
4:30PM 3 I said, "I'm not a medical doctor by no form or fashion, never
4:30PM 4 will claim to be. But I've been in a lot of cath labs and seen
4:30PM 5 a lot of stuff."
4:30PM 6 So, immediately, I -- the doctor come in and says,
4:30PM 7 "Brad, what do you think?"
4:30PM 8 I said, "I'm going to tell you, you tell me your
4:30PM 9 opinion, but this don't look good."
4:30PM 10 The widow-maker, everybody's heard of the
4:30PM 11 widow-maker. It was probably 95, 98 percent occluded. And he
4:30PM 12 says -- he looked at me and said, "What to you think?"
4:31PM 13 And I says, "You can't -- you can't stent that."
4:31PM 14 He says, "Nope."
4:31PM 15 My dad was -- by this time, was -- my dad panics in
4:31PM 16 bad situations. And I mean panics. And he said -- he was
4:31PM 17 begging for information. The doctor says, "She's got to have
4:31PM 18 open heart surgery tomorrow." And so --
4:31PM 19 **Q.** So she had open heart surgery?
4:31PM 20 **A.** She did. She did.
4:31PM 21 **Q.** As a result of the Berkeley test?
4:31PM 22 **A.** Actually, yes, because they would -- she would have never
4:31PM 23 got it, never seen it, never known it. But, you know, we talk
4:31PM 24 about that in here all the time. You know, the technology --
4:31PM 25 that information is so great. I mean, I could talk all day

about doctors calling me saying, "Hey, it saved my brother. It saved my family member. It saved my cousin."

Q. Actually, you can't, because we're going to move on to --

A. I know. Let me go ahead and finish the criteria. Is that okay?

Q. Yeah. And I think you were describing --

A. Let me finish how to get the blood, make it easy for everybody here.

You can have a lab-to-lab agreement with them or a hospital. A hospital, I'm sure everybody in this room has probably been in a hospital at one time or another. It takes an act of Congress to even find the person who makes a decision. Unfortunately, it's the same way in any hospital. It's just got to go up the chains. You're looking at three to six months if you're looking to find somebody that can sign off on something, especially a legal document.

Also -- we also had -- what we started to use is what's called mobile -- mobile phlebotomist where we'd send somebody to their house and draw. And Tonya came up with something that was beyond unique. It's like an Uber app, which means you could hit a button and somebody could come to your house and draw your blood, do it at your own convenience, which is pretty cool. So draw your own blood.

Next item. "Physician is on average smarter than the average physician or at least he believes he's smarter than the

4:32PM 1 average physician."
4:32PM 2 And I know when you read this, you think, well,
4:32PM 3 that's kind of comical. But one thing about physicians,
4:32PM 4 they're a physician. They're going to tell you their thoughts,
4:33PM 5 period. And you can't tell them something. So one of the
4:33PM 6 advantages about selling this test, if they're a smart, smart
4:33PM 7 guy, they'll ask questions. If they think they're smarter than
4:33PM 8 you, they'll just make up something and tell you something.
4:33PM 9 So -- but that was a huge criteria.
4:33PM 10 "Small groups of physicians (three or four max)."
4:33PM 11 The reason I went for small groups of physicians, everybody has
4:33PM 12 heard of the word "politics." So you split a room up, you're
4:33PM 13 going to have 50 percent on this side, 50 percent on the other
4:33PM 14 side. Everything's fine. If I hadn't witnessed it in the
4:33PM 15 first two months I was at Berkeley, I would never have believed
4:33PM 16 it in my life.
4:33PM 17 So "have some access." If you can't get in to see
4:33PM 18 the physician because -- remember, the average pharmaceutical
4:33PM 19 rep has three point -- about 3 minutes and 20 seconds average
4:33PM 20 time with the physician. So when you see somebody walk into an
4:33PM 21 office, they're not back there very long.
4:33PM 22 "Money hungry." I put that down. I did. I'm not
4:33PM 23 going to lie. Likes money or at least the thought of making
4:34PM 24 money. All right. Let's address that, big word, go through on
4:34PM 25 this one.

4:34PM 1 All right. One, you have to realize these guys are
4:34PM 2 more cutting edge. These guys do make the majority of the
4:34PM 3 money. They're physicians that do the best out there. They're
4:34PM 4 the ones that also have the nuclear machines. They're the ones
4:34PM 5 that have the DEXA scans. They're the ones that see the most
4:34PM 6 patients. If you look, they're also the ones -- like Dr. Alam
4:34PM 7 was talking.
4:34PM 8 Dr. Alam, this guy -- I think at one time he had five
4:34PM 9 nurse practitioners and PAs in his practice. That's big. You
4:34PM 10 want those people in that situation. And it's huge. If they
4:34PM 11 have a nurse practitioner, a PA, it's a plus. And that goes
4:34PM 12 right along with it.
4:34PM 13 And the last, "If they have done advanced testing in
4:34PM 14 the past." Okay. If you read that, "if they stopped doing
4:34PM 15 testing due to billing problems." In our industry, you're
4:34PM 16 going to learn real quick-like in this business. Somebody will
4:34PM 17 look you in the face and says, "This is what we're going to
4:34PM 18 do." The next day, they'll do something different.
4:35PM 19 When I started in this industry, LipoScience had done
4:35PM 20 a no-balance billing policy in Alabama. Six months after
4:35PM 21 rolling it out, they retro balance-billed everybody. And we
4:35PM 22 ain't talking a couple of dollars. We're talking 3, 4, $500 a
4:35PM 23 pop. So I rolled into a hotbed when I started in this
4:35PM 24 business. It wasn't nice, friendly, how are you doing today?
4:35PM 25 You know, most people looked at you and said, "Hey, you're a

liar."

And so any changes in stuff is huge. But if they've done advanced testing, it means they believe in the science. And that's great.

Q. Okay. Going back to this money hungry, Item Number 6, let me just ask you point blank --

A. Sure.

Q. -- did that have something to do with the likelihood that a doctor might be more willing to do these tests so he can get process and handling fees?

A. No, it did not. Not at all. Not on any level. I mean, doctors like control. That's the biggest issue. They want that control in their practice. And so that's not it at all. When I drafted it and wrote it -- as I said, I did it in 2002, it had nothing to do with the process and handling fee. It didn't have anything to do with it, actually. Actually, it wasn't even mentioned. So --

MR. COOKE: You can take that down.

THE WITNESS: I wish -- all I'd get out of it -- I'd have used different terminology. But I worked -- in 2002, we was driving in the car with my boss. And we did sales -- I had been driving 12 hours a day sometimes to see people.

BY MR. COOKE:

Q. So these were just common elements that you had observed --

4:36PM 1 **A.** They were. They were very much common elements. You
4:36PM 2 know, I could even add more common elements.
4:36PM 3 Cardiologists, very rare. We didn't like to see them
4:36PM 4 very often, because they make the majority -- the way they see
4:36PM 5 their patients is they only see, on average, 15, 18 patients a
4:37PM 6 day. So the best I would get off one of those -- the average
4:37PM 7 physician does less than 15 percent of their practice, I might
4:37PM 8 get two patients a day drawing the blood. So that's not a lot
4:37PM 9 of tests.
4:37PM 10 **Q.** So when you were selling for Berkeley, how did you broach
4:37PM 11 the subject of process and handling fees to the doctor?
4:37PM 12 **A.** Actually --
4:37PM 13 **THE WITNESS:** And I definitely don't want to give a
4:37PM 14 sales presentation, Your Honor. Is that okay?
4:37PM 15 **THE COURT:** That's fine.
4:37PM 16 **THE WITNESS:** I hope you don't ask me to.
4:37PM 17 But, typically, when you walk into a physician's
4:37PM 18 office, presentation with Berkeley, "Listen, I'm Brad Johnson.
4:37PM 19 I'm a lipid clinic sales consultant for Berkeley HeartLab."
4:37PM 20 And most of them would look at you and go,
4:37PM 21 "Okay. Okay." And I would show them a case study. The
4:37PM 22 marketing materials people say we used, they were never really
4:37PM 23 any marketing materials. I'd show them the case study. And
4:38PM 24 I'd say, "We offer the most advanced testing in the entire
4:38PM 25 country at this moment in time."

4:38PM And then you stop. I don't know how many people has ever played poker before. You're reading. You're reading their expressions. If they look at you and go, "Okay." It's done. There's no need of really trying to convince this physician that this is the best stuff on the market. They don't want to learn. They're happy with what they're doing.

We learned that when I sold cholesterol medicines. But if they looked at the test and went, "This is pretty cool," and they looked at all the colors and they started looking into it, then you'd say, "Robert Superko, he's one of the leading guys in the country." And then you'd start talking about 50 percent of people drop dead of a heart attack with a perfect lipid panel. Have you had anybody that way?

I loved asking people questions like that. Why? Because they jumped into it. I mean, they was all on board. And then they started getting into it and stuff. And, you know, we've had physicians come in here, but there's subsets of everything. You know, you've got the HDL2b, which is actually better than better. It's considered a life longevity marker in the market. It's the best of the best.

You got the FDA-approved test for stroke. Plaque test, phenomenal. Off the charts. When you tell somebody, "Hey, listen, we have the stroke test," people take notice. Everybody knows somebody that's had a heart attack -- or not died, but had a heart attack. They're normal. They're

walking around normal. And if they have a stroke, it's a whole different ballgame.

So what does most people do when they see somebody with a stroke? I don't want to have a stroke. That's just the way it is and stuff. And so it was an attention-grabber. You grabbed them and you jumped in.

Then I went on with the rest of the stuff and went over the tests. I'm not going to go into detail.

So one of the things, though, I did with the staff. And y'all will probably like this more than anything. The staff, we'd sit at lunch and you shoot the bull. And I'd always say, "Hey, let's kind of play 'Jeopardy' game."

They'd go, "Okay. Cool."

I'd say, "Who dies first of a heart attack: A person with a 80 percent blocked artery or a person with a 50 percent blocked artery?" 80 percent blocked artery or a 50 percent blocked artery?

Physicians know the answer; most people don't. It's the 50 percent. People always believe it's the 80. It's not. I mean, I can go into detail and explain why, but, for the sake of this discussion, I'm probably not going to go into that much detail.

Then I'd look at people and go, "How would you like to be told you could be on a high-fat diet?"

And people would look at you, "Well, what do you

mean?"

Well, the genetic test, ApoE, if you look at it, it's got the parameters. You can be on an extreme high-fat diet, or you need to be on an extreme low-fat diet. Who dies first? The people with the four leaks. For cardiovascular visits, that's what we talked about.

Now, Athena labs had a patent regarding Alzheimer's testing, so you would mention it. Because I learned real quick, like, in the first six months, after I got screamed at by a doctor in front of his office. I didn't tell him that that was the same test for cardiovascular disease as Alzheimer's. And it can give you the markers, high risk for a person with Alzheimer's.

So I would always ask simple questions like this to the staff. And all of a sudden, the staff would start looking and start asking questions and wanting to know more. And that's -- and that's pretty much how you did it.

BY MR. COOKE:

Q. Where did process and handling fees come in?

A. They always come in after the physician was committed. If the physician was committed, I would already have an idea at the end how I'm going to get the blood. Is Nurse Nancy or Phlebotomist Joe going to draw the blood? All those things, I would have an idea. And so then I would present it.

Q. Now, does that mean that the physician has to have told

you that he's on board or --

A. Yeah, you'd know -- as I mentioned to you, you'd know in the first five minutes. It's like someone -- I would assume it's like selling a car, if you really look at it. Because you walk up and you see a nice shiny, bright Lexus, you know how your pupils dilate, you get excited. And you go, "Okay. Can I afford this?" That's the same mentality. That's what you're looking for in those physicians.

Q. Let's talk about no-balance billing or balance billing.

A. Okay.

Q. Did they do that at Berkeley?

A. Oh, big time, a hundred percent. Let me walk you through the no-balance billing. This is interesting as well.

I was doing pretty good at Berkeley at the time. Sales were going good. And somebody made the statement -- we had went from a 715-minus program to a 329-minus program -- or a 329-plus program, which means we had to have above $329 to not balance bill a patient. Well, somebody said, "Well, how about let's try no-balance billing and see how it works?"

So my sales ended up taking off even more. They started going up. Because you realize, before, these tests were only for the richest people. I mean, I hate to say it, but the average person couldn't go get one unless you was going to pay a ton of money out of pocket. I mean, that's just the way it was.

4:43PM Now, they ordered it on Medicare patients because, again, there's no cost to the patients. So you're sitting here and business is good. Frank Ruderman, the CEO, goes, "We're rolling no-balance billing out. We're going to focus on our key areas: Miami, South Carolina, and Chicago." Okay? We're going to roll it.

Four months go buy. Sales are zero, zero, zero in those geographies. And they say we're a washout. But at Berkeley, I kept the no-balance billing the whole time. Now, somebody said, well, we know you changed it in 2009. We never changed it. The misconception is we went in network with Blue Cross Blue Shield. When you go in network with an insurance company, it depends on the contract, really, you have to attempt to collect copays or deductibles to get it working. Okay?

So what happened in 2009 at Berkeley -- and Berkeley had already had four different billing programs out across the country, the 349-minus and everything else. So the thing is, at Berkeley, they made -- they had already been acquired by Celera for about 200 million-some. Compliance was pretty strong because Celera had mapped the Human Genome Project, to give you an idea, which is beyond cutting edge now.

So the thing was -- is they did something that was stupid. They said, "We got a lot of money sitting out there that we need to bill for it." They didn't know if you owed

money or not. One of the guys who was going to be put on the stand, Gary Tom, who did the billing at HDL -- or not HDL but Berkeley, he called me and said, "Brad, heads-up."

I said, "What are you talking about?"

He said, "We're fixin' to send out 5,000 retail bills."

And I said, "What do you mean?"

He said, "My resignation is in, so I can tell you. It's not a big deal. But I'm just telling you to be prepared."

And I'd been telling physicians for seven years there's no cost to your patient. There's no cost to your patients and things like that -- in Alabama. Other states have different billing problems or billing circumstances.

All of a sudden, my mom and dad got turned in to collections. They got $2000-something bills. So imagine your good friend, all of a sudden, at the doctor's office or whatnot, you're a doctor. And all of a sudden, your good friend calls you and says, "Hey, I got a 2,000-freaking-dollar bill."

What are you going to do? You're going to call who? The salesperson, and start screaming. And it went from one or two client service calls a day, or something like that on average -- you'd have to ask Corrine -- to 50 to 100 a pop. I mean, it just went like that. I mean, it was unbelievable how fast problems arose.

4:46PM 1 **Q.** From patients who were receiving bills?
4:46PM 2 **A.** Yes. It wasn't a bill they owed. That was the killing
4:46PM 3 part. That was the bad part. Nobody could tell you where the
4:46PM 4 bill came from, the amount, at all.
4:46PM 5 So what happened then? They said, "Was it
4:46PM 6 successful?" I was told less than 1 percent of people paid.
4:46PM 7 So in April to May, they rolled that baby out to about 15,000
4:46PM 8 patients. But nobody ever checked to see if it was -- if it
4:46PM 9 was successful, which is -- a lot of companies don't pay
4:47PM 10 attention. And so boom.
4:47PM 11 **Q.** All right. So --
4:47PM 12 **A.** Go ahead, sir.
4:47PM 13 **Q.** I'm confused about one thing you said. You said that when
4:47PM 14 you tried no-balance billing, your sales soared, but when the
4:47PM 15 company rolled it out, nothing happened. Can you explain that?
4:47PM 16 **A.** Well, I think it goes to a bunch of things. Some people
4:47PM 17 are better at the clinical information. You know, some people
4:47PM 18 are better at how do you find people? Some people are better
4:47PM 19 at building relationships.
4:47PM 20 One of the biggest things about this is
4:47PM 21 relationships. And if I can go over and I have trained and
4:47PM 22 hired every Decatur rep in the state of Alabama, and I can make
4:47PM 23 a phone call to them and tell them this is kind of what I'm
4:47PM 24 looking for in a physician, every one of them can say they can
4:47PM 25 give me five doctors' names, which tells me one to two of them

may do this test or may be what I'm looking for. Okay?

So, immediately, I was thataway. And so that's why one of the biggest reasons for success at BlueWave was we hired sales reps that already had lab experience, that already knew all the customers across the territory. And that was a huge advantage. So it was better than taking somebody out of the field who -- or not in the field who had never worked in this industry and had no relationships. So --

Q. On the subject of no-balance billing, did you find that there were different rules applicable for different states and based on different insurance policies?

A. Did not get told anything about that until -- I want to say somewhere near 2013.

Q. So that was when you were at BlueWave?

A. Yes. Nobody -- there was never one word communicated.

Actually, here was the word that was communicated: We're not getting paid crap for Cigna and Aetna in Miami. That was one issue. We're not getting paid crap for Cigna and Aetna in Georgia, so we're going to have to assign some sort of dollar amount to make sure we make something. And that's what I got told. And that was probably the biggest complaint.

Q. Did you ever -- did you ever hear -- when you were talking about no-balance billing, were you talking about Medicare or Medicare patients?

A. No. And this is an interesting conversation as well.

4:49PM 1 Ever since I've been in the lab business, you cannot
4:49PM 2 balance bill a Medicare patient, period. I was interviewed in
4:49PM 3 April of 2014 with Ms. Strawn. And Ms. Strawn said, "Why
4:49PM 4 aren't you balance billing Medicare patients?"
4:49PM 5 And I said, "Ma'am, first of all, BlueWave, we don't
4:49PM 6 bill." That's the first statement. The second thing I said,
4:49PM 7 "It's illegal to balance bill Medicare patients."
4:49PM 8 And so she grabbed her notepad and says, "Well, how
4:49PM 9 about TRICARE?"
4:50PM 10 And I says, "I thought they were the exact same."
4:50PM 11 And she said, "Well, you need to know."
4:50PM 12 And I said, "Are they?"
4:50PM 13 And she said, "Well, you need to look it up."
4:50PM 14 So immediately after that meeting in Birmingham in
4:50PM 15 April 2014 or May 2014, I went out and -- straight after. I
4:50PM 16 walked out of the government building that day. Okay? I
4:50PM 17 picked up the phone, and I had one conversation that was -- I
4:50PM 18 had one big conversation before I had the other.
4:50PM 19 The second conversation I had that day was with Cal.
4:50PM 20 I asked him about the TRICARE billing. He said, "Brad, I think
4:50PM 21 it's the exact same as Medicare."
4:50PM 22 And so I called Tonya. And she said, "Brad, I'm not
4:50PM 23 a hundred percent sure, but I'll double-check and make sure
4:50PM 24 that's right." She said, "But I believe it's the same."
4:50PM 25 I called Gary Tom. Gary Tom did the billing at

Berkeley, Singulex, came in as a consultant for about a month at HDL, and had a -- ran a billing company as well. He said, "Brad, it's the exact same as Medicare." I said, "Okay."

So I did one more thing. I called one of the Boston HeartLab reps. And I says, "Hey." I said, "Do y'all bill TRICARE patients?"

He said, "No. It's the same as Medicare, isn't it?"

I said, "Okay. That's all I need to know."

So that was the extent of that up until, I guess, November -- November, December 2014. The next time I got told you're supposed to bill Medicare patients was the new CEO at HDL says, "Hey, the government has told us we're supposed to bill these." And I guess their legal team or somebody had said something. And of course they didn't tell the salespeople; they just did it.

Q. That was in 2014?

A. Yeah, the end of 2014. That was -- yeah, the end.

Q. So up to that day that you met with Ms. Strawn, had you ever heard that you're supposed to bill patient responsibility or copays or deductibles to some TRICARE patients?

A. No. As said to you, I've been under the impression Medicare, TRICARE are one and the same, no difference across the board.

As I said, I confirmed with other labs. And, actually, in 2014, I reconfirmed it with other labs just to

see.

See, you got to realize, in this industry, as I said, by this time there's maybe 450 in the whole industry sales reps-wise. Well, I either hired or trained or personally knew about a hundred of them. So -- and by that time we was trying to get -- cancer diagnostic lab was new cutting-edge technology as well. And I hired six of the Arthrotec reps -- I hired four of the Arthrotec reps, I think six of the LipoScience reps, one of the Boston reps, a bunch of Cleveland HeartLab reps.

I mean, all I had to do is pick up a phone call and say, "Hey, what did you all do?" And they'd go this and this. So I had a good idea.

Q. So up to that day in 2014, do you remember actually telling doctors that you wouldn't balance-bill TRICARE? Or did that even come up?

A. Actually, up until that day, that was 100 percent my understanding, correct.

Q. So the time came when you decided to leave Berkeley. When was that and why did you --

A. Okay. That's an interesting thing. I don't know if you want me to go into it since we're at our 5:00 number.

Q. Well, let's go ahead.

A. Well, it's Friday. That's why I was thinking.

Q. That should be a good guide for you.

THE COURT: How short you should talk about that.

4:53PM **THE WITNESS:** That's why you might not want me to talk about that, but I can.

Berkeley had done the billing, the retail bills as well. And it just, I mean, hammered my customers. I was losing relationships like that, just as fast as you could imagine. And so at that moment in time, I'd already -- three years prior to that, I told Berkeley -- I told my new -- my boss I'm resigning. I said I'm going to retire.

He says, "What do you mean, retire?"

I said, "I'm going to retire. I don't need to do this anymore."

And that's when he says, "I tell you what. If I hire Burt" -- y'all heard Burt on the stand. He's my best friend since college. He said, "If I hire him, will you stay?"

I said sure.

And two years later they hired my other best friend to get me to stay.

Well, that summer I was sitting there watching business being just decimated. And I'm sitting here thinking about what am I going to do? We're at a meeting. Cal and all of us are there. I says, "I'm definitely going to leave."

Cal goes, "Hey, listen. Go I go into business with you? Can we do something?"

At this time I already had several successful companies. I owned the only 503B sterile pharmacy in the state

of Alabama, and it was doing very good, and the sales did as well, a bunch of different things. So life was good.

So Cal calls me about two months later and said, "Hey, I got a call. And somebody's got a new lab," because we had even talked about opening our own lab. But I was already realizing that's not my strength. I can't do it. I don't know enough. I'm not smart enough. I just can't do it.

So Cal had said something about Russ Warnick and Tonya Mallory. And I said okay. And I said, "Hey, you know, y'all interested in having a meeting?"

Sure.

So we ended up meeting in August or September, somewhere in those months right in there. August, September, October. I get them all the dates wrong. We met, had a meet-and-greet, socialized, made sure we was a good fit, just like anybody. You know, if you're going in business with somebody or you're meeting your new boss, you want to shake hands and make sure y'all can communicate.

And so Tonya says, "Hey, we're interested in bringing you on as sales reps, as employees."

Now, at Berkeley -- and Cal alluded to this just a little bit, but he wasn't there my first three years. And I had had numerous times when I got walked into -- the COO walked in and said, "Hey, Brad. We got a new commission plan for you."

I said, "Okay. I'll look at it," and said, "We going to roll this out next year, then?"

He goes, "No, let's roll it out right now."

I said, "Wait a minute. I'm due to get my commission check next week."

He says, "We're not going to pay you that."

And so I was like, are you kidding me?

And so long story short, I consulted a lawyer at this time. He said, "Hey, there's nothing you can do. You're a dead man walking." This was 2002.

And I said -- so they offered me a raise, wanted to give me a contract to lock me down so I could not renegotiate my commissions and all this other stuff. And they did that numerous times, to give you an idea.

So when Tonya said "employees," we was like, "No offense," I said, "but we want the sales rights." And I said, "I don't know how that would work," but I said, "We want the sales rights." That was my focus. Not independent contractor. Never even thought about independent contractors on that word or verbiage at that time. I wanted the sales rights. And --

BY MR. COOKE:

Q. You're talking about Tonya Mallory?

A. Tonya Mallory, correct.

Q. Did you know her at Berkeley?

A. I never had met Tonya. I didn't know anything about her.

Cal said he thought he might have met her one time walking through the lab. He said, "But I don't believe. I'm not sure. I don't think so." So I didn't know her.

I knew Russ because Russ has published a book about -- about yea thick. And I honestly -- you want to read something that put you to sleep in about two seconds, pick his book up because it'll -- it's tough.

Q. Where did Tonya work in Berkeley?

A. I assume she worked in the lab, based on my understanding. And what I later learned is Celera, when they had acquired Berkeley, they were doing what's called an earthquake lab. So California, what are they susceptible to? Earthquakes.

So California -- I mean, so Tonya, based on our conversation, she said she had been tasked with finding another viable spot. If an earthquake hit California, you wouldn't lose all your business. Right?

So Richmond was the viable spot. And apparently they pulled the plug on that, and so -- but she had already done the work, so she knew it. So I guess that's how HDL originated.

MR. COOKE: Your Honor, you had asked me to let you know if we were at a breaking point. This might be one.

THE COURT: I don't think we'll have any quarrel with that.

Ladies and gentlemen, we've come to the end of the day. I want to remind you not to do any research, to

discuss this case with anyone; and, hopefully, we'll move things along on Monday. Please be here at 9 a.m.

Have a good weekend. Thank you.

(Whereupon the jury was excused from the courtroom.)

THE COURT: Okay. Please be seated.

Okay. Folks, since we don't really know what either the defendant -- you know, I guess we think we have the last witness for BlueWave, but they certainly have their own prerogatives about what they want to do. And then we don't know what Mr. Ashmore wishes to do. He still has his prerogatives. The government has its reply prerogatives. And we don't know how long the direct and cross will take.

So I will tell you that if we get rather late in the day, I'm certainly not going to try to cram all of this in, that is to do a charge conference and then to do closing -- closing arguments and a charge, because I just find jurors get tired and it's just not a great idea.

So what I'll probably do on Monday, assuming we -- we finish at a reasonable hour, I will provide you the charge and give y'all several hours to review it. This is stuff that's not really foreign to y'all. You'll all go pretty much quickly and see where I went. And then we'll have the charge conference.

And then my plan would be, assuming all that works, that we will have closing argument and charge on Tuesday

morning, and then let the jury deliberate.

That's all subject to change if we have more witnesses or whatever, and I'm not rushing anyone because it'll go until it finishes.

My wife said to me as I walked out of the house this morning, "Why don't you put those guys on a clock?"

I said, "Well, it's not really that simple." Right? It's -- in theory -- you know, I know some of my colleagues do that, but, you know, what we do is too important to try to -- and if I thought somebody was filibustering, I'd fuss with you about it. But I haven't seen that.

So would that be a reasonable schedule? Anybody got any concerns or problems with that schedule?

MR. LEVENTIS: No, none, Your Honor.

MR. COOKE: No. I think I that makes sense.

MR. ASHMORE: Your Honor, and if I call Ms. Mallory, I would expect her direct to be 30 minutes or less.

THE COURT: Well, let me just say, and I keep saying this, Mr. Ashmore, whatever you want to do. I was a trial lawyer, doing exactly what you did. And sometimes you go home, and over the weekend you got a bright idea and you want to shift it. And I don't want you to feel like you're committed to me on anything you do.

MR. ASHMORE: Thank you, Your Honor.

THE COURT: Very good. I'll see you 9:00 Monday

morning. Yes?

MR. COOKE: My client's on the stand, and ordinarily I would say that means I can't go anywhere near him. It's kind of a difficult situation because we'll be preparing closings and talking about strategy for the case. Is there any carve-out --

THE COURT: Need to leave him out of it. Listen, you've had plenty of time to talk to him. You've got the other defendant who can help. He's on the stand. I think you need to stay away from him.

MR. COOKE: Could I ask -- have one idea.

THE COURT: Okay.

MR. COOKE: Could I just have him send me an email with ideas he might have for closing with no response?

THE COURT: Sure. I don't think that's a problem. Just don't respond.

MR. COOKE: Right. I won't respond.

THE COURT: Okay. But -- but he's -- you know, I always say, what could you do if the trial was continuing right then? You obviously couldn't go up and have a conversation with him. You couldn't have dinner with him. It's an awkward situation, but, you know, we're in the middle of trial. This is what we do.

MR. COOKE: That will be helpful.

THE COURT: I think he can certainly send you an

email as long as you don't reply.

MR. COOKE: I'll do that. Thank you.

THE COURT: Okay. Well, we are finished for the day, and we'll see you bright and early Monday morning.

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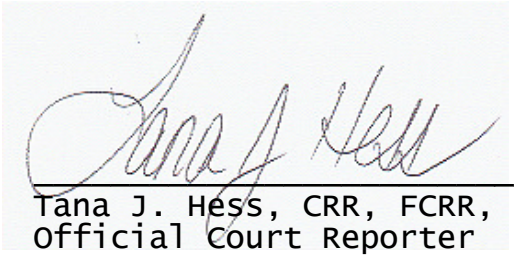
CERTIFICATE

I, Tana J. Hess, CCR, FCRR, Official Court Reporter for the United States District Court, District of South Carolina, certify that the foregoing is a true and correct transcript, to the best of my ability and understanding, from the record of proceedings in the above-entitled matter.



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